CHAPTER-V
THE IMPACT OF PRODUCT PATENT REGIME ON PRICES OF DRUGS AND THEIR ACCESSIBILITY

‘Earth provides enough to satisfy every man’s need, but not every man’s greed.’
- MAHATMA GANDHI

5.1 INTRODUCTION

India, in fact, stands out among this group as a country with advanced capabilities in production and R&D on the one hand, and a vast market for pharmaceutical products due to its sheer size on the other. At the same time, it is a country with a large poor population, making the concerns around pricing and availability urgent in the context of public health. The answer to both the questions for India lie in the pattern of patent applications it has received so far: the majority of the applications are for Non Communicable Diseases making it immediately apparent that patent applications follow the market trends closely, and applications are mainly targeting the diseases that translate into market shares and profits. Non-communicable diseases which are deemed as rich man’s disease because of the reason that they can manage the disease where as the poor persons cannot, the fact is disease, comes irrespective of your financial status, it has no measured scale to attack a human body.

Currently, the increasing trends of NCD in the country as also globally is making the market lucrative for drugs that treat heart diseases, diabetes, neurological disorder, cancer, mental illness etc. Only a small number of applicants are aiming for communicable diseases in any case, indicating that the grant of patent by itself cannot distort the market for priority diseases. When the prices of domestic drugs rise drug providers and drug consumers do not necessarily switch to the foreign drugs, and vice versa. Mostly, the demand for drugs is driven by what the physicians prescribe, especially in developing countries like India where regulation standards are quite low. There is a slow but increasing body of evidence on physician behaviour that indicate that physicians behave as imperfect agents in the presence of asymmetric information. For instance, evidence indicates that within systems where physicians both prescribe and dispense, there is a tendency towards rent-seeking behaviour, with physicians prescribing brand-name drugs
instead of generic ones\textsuperscript{1}. Another study indicates that both physicians’ habits and patients’ preferences are the most important factors in choice of drugs \textsuperscript{2}. The Governments especially India being a developing country is unable to provide funds to the health sectors particularly in meeting the free supply of medicines to the needy poor patients which is the core question to be answered as to how public health policy can be made more efficient and strong to bridge the conflicting gap of health and patent systems. Moreover Indian sentiment to self demolition i.e. suicide is a Sin hence Right to euthanasia ‘Right to die’ is not recognized under Indian laws so it becomes binding on the patients to consume drugs even if they are not curable. They are forced to take the prescriptions for the only reason to survive painlessly as long as natural death occurs. India lacks facilities to provide palliative care for many cancer patients and this worsens their conditions as they have to meet their medical expenses only to die peacefully minimizing the pain.

The enactment of Patents (Amendment) Act, 2005, the process of bringing Patents Act in line with the TRIPs Agreement extending the product patent to all the fields of technology including the medicines the new patent regime is expected to have an impact on prices and availability of medicines for the following reasons:

(a) At any given points of time, globally only 5-10 percent of the drugs would be under patent protection.

(b) The price competition among different drugs in the same therapeutic group should keep the prices under control.

(c) Since majority of the patients in India pay from their pocket, the limited purchasing power will act as a check on very high price.

(d) Government continues to have powers to regulate the prices of medicines.

(e) Safe-guards like compulsory licensing, parallel imports etc. exists.

(f) The drugs covered in the list of Essential Medicines are not likely to be covered by patent - these would continue to be abundantly available at reasonable prices.

\textsuperscript{1} Liu, Ya-Ming Liu, Yea-Huei Kao Yang, Chee-Ruey Hsieh (2009), Financial incentives and physicians’ prescription decisions on the choice between brand-name and generic drugs: from Taiwan. \textit{Journal of Health Economics}, 28(2), March, Pages 341-349.

Having regard to these aspects and discussions made in earlier chapters proving of the hypothesis has been made in the Indian context as to how India will be able to tackle the practical difficulties in the light of TRIPs Agreement.

The price effect is particularly important for low- and lower middle-income countries, which are the most likely to face financial constraints. The cost of ARV drugs and ART coverage in upper-middle-income countries, suggesting that prices of ARV drugs do not constrain access to ART in these countries the use of compulsory licensing in Brazil and Thailand has not made any impact in reducing the prices of the medicines, procurement by the government for free supply and accessibility by the poor patients. All the factors above, Brazil and Thailand do not show higher levels of access than other countries since the issuing of compulsory licenses. Most of the governments have expressed their inability to procure patented drugs for the purpose of supply of medicines at free of cost to the needy persons due to financial constraints and low growth of GDP. The funding done by the government of India is only meager about 4.5 of GDP in total and only a small percentage is being spent on medicines only generic versions are supplied in the most parts of the country. The patented drug pricing has not been excluded from the price controls nor are they regulated. Indian courts have given several judgments enforcing Right to health but due to the reason that Government of India has expressed that “Although India is a welfare state and the State owes responsibility to protect its subjects but not as a duty since it comes under the Directive Principles of the State Policy, Right to health is not enforced as is done under Right to life. Right to health is not recognized in an efficient manner as contained in the Indian Constitution. The very purpose of Art.21 of the Indian Constitution is to enforce Right to life which includes Right to health, an effective tool in the hands of the common man as policy makers take the shelter under Directive Principles of State Policy.

The case in the Supreme Court in which LOCOST, Jana Swasthya Sahyog (JSS), All India Drug Action Network (AIDAN) and the Medico Friend Circle (MFC) are co-petitioners who have collectively filed a series of affidavits in the matter questioning the wisdom of the criteria for drug price control in Pharmaceutical Policy 2002 (PP 02), It is submitted that the policy will increase the price of medicines and therefore have a long-term effect, for the worse, on the health of people, especially poor people. The related SC order of 10-3-2003 says,
“… We direct that the petitioner shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control…” This litigation is also occurring at a critical juncture where India’s state of public health is still grappling with old diseases while new ones like HIV/AIDS, diabetes and cardiovascular problems have got added on to the disease burden. Complicating this issue is the impending regime of TRIPs of WTO effective from January 2005.

This combined publication of these above stated institutions who are actively involved in surveying and reporting persistently to addresses pricing and related issues of the drug industry in India. It draws upon the experiences and insights of people, who have, over the past 25 years, consistently engaged the government to ensure access to less expensive, safer, and more rational medicines. We hope that it would enlarge the circle of public-spirited individuals and organizations that are concerned about these issues and drive them to do something about it. Their works and publications is a plea for action to do something in reforming the conflicting issues.

Wherever required the statistics of various organizations; works of earlier researchers, experts are used in the research. Such responses are an indication that trade and health issues are not currently factored into decision making processes, or that the GOI did not see the need to do so; warranting further research.

Some of the research questions cannot readily be answered at present because of a lack of capacity and information on the topic. Individuals had incomplete knowledge of the whole system making it critical to cross-reference information from several different sources. This wasn’t always possible within the scope of this project, and so sometimes raised more questions than answers. The qualitative nature of this research methodology means that this cross-section of organizations and cross-referencing of information is very important. Finally, where divergent materials are used analytical rigor to clarify the issues that were raised. In the very few cases, when different answers were made, it was highlighted both sides of the issue and identified the need for subsequent research. This occurred in particular in discussions about the appropriateness of using human rights to

advocate for trade and access to medicines, exemplifying the tension with customary rights in the society. Due to limited scope, budget and time, the pharmaceutical innovation initiatives and the prices of the medicines and its accessibility mapped are not exhaustive. A few illustrative, thought-provoking examples have been chosen, based on their unique contributions to specific components of pharmaceutical innovation and accessibility of the medicines. Field work was not possible as to access to medicines is concerned, due to the reason that nobody discloses the fact of their being ill and is closely related to ones sentiment.

5.2. HYPOTHESIS TESTED

1. There is a conflict in product patent protection and protection of public health.

2. The product patent regime in the field of medicines and drugs has a negative impact on public health policy.

3. The product patent regime in the field of medicines and drugs has increased the non-affordability of the life saving drugs for common man due to high tendency of monopoly.

4. Priority to the health is not given in Indian Patents Act in utilizing the flexibilities to regulate the effect of prices of product patents in the field of medicines and drugs after its amendments in 1999, 2002 and 2005.

5. Disease Sufferers right to have access to medicines and drugs is inefficiently addressed under the existing laws such as Indian Patents Act and Drug price control policy (DPCP) of Government of India.

6. There is a need to amend the existing national and international laws and policies to extend the fundamental right to health on par with the fundamental right to education.

After having dealt with various aspects of TRIPs and patents from the beginning of formation of W.T.O to the implementation of product patent regime in the previous chapters we shall now deal with their impact on public health and affordability of patented medicines by undertaking the hypothesis testing in this chapter wherein each hypothesis is put to test by analyzing taking into various provisions of law interpretations to clarify how to use flexibilities and statistical tables and comparative statements of prices of patented products and out of pocket expenditure of the patients.
5.3 THERE IS CONFLICT IN PRODUCT PATENT PROTECTION AND PROTECTION OF PUBLIC HEALTH

5.3.1. Human Rights Provisions in the Patent as Exceptions

The various provisions which protect the interest of the human rights in the TRIPs Agreement that have been included in TRIPs Agreement which helps to balance the public and private interests in intellectual property rights is typically informed by constitutional rules or principles’ the TRIPs Agreement attempts to transpose a constitutional balance between private’s stakeholders and public interest to the multilateral level. There is a strong argument that transposing constitutionally-balanced rights into a multilateral organization with limited internal capacity for constitutional balancing is an inherently problematic undertaking. Various TRIPs internal mechanism reflects the public interests side of balancing relevant provisions includes *inter-alia* the Preamble regarding objective of non-distortion trade recognition of public policy objectives of national laws maximum flexibility for least developed countries etc. The following provisions of the TRIPs Agreement reflect the right to health policy:

Article 1 Right of states to implement as appropriate to national legal system and practice.

Article 2.1 Incorporation of other multilateral instruments “. Eg. Article 5 of Paris Convention.

Article 6 Inclusion of dispute settlement regarding exhaustion

Article 7 Reference to contributions to dissemination of technology Advantages to users and contribution to social welfare.

Article 8.1 References to public health and nutrition vital areas of socio-economic and technological development

Article 8.2 Prevention of anticompetitive practices

Article 27.1 Flexibility - in application of conditions of patentability and permitting of differentiation (as contrasted with discrimination) in field of technology whether imported or locally produced.

Article 27.2 Permitting of exclusions for public order morality protection of human, animal, plant life and health, and environment.

---

Article 27.3 (a) Permittting of exclusions for diagnostic, therapeutic and surgical methods

Article 27.3(b) Permittting of exclusion for plants, animals and essentially biological processes” other than non-biological and microbiological processes and flexibility in protection of plant varieties

Article 30 Exceptions to patent rights

Article 31 Authorization of grant of compulsory licenses

Article 39 Implicit recognition of non-protected status of information in public domain

Article 39.3 Limitation of data protection to that “against unfair commercial use”

Article 40 Authorization of legislation and enforcement of competition Principles to IPRs

Article 41.5 Recognition of limitations on enforcement resources.

Article 42 Elaboration of defendants rights in civil proceedings

Article 65 General application of ‘transitional arrangements

Article 66.1 Extended transition period for least developed countries, and indication of intention to allow extensions “duly motivated”.

Article 66.2 Obligation on developed countries to provide incentives for technology transfer to least developed countries.

Article 67 Encouragement of technical assistance

Article 71 Security exceptions, limited but including recognition of obligation to maintain international peace and security.

The relationship between human rights and intellectual property is a troubled one and is epitomized by the contentious issue of access to patented medicines. Patent protection can interfere with access to medicine in two key ways: by granting monopolies in pharmaceutical production, raising the cost of medicines to often unaffordable prices; and by providing a profit mechanism that incentivizes research of diseases primarily affecting countries with lucrative markets. 

---

diseases prevalent in developing countries\textsuperscript{6}. The result is a “global drug gap” wherein novel drugs are often inaccessible to most of the world’s Population\textsuperscript{7}.

Reasoning developed with regard to Article 30 and 32 will also apply to Article 31, as the purpose of all these three provisions must be termed to ensure wider access to patented goods, while also taking into consideration the impact for the patent holder and the long-term effects on the development on new products.

5.3.2 TRIPs does not Include Anything Protecting Health as a Right to Health

South Africa has the largest economy in Africa with a per capita income of well above $3,170 (1999 figures), and accounts for 40 percent of the total gross domestic product (GDP) of sub-Saharan Africa. Nevertheless, how to treat the 4.7 million people who are HIV-positive is a serious issue requiring urgent measures. Thus, in 1997, the government revised the South African Medicines and Related Substances Control Act to allow the abrogation of all patent rights for pharmaceutical products. Ministerial Discretion was to decide on compulsory licensing and parallel imports of a generic version of antiretroviral (ART) drugs from India. The proposed revisions were challenged on the ground that it breached the Patents Act and the Constitution of South Africa by 39 pharmaceutical companies including the four multinational corporations, Merck, GlaxoSmithKline, Bristol-Myers Squib and Boehringer Ingelheim, backed by the US government.

In 1997, the South African government passed a law that would have permitted parallel imports\textsuperscript{8} and compulsory licensing of HIV/AIDS drugs. International pharmaceutical companies initiated litigation against South Africa, claiming that the law violated South Africa’s constitution. The pharmaceutical companies also alleged that the law violated TRIPs provisions. The United States government backed its pharmaceutical companies by pressuring the South African government to amend the law, including by placing South Africa on the U.S.

\textsuperscript{6} Id. at 140. The authors add that a number of other obstacles, such as poverty and limited government funding of health care, also interfere with access to medicine in developing countries.

\textsuperscript{7} Ibid at 140.

\textsuperscript{8} Parallel imports (also known as Grey Market imports) are goods produced under patents (trademarks or copyrights) and placed into circulation in one market and imported into a second market without the authorization of the owner of the intellectual property right. Parallel importing would let South Africa to import patented drugs sold in other nations at cheaper prices into the country, since international pharmaceutical companies price-differentiate their drugs globally.
Special 301 Watch List\(^9\). However, a combination of unfavorable press coverage and strong opposition from the public led the companies to drop the lawsuit in April 2001, and the U.S Government to terminate the Special 301 investigation. However, the suit was withdrawn due to great political pressure from both domestic and international quarters. This reflects the growing concern that a rigid implementation of pharmaceutical patents has a detrimental impact on the public health policies of developing countries. For many sufferers in the developing countries, this was a positive move. Immediately after the South African government’s victory, Kenya passed a Patent Act including a provision on compulsory licensing and parallel importation rights of antiretroviral medicine\(^10\).

The South Africa case started international controversy that was a prelude to the controversy over TRIPs and access to medicines during the Doha Round of WTO negotiations. The South Africa-United States dispute highlighted major issues with regard to TRIPs and access to medicines, including the interpretation of Article 31, even though compulsory licensing was not the only issue in the South Africa dispute.

The Doha Declaration on TRIPs and Public Health (“the Doha TRIPs Declaration”), issued at the WTO Ministerial Meeting in Doha, Qatar, in November 2001, was a response to the above concerns. The purpose of the Declaration was to clarify the language of Article 31, in the context of public health.

The Doha TRIPs Declaration has two key elements;

First, it states that “…Each Member has the right to grant compulsory licenses, and the freedom to determine the grounds upon which such licenses are granted.”\(^11\) This specification is arguably the most important element of the Declaration. It explicitly confers discretion to grant compulsory licenses to developing countries, effectively putting to rest the debate on national emergency/extreme urgency as a requirement for compulsory licensing. The developing countries can decide to use compulsory licensing when faced with public health crises, without worrying about legal action from pharmaceutical companies.

\(^9\) Special 301 is a U.S. statute that authorizes the U.S. Trade Representative to identify countries that fail to provide adequate intellectual property protection, and take action against countries found to be violating intellectual property rights.


\(^11\) Doha Declaration, Paragraph 5b.
Second, the Doha TRIPs Declaration states that “…the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health…”\textsuperscript{12} and reaffirmed “…the right of WTO Members to use, to the full, the provisions of the TRIPs Agreement, which provide flexibility” for the purpose of public health. These statements clarify the impact of TRIPs on access to medicine in a direction that favors developing countries. Though not legally binding, the Declaration serves as an authoritative tool to interpret the TRIPs Agreement in a manner supportive of Member’s right to protect public health and promote access to medicine. In practice, this provision explicitly confers to WTO Members right to use compulsory licensing to address public health crises.

The Doha Declaration left unresolved the key issues of access for countries with inadequate in-country capacity for producing the required drugs. The compulsory licensing provisions of the TRIPs allow compulsory licenses to be issued only for domestic use. Specifically, Article 31(f) of TRIPs states that production under compulsory license “…shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.”\textsuperscript{13} This is interpreted as prohibiting products produced under a compulsory license from being exported. Article 31(f) creates a practical barrier to developing countries with inadequate or no indigenous drug-making capacity from benefiting from Article 31 flexibilities. Namely, Article 31(f) prohibits countries with drug manufacturing capacity (such as Brazil, China, India and Thailand) from exporting pharmaceuticals produced under compulsory license to countries with no domestic drug manufacturing capacity.

In the Doha TRIPs Declaration, WTO Members recognized that many countries would be unable to take advantage of Article 31 because of lack of domestic capacity. Specifically, this ambiguity was acknowledged in Paragraph 6 of the Declaration, which states that:

“\textit{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}"

\textsuperscript{12} Doha Declaration, Paragraph 4.
\textsuperscript{13} Article 31(f). TRIPs Agreement
for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”

WTO Members had a difficult time in arriving at a solution to the “Paragraph 6” issue due to differences in interpretations. The main issues of contention arose because the developed countries wanted (1) to ensure paragraph 6 was limited in scope, and in particular, to being available for use only in the context of treating specified infectious epidemics (namely HIV/AIDS, tuberculosis, and malaria), and, (2) to provide strong anti-circumvention/fraud provisions.

The developed countries believed that allowing compulsory licensing for export is clearly a concession and a modification of the TRIPs Agreement, and therefore, wanted to ensure as little modification as possible. The United States government interpreted the Doha Declaration as restricting its scope to specific diseases, namely HIV/AIDS, tuberculosis, malaria and other similar epidemics. Developing countries, on the other hand, wanted to maintain a wide scope of diseases to ensure they could address a wide range of current and future public health concerns.

The WTO General Council Decision of August 30, 2003, purports to provide an expeditious solution to the questions left unanswered by the TRIPs Agreement and the Doha TRIPs Declaration. In particular, the decision increases the scope of diseases beyond “infectious epidemics,” and allows developing countries with no or insufficient domestic manufacturing capacity to procure drugs. Alongside the decision, the Chair of General Council issued a separate statement “to provide comfort to the developed countries that feared that the decision might be abused and undermine patent protection.”

The decision allows any country to issue the compulsory license for exports, and sets out conditions under which countries may be eligible to import drugs, including the obligations of the exporting countries, importing countries and

---

14 Doha Declaration, Paragraph 6.
15 Paragraph 1 of the Declaration states that “We recognize the gravity of the public health problem afflicting many developing countries and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”
16 <www.wto.org/english/news_e/news03_e/TRIPs_stat_28aug03_e.htm> USTR agreed to the developing countries’ demand for an open-ended list of diseases in return for the Chair’s statement.
“generics” manufacturers. The decision defines the criteria of eligibility for importing Members and exporting Members as follows:

“Eligible importing Member” falls into two groups: (1) any least-developed country Member; and (2) any other Member that has made a notification to the Council for TRIPs of its intention to use the system as an importer…” Countries in the second group must show that they have “insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question.” As an LDC, Uganda is “deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector” and is automatically an eligible importing Member. However, a developing country like Nigeria must notify the Council that its pharmaceutical manufacturing capacity is currently insufficient to meet its need, and its intention to use the system. Ambiguities remain regarding how to establish insufficient manufacturing capacity.

The “Exporting Member” is broadly defined – it is “a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.” Developed and developing countries can participate in the system as an exporter.

In addition to defining who can participate in the system, the Decision sets forth a process and series of requirements for both eligible importers and exporters. These requirements are as follows:

a. Importers must notify the TRIPs Council about (1) names and quantities of products, (2) establishment of insufficient or no manufacturing capacities for the products, and (3) intention to grant a compulsory license, if the pharmaceutical product is patented in their territory.

b. Exporters must issue a compulsory license for production and export of drugs under the following conditions: (1) producing quantities needed solely for the purpose of export to the eligible importing Member(s), (2) identifying the products through distinguishing labeling or marking, and (3) posting on a new

---

17 August 30 Decision, Paragraph 2(a). This excludes any capacity owned or controlled by the patent owner (Annex to the Decision).

18 August 30 Decision, Paragraph 2(a).
or WTO website the quantities, destination and distinguishing features of the products\textsuperscript{19}.

c. Exporters must provide adequate remuneration to the patent holder, taking into account the economic value to the importing Members. Exporters must also notify the Council for TRIPs of the grant of the license, including the conditions attached to it\textsuperscript{20}.

The August 30 Decision also outlines additional requirements related to compulsory licensing. These requirements include

(1) Importing Member takes measures to prevent re-exportation, and

(2) All WTO Members make available legal means to prevent the importation into, and sale in, their territories of pharmaceutical products intended for eligible importing Members under this system\textsuperscript{21}.

The Chair’s statement elaborates by stating that the prevention of re-exportation applies “not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients\textsuperscript{22}.”

The Chair’s statement further states that the Decision should not be “an instrument to pursue industrial or commercial policy objectives”.\textsuperscript{23} The Decision requires that products manufactured using the compulsory license be differentiated by using special packaging and/or special coloring or shaping, and the Chair’s statement maintains that product differentiation “should not have a significant impact on the price of pharmaceuticals.”\textsuperscript{24} Some NGOs have argued that the additional stringent requirements set out in the August 30 Decision and the Chairman’s statement – such as product differentiation and prohibition on pursuing “industrial or commercial policy objectives” – would constitute \textit{de facto} obstacles to the use of the Paragraph 6 importing/exporting mechanism. The U.S. government sought to keep the whole procedure in place in order to, as it has argued, prevent circumvention of the process for illegitimate purposes such as parallel importation.

\textsuperscript{19} August 30 Decision, Paragraph 2(b).
\textsuperscript{20} August 30 Decision, Paragraph 2(c).
\textsuperscript{21} August 30 Decision, Paragraphs 3, 4, 5.
\textsuperscript{22} The General Council Chairperson’s Statement, August 30, 2003.
\textsuperscript{23} Ibid.
\textsuperscript{24} The General Council Chairperson’s Statement, August 30, 2003
On the other hand, some have argued that the U.S and other developed countries purposefully instituted the difficult procedure to prevent a meaningful use of the Paragraph 6 solution by developing countries. The August 30 Decision takes the form of an “Interim Waiver” which stands as a definitive statement of WTO law until the WTO makes a formal amendment to its intellectual property agreement.  

On the analysis of various provisions which are included in TRIPs Agreement which were specifically included in the light of DOHA agreement which facilitated the member countries to utilize the flexibilities subject to various stipulations which are difficult to implement in the member countries. This can be clearly made out by the statement raised for “the first time public health advocates raised the concern that the globalization of new international trade rules and the harmonization of regulatory requirements would restrict countries’ ability to implement drug policies that would ensure access to medicines for all.” As’t Hoen has stated, the “comments made it apparent that even drug policy experts at the time had a very limited understanding of the ramifications of new international rules on intellectual property.” TRIPs includes many relatively clear obligations, such as the requirement that patents last at least twenty years, it also includes many vague and undefined commitments, such as the requirement to engage in “reasonable” efforts to negotiate with patent holders before overriding a patent.

All the agreements of WTO, including TRIPs, came into force on 1 January, 1995. But Article 65.2 of TRIPs permits developing countries, a transition period of five years to implement the provisions of TRIPs. In addition, if a country did not provide product patent protection in any field when TRIPs came into force, then under Article 65.4, she gets another five years (in addition to the five years permissible under Article 65.2) to introduce such protection. But Articles 70.8 and 70.9 of TRIPs put a limitation on the transition periods allowed under Articles 65 for two classes of products - pharmaceuticals and agricultural chemicals. India and

25 This is according to the August 30th Decision explanation, available on the WTO website at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm.
27 Art 31(b) of TRIPs Agreement.
other developing countries were required to introduce “mail box” and “exclusive marketing rights” provisions from 1st January, 1995.28

The Doha WTO Ministerial Declaration on TRIPs and Public Health, adopted on 14 November 2001, which affirmed the right of all countries to protect public health. In the general Ministerial Declaration of the Doha Conference29, Article 17 states that the WTO countries realize the importance of the implementation and interpretation of TRIPs in a manner supportive of public health. The Doha Declaration does not amend the rights and obligations laid down in TRIPs, but provide guidance for the interpretation of the relevant parts of the Agreement.

According to paragraph 1 of the Doha Declaration the member states recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, TB, malaria and other epidemics. The TRIPs Agreement should address the health problems, and that IP protection is important for the development of medicines, but that the effects on prices is concerning. Therefore, the parties to the Declaration agreed that the TRIPs Agreement should not prevent measures to protect public health. This is developed in paragraph 4, which provides that the TRIPs Agreement “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all”. In order for countries to have flexibility in using the TRIPs agreement, paragraph 5 goes on to state, inter alia, that TRIPs shall be read in light of the object and purpose of the Agreement, found in Articles 7 and 8 of TRIPs, and that each member has the right to grant compulsory licenses and the freedom to determine the grounds for such a license30. When using compulsory licensing in accordance with TRIPs Art 31, the Doha Declaration further gives the member states the right to determine what constitutes national emergency or other circumstances of extreme urgency, which are conditions to issue compulsory

---

28 For a discussion of these transitional arrangements under TRIPs, see Ganesan 1999 in the Indian context and UNCTAD-ICTSD 2003; 2004 in the general context. Available at www.unctad.org
30 Doha Declaration, Article 5a) and b). The objectives of the TRIPs Agreement, found in Art 7, are, inter alia, to promote intellectual property in a manner conducive to social and economic welfare, and to a balance of rights and obligations. The principles, found in Art 8, state that members may 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.
licenses. Article 5 also leaves each member free to establish its own regime for the exhaustion of intellectual property rights without challenge. Recently, on 30 August 2003, a decision was reached in the WTO regarding new rules for the export of pharmaceutical products under compulsory licenses. This decision, and the debate leading up to it, and the debate which will surely follow it, derives from Article 6 of the Doha Declaration.

The article, cited in full, reads:

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.

Paragraph 7 of the Declaration provides, inter alia, an extension to the transition periods for LDCs as regards the pharmaceutical products, until 2016 and extended till 2023 recently. As was indicated above, one main area of debate since the Doha Conference has been paragraph 6 of the Declaration, which addresses the effective use of compulsory licensing. As the Council for TRIPs was given until the end of 2002 to find a solution, it did put forward a proposal. Most countries found the proposal acceptable, with the US being the only country to object to it. On 20 December 2002, as the US made clear that they would not accept the proposal, it was obvious that the Council for TRIPs had failed in the task given to it in November 2001. With a new decision in place from August 2003, some of the problems may have been solved, there is still no solid solution and this will remain one of the main issues of debate. There is also a debate on the legitimacy and interpretation of the existing wording of the TRIPs Agreement and the Doha Declaration. It is debatable whether it is a subsequent agreement on interpretation of TRIPs, evidence of practice, or a nonbinding commitment, which would not

---

31 Doha Declaration, Art 5c). It is understood that public health crises, including HIV/Aids, TB, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
32 Doha Declaration, Art 5(d).
33 The Decision on implementation of Article 6 of the Doha Declaration on TRIPs and public health.
   The decision is analyzed in section 4.
34 Doha Declaration, Art 6, emphasis added
constitute an enforceable legal obligation. The texts of the TRIPs Agreement and the Doha Declaration still contain many problems that remain unsolved.

According to the critics, IPRs are not inherent, natural rights and should not be treated as such. This debate revolves around the general issue of the monopoly and private rights granted through patents, as opposed to the public interest and social benefits deriving from science and technology. Due to this conflict, patent laws that are strong for protecting private interest are thus weak for protecting the public interest, at least initially.

The most important parts of the TRIPs Agreement regarding pharmaceutical patents which are enumerated in articles 28 (rights conferred), 30 (exceptions to rights conferred) and 31 (other use without authorization of the right holder). One of the problems addressed by the Doha Declaration is the compulsory licensing rules under TRIPs, found in Art 31(f).

Article 6 of the Doha Declaration gives the member countries until the end of 2002 to address the specific problem. At the end of 2002, all members of the WTO, except the US, had accepted a draft presented by the Chairman of the Council for TRIPs. However, since an agreement could not be reached, a solution is still on the agenda for the WTO. If the international policy changed in favor of developing countries, or if the wording of the Doha Declaration was taken seriously, and a change in the TRIPs Agreement or the interpretation thereof took place, there are a number of possibilities to create such a legal framework. As will be developed further below, it is considered by many economically insufficient to require domestic production for every medicine a country may need. When a developing country that


36 W. Pretorius, in Drahos and Mayne (eds), Global Intellectual Property Rights, 183.

37 Ibid. Pretorius claims that some interest groups are promoting IPRs as natural rights – “rights that have a moral force that somehow elevates them above political challenge”.


39 Doha Declaration, paragraph 6. TRIPs, Art 31(f): “any such use [of compulsory licensing] shall be authorised predominantly for the supply of the domestic market of the Member authorising such use”.

has a significant drug manufacturing capability, like Brazil and India, implement pharmaceutical patent enforcement, the ability to develop and export generic versions of patented drugs in those Member states may disappear, or at least the costs of the drugs will increase significantly. The clarification of the relationship between the TRIPs Agreement and the GATT/WTO may be crucial for the interpretation of several aspects of the Agreement, such as the permissibility of banning parallel imports, the extent to which exceptions can be established under Article 8.1, and, more generally, the criteria to be applied to the interpretation of exceptions provided under the TRIPs Agreement. Under GATT/WTO jurisprudence the exceptions to the obligations of states have been generally construed narrowly. This also applies to the case of TRIPs as illustrated by the panel’s opinion in Canada—Patent Protection for Pharmaceutical Products on the exceptions to exclusive patent rights conferred by Article 30 of the TRIPs Agreement. However, IPRs themselves constitute exceptions in terms of the GATT—authorized by GATT Article XX (d)—since by their very nature such rights restrict trade.

Article 8.1 of the TRIPs Agreement provides that: Members may, in formulating or amending their national laws and regulations, 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, provided that such measures are consistent with the provisions of this Agreement. Some developing countries, notably India, have expressed concerns about the implications of the phrase “provided that such measures are consistent with the provisions of the TRIPs Agreement”, since it might be interpreted as not allowing any derogation from the obligations of the Agreement”. If this were the case, public

---

41 The word “generic” is given a wide definition here, not only covering drugs with no patent protection but also patented drugs produced by producers using licensing or piracy. The medical definition is “Medication sold without an indicated brand name and not protected by trademark”, a definition which supports a wider use of the word.

42 C Correa, Intellectual Property Rights, the WTO and Developing Countries – The TRIPs Agreement and Policy Options (2000), 163.


44 “As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded. Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner’s rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products”. Canada—Patent Protection for Pharmaceutical Products, supra note 23, at p. 7.45.

45 The Preamble of the TRIPs Agreement, first paragraph.
interest factors (including human health) would receive less protection under the TRIPs Agreement than under GATT, SPS or TBT\(^\text{46}\). In order to be meaningful at all, the consistency test of Article 8.1 should be assessed in the light of Article 7 which defines the “Objectives” of the Agreement and of the Preamble, i.e., taking social and economic welfare into account. In particular, nothing in the TRIPs Agreement should be read as preventing Members from adopting measures to protect public health, as well as from pursuing the overarching policies defined in Article 8\(^\text{47}\).

The “consistency” requirement may permit, for example, patentability exclusions in cases of distinct public health emergencies as defined by the national government, and as distinct from or everyday health and nutrition measures\(^\text{48}\).

Emergency cases could trigger the application of a different test of “inconsistency” (as provided for under Article 8.1) or qualify as a situation not “conducive to social and economic welfare” (as provided for under Article 7). In such a case, a suspension or exclusion from patentability\(^\text{49}\) might be linked to and justified by a specific emergency. Once the emergency subsides, the TRIPs requirement of patentability could be restored.

\(^{46}\) In the case of the SPS Agreement, Members have the right to take measures they deem appropriate to protect human, animal or plant life or health, but must ensure that they are “not more trade restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility” (Article 5.6). The Preamble of the TBT Agreement recognizes that “no country should be prevented from taking measures necessary . . . for the protection of human, animal or plant life or health . . . “. Article 2.2 allows to authorities to consider, in assessing the risks “ . . . available scientific and technical information, related processing technology or intended end-uses of products”. In the case of a dispute, the complaining country may have to provide prima facie evidence that there is an unnecessary obstacle to trade, and the defending country may have to give evidence that the adopted standard is not more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks that non-fulfillment would create (Article 2 of the TBT Agreement).

\(^{47}\) The Council for TRIPs convened special sessions (which were held in June, August and September 2001) to deal with the relationship between health and TRIPs. See the submissions made by the European Communities and their Members States on The Relationship Between the Provisions of the TRIPs Agreement and Access to Medicines, IP/C/W/280 (June 12, 2001); the paper submitted on the same issue by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, TRIPS and Public Health, IP/C/W/296 (June 29, 2001). See also, Special Discussion on Intellectual Property and Access to Medicines, IP/C/M/31, (July 10, 2001).


\(^{49}\) It is debatable whether an exception to patentability may be justified under the general GATT exception to trade disciplines, when the exception is necessary to protect human health. Article XX(b) has been interpreted and applied rather narrowly in GATT/WTO case law. In addition, it is doubtful whether GATT Article XX(b) would apply in the TRIPs context, since the TRIPs Agreement constitutes the lex specialis in the WTO system to deal with intellectual property issues. See India—Patent Protection for Agricultural and Chemical Products.
The Doha Declaration established in paragraph 5 (b) that “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”.

This paragraph confirms what an unquestionable right of Members States is: the right to determine “what constitutes national emergency or other circumstances of extreme urgency”. Such determination may be relevant for the establishment of exceptions under Article 30, the granting of compulsory licenses, or the adoption of other measures permitted under Article 8.1 of the Agreement. It clarifies that “public health crises” can represent “a national emergency or other circumstances of extreme urgency”, thereby allowing for the granting of compulsory licenses when provided for under national law and, pursuant to TRIPs Article 31(b), without the obligation for prior negotiation with the patent owner. The reference to “HIV/AIDS, tuberculosis, malaria and other epidemics” indicates that an “emergency” may be not only a short-term problem, but a long lasting situation, as is the case with the epidemics specifically mentioned for illustrative purposes.

If a Member complains about the qualification of a specific situation by another Member as a “national emergency or other circumstances of extreme urgency”, the language of paragraph 5 (c) places the burden on the complaining Member to prove that such emergency or urgency does not exist. This represents an important difference with respect to earlier GATT/WTO jurisprudence outside of the TRIPs context that, under the “necessity test”, put the burden of proof on the Member invoking an exception to its obligations. A key consideration is clearly the purpose for which any subject-matter exclusion was to be adopted and the proportionality of the adopted measure. If, for example, the same objective could be obtained by imposing

---

50 In May 2002, the Minister of Justice, Legal and Parliamentary Affairs of Zimbabwe issued a Declaration of Period of Emergency (HIV/AIDS Notice, 2002). In view of the rapid spread of HIV/AIDS among the population of Zimbabwe, the Minister declared “an emergency for a period of six months, with effect from the date of promulgation of this notice, for the purpose of enabling the State or a person authorized by the Minister under Section 34 of the Act (a) to make or use any patented drug, including any antiretroviral drug, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions; (b) to import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions”. A Declaration of Sanitary Emergency—until 31 December 2002—was also issued by the Executive Power of Argentina (Decree 486, 12 March, 2002), but it does not make explicit reference to patent law provisions.

permissible compulsory licenses under TRIPs Article 31, an exclusion of patentability could be seen as an attempt to circumvent the preconditions of Article 31, in contradiction with the last sentence of Article 8.1. If, instead, local situations posed such unusual problems as to merit a public interest exception, these problems might also justify overriding or limiting other Articles, such as Article 31, in favor of some non-permanent exclusion of subject matter, if that exclusion was necessary for solving the problem. Important issue is the extent of the exceptions to exclusive rights allowed under the TRIPs Agreement. The panel in Canada—Patent Protection for Pharmaceutical Products took a narrow approach to this issue in relation to Article 30. It made a detailed analysis of some of the elements in Article 30 and held that the exceptions must be read narrowly. It failed to adequately consider the principles and objectives of the Agreement as set forth in Articles 7 and 8, thereby arriving to an interpretation that disregarded the broad economic and social interests that patents are intended to serve. As noted by Howse, in making such analysis the panel ignored the provision of Article 7 “about balance and mutual advantage, interpreting the patent provisions of the TRIPs Agreement primarily from the perspective of intellectual property rights holders, largely dismissing competing social interests, and reducing considerably the range of regulatory diversity permitted under TRIPs.52

A similar line was followed in U.S—Section 110(5) of the US Copyright Act case, where Article 13 of the Agreement was examined. The panel reasoned that whether a limitation or exception conflicts with the normal exploitation of a copyrighted work is to be judged for each exclusive right separately53, that the “legitimate interests of the right holder” were not necessarily limited to the economic value of exclusive rights, and that an “unreasonable” prejudice to such interests existed when an exception caused or had the potential to cause an unreasonable loss of income to the copyright owner. Again the panel missed an opportunity to introduce a more balanced approach in its reasoning as required by the terms of Article 7 of the TRIPs Agreement, and limited its superficial analysis on the “crucial question” of unreasonable prejudice to the economic impact of

52 See, Sara Williams, Developing TRIPs Jurisprudence—The First Six Years and Beyond, 4(2) The Journal of World Intellectual Property 191(2001). For a criticism of the panel’s failure to take the wording of Article 7 into account and reducing the range of regulatory diversity permitted under the TRIPs Agreement, see also ROBERT HOWSE, The Canadian Medicine Panel: A Dangerous Precedent in Dangerous Times, Bridges: Between Trade and Sustainable Development, Year 4, No. 3, at 3.

53 United States—Section 110(5) of the US Copyright Act, at p 6.173 and 6.174
the exception on right-holders’ profit, without any consideration to the possible impact on consumers or the society as a whole.\footnote{United States—Section 110(5) of the US Copyright Act, at page 6229.}

Many national laws require that the compulsory licensee undertake the production of the patented invention in the country where the license is to be granted. However, not all developing countries possess either the entrepreneurial and technical capabilities necessary to permit the local production of inventions or the markets large enough to justify it. Nothing in the TRIPs Agreement prevents a Member from establishing that a compulsory license be worked through importation rather than local production. However, it may not be possible to find independent foreign sources for the importation of a protected product other than the patent owner or its voluntary licensees, meaning that a compulsory license would be de facto impracticable. The only alternative source of supply might be another compulsory licensee for the same patent in a foreign country, but this approach also has a limitation: a compulsory license must be granted, in accordance with Article 31(f) of the TRIPs Agreement, to supply “predominantly” the domestic market.

The European Commission has pointed to another possible interpretation of the Agreement that would allow a Member to issue a compulsory license to a manufacturer in another country, provided that the government of that other country recognized the license (which it would not be obliged to do under the Agreement), and provided that all the goods manufactured under the license were exported to the country granting the license.\footnote{The Relationship Between the Provisions of the TRIPs Agreement and Access to Medicines, The Council for TRIPs convened special sessions (which were held in June, August and September 2001) to deal with the relationship between health and TRIPs. See the submissions made by the European Communities and their Members States on The Relationship Between the Provisions of the TRIPs Agreement and Access to Medicines, IP/C/W/280 (June 12, 2001); the paper submitted on the same issue by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, TRIPs and Public Health, IP/C/W/296 (June 29, 2001). See also, Special Discussion on Intellectual Property and Access to Medicines, IP/C/M/31, (July 10, 2001).} It is, however, far from certain whether such a reading of the Agreement would withstand scrutiny by a panel or the Appellate Body.

This seems to ignore the basic principle of independence of patents, as enshrined in Article 4bis of the Paris Convention. In such case, the validity of the proposed scheme would depend on the national law of the exporting country, which may exempt under Article 30 of the Agreement the exploitation of an invention solely for export purposes. In this case, there would be no need to grant a compulsory license in the exporting country. If exports were made under a...
compulsory license, the importation may also be deemed covered under the “exhaustion principle”. If so, it would not be necessary to issue a compulsory license in the importing country (since “parallel imports” would be legitimate).

The obligation to “work” a patent—understood as the local manufacture of the patented product or use of the patented process—The U.S. government and some commentators have argued that the mere importation of a patented product (or of a product made with a patented process) constitutes the “working” of a patent. They have also argued that Article 27.1 of the Agreement effectively outlaws compulsory licenses based on non-working of the invention, since that would constitute discrimination between imported and locally manufactured products.

This is not the view, however, that prevails among developing country Members of the WTO, nor is it reflected in the national laws of many Members who have adopted local working obligations. The Uruguay Round records also reveal that during the negotiations several developing countries argued for the right to impose working requirements.

---


57 See generally TRIPs and Public Health.

58 A draft review of comparative law conducted by Oxfam found working obligations in the patent laws and regulations of Indonesia and Cuba (similar to Brazil); Ghana, Ireland, South Africa, Sudan and Zimbabwe (based on former United Kingdom laws); Greece and Lesotho (compulsory licensing linked to local working); Turkey, Spain and Portugal (certificate of working required); Sweden, Norway, Finland and Iceland (local working tied to reciprocity); India; Israel; Zaire; Thailand; Pakistan; Liberia. Oxfam, Local Working Requirements and the TRIPs Agreement: Using Patent Law as a Means of Ensuring Affordable Access to Essential Medicines. A Case Study from the U.S.-Brazil Dispute (draft) (2001), available at http://www.field.org.uk/papers/pdf/twrta.pdf.

It would be an incorrect interpretation of the negotiating history of the TRIPs Agreement to consider that those countries withdrew their position when they accepted the ambiguous text adopted in Article 27.1 of the Agreement.

The United States initiated a case against Brazil arguing that Article 68 of the Brazilian patent law was inconsistent with the TRIPs Agreement. That provision authorizes the government to grant a compulsory license if the patent owner fails to work the subject matter of the patent in Brazil. A critical issue in addressing the consistency or not of working obligations is whether the non-discrimination clause in TRIPs Article 27.1 governs Article 31 (conditions for the granting of compulsory licenses). Developing countries have expressed the concern that Article 27.1 may be read in a way that restricts the use of compulsory licenses, for instance, on the grounds of non-working. The non-discrimination clause may also be used to challenge compulsory licenses specifically dealing with certain sectors, such as pharmaceuticals. Developing countries have argued in this respect that:

As regards the relationship of the provisions related to compulsory licenses with Articles 27.1 and 28 of TRIPs, we believe that both set of provisions address different matters and circumstances. In no way do Articles 27.1 and 28 limit the right of Members to issue compulsory licenses.

A patent shall confer on its owner the following exclusive rights:

(a) Where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;

(b) Where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

---

60 TRIPs and Public Health, The Council for TRIPs convened special sessions (which were held in June, August and September 2001) to deal with the relationship between health and TRIPs. See the submissions made by the European Communities and their Members States on The Relationship Between the Provisions of the TRIPs Agreement and Access to Medicines, IP/C/W/280 (June 12, 2001); the paper submitted on the same issue by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, TRIPs and Public Health, IP/C/W/296 (June 29, 2001). See also, Special Discussion on Intellectual Property and Access to Medicines, IP/C/M/31, (July 10, 2001).
An interpretation of Article 27.1 read in conjunction with Article 28.1, based on the rules of the Vienna Convention, suggests that the products mentioned in Article 27.1 are infringing products, not the products of the patent owner itself, since patents only confer exclusionary rights in relation to the former. In other words, Article 27.1 forbids discrimination between infringing imported and infringing locally-made products, but it does not prevent the establishment of differential obligations with regard to non-infringing imported and locally-made products (i.e., products made or imported by the patent owner or with his/her consent).

It should also be noted that Article 5(A) (2) of the Paris Convention provides that each party to the Convention “shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.” (Emphasis supplied). Article 8.1 of the TRIPs Agreement expressly contemplates that Members may adopt necessary measures “consistent with” the Agreement to address “the public interest in sectors of vital importance”. Would it be possible to establish specific types of compulsory licenses for, e.g., pharmaceuticals or products needed to remedy environmental damages? In Canada—Patent Protection for Pharmaceutical Products the panel held that Articles 30 (exceptions) and 31 (compulsory licenses) of the TRIPs Agreement were subject to Article 27.1 of the Agreement. However, the factual and legal basis for this finding are unconvincing, since it would seem logical to limit certain exceptions or modalities of compulsory licenses to certain fields of technology, rather than being forced to apply them to fields where such measures are not required.

The panel in fact clarified that the conduct prohibited by Article 27.1 is “discrimination” as to the field of technology that “discrimination” is not the same as “differentiation”, and that WTO members can adopt different rules for particular product areas, provided that the differences are adopted for bona fide purposes. The panel held that Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with

certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than frustration of purpose.

France provides one example of a patent law that differentiates the treatment of pharmaceutical products on public health grounds. The French patent law provides that:

“Where the interest of public health demand, patents granted for medicines or for processes for obtaining medicines, for products necessary in obtaining such medicines or for processes for manufacturing such products may be subject to ex officio licenses in accordance with Article L. 613–17 in the event of such medicines being made available to the public in insufficient quantity or quality or at [abnormally high prices] by order of the Minister responsible for industrial property at the request of the Minister responsible for health”62.

Finally, it is pertinent to recall that the Preamble to the TRIPs Agreement, as well as Articles 7 and 8, make it clear that one of the important objectives of the Agreement is to promote technology transfer, which may be ensured in some circumstances by means of compulsory licenses for nonworking.

The age of TRIPs implementation will constitute a new kind of global community of disagreement about the terms of IP law. TRIPs have pulled Indian Parliamentarians and patent examiners alike into a transnational discourse of patent law. This has important implications for how India implements its new law, and for how we conceptualize the operation of international law more generally. Although India has incorporated an exceptionally broad range of flexibilities into its patent law, the dynamics identified here (related to resource limitations, transnational legal cultures, and the continued existence of extralegal pressure) make it difficult for India to implement these flexibilities.

TRIPs have caused the most controversy in the domain of access to medicines because it requires patents on pharmaceutical products, which at least fifty developing countries did not offer at the time of its adoption63. Patents tend to

---

generate deadweight social losses in the form of higher prices\(^{64}\) for consumers. In the domain of medicines, such losses translate into more limited access to medicines, particularly in developing countries\(^{65}\). The most important potential gain associated with stronger patent law is the marginal incentive for pharmaceutical innovation that will be provided by additional exclusivity in the new country\(^{66}\). But the marginal effects of patents in jurisdictions that are a very small portion of the world’s market will be small, and not likely to outweigh the costs to local consumers\(^{67}\). It is thus fairly clear from the economics literature that higher patent standards for medicines will reduce welfare in developing countries\(^{68}\).

The Indian Patents Act provides that an application for the grant of compulsory license can be made only after three years from the date of grant of the patent unless exceptional circumstances like national emergency or extreme emergency can be used to justify the grant of a license on an earlier date. Three broad grounds for the grant of the compulsory licenses have been spelt out thus: (a) reasonable requirements of the

\(^{64}\)See, e.g., F. M. Scherer, A Note on Global Welfare in Pharmaceutical Patenting, 27 WORLD ECON. 1127, 1128 (2004). Perfect price discrimination could eliminate this deadweight loss but is not expected in practice.

\(^{65}\)Generic medicines are typically substantially less expensive than patented versions, and patients in resource-poor settings are particularly reliant on generic medicines. World Health ORG., The World Medicines Situation, 31, 68-69 (2004).

\(^{66}\)Alan V. Deardorff, Should Patent Protection Be Extended to All Developing Countries?, 13 WORLD ECON. 497,503 (1990). Extending patent protection to a new jurisdiction could produce gains other than innovation. For example, if a firm refuses to sell in a market and others cannot copy the product (e.g., because it requires closely held know-how), the introduction of patents could induce the firm to enter the market and thus improve social welfare. In the pharmaceutical sector, however, reverse engineering is common and rapid. See supra text accompanying notes 33-34. Stronger IP protection could also stimulate foreign direct investment (FDI), but “[i]t is difficult to establish strong theoretical and empirical linkages between intellectual property rights and FDI and technology trade.” Keith E. Maskus, Implications of Regional and Multilateral Agreements for Intellectual Property Rights, 20 WORLD ECON. 681, 689 (1997).

\(^{67}\)See Carlos A. Primo Braga and Carsten Fink, the Economic Justification of the Grant of Intellectual Property Rights: Patterns of Convergence and Conflict, 72 CH.-KENT L. REV. 439, 442-43 (1996). Scherer shows that if extending patents to all low-income nations increased rents by these nations’ share of global GDP (20 percent), the innovative effect would be far less than required to offset the projected deadweight loss. See Scherer, note , at 1128-29. If lesser patent protection in low-income countries eroded protection in wealthy countries, for example because of arbitrage between markets, it could lessen incentives to innovate in wealthy countries and thus diminish welfare for patients in poor countries who could benefit from cheap copies of these innovations. But evidence from the AIDS drugs context suggests that such arbitrage is still for the most part theoretical, despite substantial existing price differentials across countries. See Kevin Outterson, Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets, 5 YALE J. HEALTH POL‘Y L. and ETHICS 193, 262-65 (2005).

\(^{68}\)See Scherer, 42, at 1128 (“It is reasonably well established in the economics literature that, especially in a world of AIDS and resistant tuberculosis epidemics, low-income nations enjoy higher economic welfare when they can free-ride on pharmaceutical innovations made and patented in the first world than when they must pay monopolistic prices for the newest and most effective drugs.”).
public with respect to the patented invention have not been satisfied, (b) the patented invention is not available to the public at a reasonably affordable price, and (c) the patented invention is not worked in the territory of India. The Patents Act sets out the circumstances under which “reasonable requirements of the public” would not have been met. Such circumstances would arise if the patent holder refuses to grant a license on reasonable terms, and which, in turn, affects: (i) development of new trade or industry in the country, and (ii) establishment or development of commercial activities in India, and (iii) development of the export market for a patented article manufactured in India. The last mentioned provision is aimed at ensuring that India has the option to export the products that have been produced using the licenses from the patent holders. The major impact of this provision could be felt in the pharmaceutical sector, where India could well emerge as a major supplier of generic pharmaceuticals to the developing countries that do not have sufficient domestic manufacturing facilities.

But while the above-mentioned conditions for the grant of compulsory licenses can be seen to be facilitating the grant of the licenses, the Act also stipulates that the relevant authority have to take into consideration four additional factors before the licenses can be granted. These include: (a) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensees to make full use of the invention; (b) the ability of the applicant to work the invention to the public advantage; (c) the capacity of the applicant to undertake the risk in providing capital and working the invention, and (d) the efforts made by the applicant to obtain a license from patentee on reasonable terms and conditions and that such efforts were not successful within a reasonable period.

Consideration of these factors for granting compulsory licenses gives rise to several problems. First, the procedural requirements are too onerous and could consequently result in delays. Second, it is not clear whether the grant of a compulsory license would automatically follow the refusal of a patentee to issue a voluntary license on reasonable commercial terms. Third, the grounds for the determination of anti-competitive practices have not been spelt out either the Patents Act or Competition

---

69 The third amendment provided some crucial clarifications pertaining to this condition. The designated authority has been allowed to interpret the term “reasonable period” to mean a period not ordinarily exceeding six months (Section 84(6)).
And, finally, there is no ceiling on the remuneration payable to the patent holder, which will inevitably lead to demand for excessive royalty and unnecessary litigations. As would be discussed below, the last mentioned problem has the potential of blocking the way for the use of compulsory licensing system.

This can be clearly made out in the Indian case where the Indian government has for the first time issued the compulsory license and the oppositions were raised by other countries as to the legitimacy of the effectiveness of the Indian Patents Act. Associates of foreign firms operating in India also have serious reservations about the compulsory licensing provisions included in Patents Act, 1970, as amended.

Some of these firms have pointed out that the existing triggers for issuing a compulsory licensing are far too many in number, which, according to the respondents, goes well beyond the realm of Public Health exigencies and extends sweeping CL provisions across the board and not just to “national emergency” situation, as envisaged in TRIPs and as clarified by the Doha Declaration.

The remuneration that a patent holder could demand following the decision to grant compulsory license for the “working” of patents in the country of grant act may become a serious constraint for the smooth functioning of the compulsory licensing system. This situation arises because the Agreement on TRIPs provides the rights holder a distinctly superior bargaining position. Article 31(h) of the TRIPs Agreement, which provides the guideposts in this regard, states that “the right holder shall be paid adequate remuneration … taking into account the economic value of the authorization” (emphasis added). This Article has the potential of rendering the cost of the license prohibitive for the drug majors have claimed that the average cost of bringing one new medicine to market is at least a billion US dollars.

Royalty payments would be a critical issue in the implementation of the compulsory licensing system as is provided in the Indian Patents Act. Besides the

---

70 In fact, India’s Competition Act (enacted in 2002) does not address abuses of patent rights. Section 3(5) of the Competition Act, states: “Nothing contained in this section shall restrict … the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights which have been or may be conferred upon him under … the Patents Act, 1970. See Govt. of India (2003)

71 The Pharmaceutical Research and Manufacturers of America (PhRMA) states that it takes as long as 15 years and cost nearly 1 billion dollars to bring a new medicine from the laboratory to a pharmacy shelf. This figure has, however, been challenged by several public interest groups. See PhRMA (2006).www. PhRMA.org
problems alluded to above, there are evidences galore of developing countries being unable to afford proprietary technologies because the high cost of acquiring such technologies. This situation has occurred primarily because the owners of technology have been able to use their superior bargaining position to seek terms that have suited their interests. In an age when a web of patents covering a single product (better known as patent thickets) has become common place, multiple licenses are often required to be negotiated before any enterprise can commence production. Patent thickets have also given rise to another problem, viz., royalty stacking. According to an OECD study, firms have reported that in some cases royalty payments can exceed 20 percent of their net sales. And, in South Africa, GlaxoSmithKline demanded a royalty of 25 percent before the courts intervened. A higher royalty will increase the price of generic drugs and this, in the ultimate analysis would militate against the existence of the generic producers whose raison d’être is to supply medicines at affordable prices.

The changes made in Section 3(d) of the Act, particularly the exclusion of a new form of a known substance from patentability, attracted much debate and litigation in India. It was alleged, in the Novartis case before the Madras High Court that this provision is in violation of India’s TRIPs obligations. The court, however, refused to examine this issue, which it considered to be outside its jurisdiction. It was also alleged that this provision may have a potential negative impact on indigenous innovation. If one examines Section 3(d) in detail, it is evident that the provision excludes the mere discovery of new forms (derivatives) of known substances from patentability unless they result in the enhancement of known efficacy of the substance. The explanation further clarifies that the “efficacy” requirement relates to substances that “differ

---

72 A well-documented Indian case from the pre-1970 phase, when the country had a product patent regime cogently illustrates this issue. In response to an application for compulsory licence by a government-owned research institute, Haffkine Institute, the patentee indicated that it was willing to grant a voluntary licence. At the end of the negotiations, however, the patentee demanded a royalty of 25%. Further negotiations followed, and after more than four years, the patentee agreed to reduce the royalty to 10 per cent, which was still higher than 5% limit fixed by the government. This protracted process of negotiations for obtaining a licence was found too costly by the prospective licensee and it was forced to abandon the project. For details see, Lok Sabha (1969).

73 A more formal definition of patent thicket is the following: it is a “dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology”, see Shapiro (2001) quoted in Federal Trade Commission (2003).

74 High Court of Judicature at Madras, August 2007. The case concerned a petition under Art.226 of the Constitution of India asking the court to declare that s.3(d) of the Patents Act, 1970 as substituted by the Patents (Amendment) Act 2005 (Act 15/2005) was unconstitutional: http://judis.nic.in/chennai/jchjudis.asp

75 Novartis AG v. Union of India, W.P. Nos.24759 and 24760 of 2006 decided on 06.08.2007 (Madras High Court).
significantly in properties with regard to efficacy”. This restriction is aimed at preventing ever greening. There is much debate with respect to the scope of the term “efficacy”. In the Novartis case\(^76\), it was alleged that this term is not properly defined and that insufficient guidelines are provided for its interpretation\(^77\). The Court held that the argument that the amended section must be held to be bad in law since for want of guidelines it gives scope to the Statutory Authority to exercise its power arbitrarily, has to be necessarily rejected since, we find that there are in-built materials in the amended section and the Explanation itself, which would control/guide the discretion to be exercised by the Statutory Authority\(^78\).

The Court further observed that the amended Section does not suffer from vagueness, ambiguity or arbitrariness. In reaching this conclusion the Court interpreted “efficacy” to mean “the ability of a drug to produce the desired therapeutic effect”. The Court interpreted “therapeutic” in the following manner:

“Darland’s Medical Dictionary defines the expression “efficacy” in the field of Pharmacology as “the ability of a drug to produce the desired therapeutic effect” and “efficacy” is independent of potency of the drug”.

Dictionary meaning of “Therapeutic” is healing of disease—having a good effect on the body. Going by the meaning for the word “efficacy” and “therapeutic” extracted above, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease / having a good effect on the body. In other words, the patent applicant is definitely aware as to what is the “therapeutic effect” of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for. Therefore it is a simple exercise of, though

---

\(^76\) Novartis AG v. Union of India, W.P. Nos.24759 and 24760 of 2006 decided on 06.08.2007 (Madras High Court).

\(^77\) It was argued by the petitioner that: “Under the amended section, the patent applicant is required to show that the invention has enhanced efficacy of the known substance. Though the efficacy of a known substance may be well known, yet, unless there are some guidelines in the amended section itself to understand the expression ‘enhancement of the known efficacy’ namely, what would be treated as ‘enhanced efficacy’, an uncontrolled discretion is given to the Patent Controller to apply his own standards, which may not be uniform, in deciding whether there is enhancement of the known efficacy of that substance. Such wide discretion vested with a Statutory Authority without any guidelines to follow, would result in arbitrary exercise of power. In other words, the Patent Controller may be in a position to decide any case, based on his whims and fancies namely, whether there is enhancement in the known efficacy or not. On this short ground, the section must be held to be violative of Article 14 of the Constitution of India.” Ibid., Para 3.

\(^78\) Ibid., para 16.
preceded by research,—we state—for any Patent applicant to place on record what is the therapeutic effect/efficacy of a known substance and what is the enhancement in that known efficacy. The amended section not only covers the field of pharmacology but also the other fields. As we could see from the amended section, it is made applicable to even machine, apparatus or known process with a rider that mere use of a known process is not an invention unless such a known process results in a new product or employs at least one new reactant. Therefore the amended section is a comprehensive provision covering all fields of technology, including the field of pharmacology. In our opinion, the explanation would come in aid only to understand what is meant by the expression “resulting in the enhancement of a known efficacy” in the amended section and therefore we have no doubt at all that the Explanation would operate only when discovery is made in the pharmacology field\textsuperscript{79}. The Court concluded that, scientifically it is possible to show with certainty what the properties of a “substance” are. Therefore when the Explanation to the amended section says that any derivatives must differ significantly in properties with regard to efficacy, it only means that the derivatives should contain such properties which are significantly different with regard to efficacy to the substance from which the derivative is made. Therefore in sum and substance what the amended section with the Explanation prescribes is the test to decide whether the discovery is an invention or not is that the Patent applicant should show the discovery has resulted in the enhancement of the known efficacy of that substance and if the discovery is nothing other than the derivative of a known substance, then, it must be shown that the properties in the derivatives differ significantly with regard to efficacy\textsuperscript{80}.

The Draft Manual of Patent Procedure and Practice 2008 quotes from the Madras High Court decision in the \textit{Novartis case} to explain the term “efficacy”\textsuperscript{81}. It may be noted that while most Indian pharmaceutical companies are opposing patent extensions through ever greenining, and are insisting on strict criteria for patentability, some multinational companies argue that patenting of incremental

\textsuperscript{79} \textit{Novartis AG v. Union of India}, W.P. Nos.24759 and 24760 of 2006 decided on 06.08.2007 (Madras High Court), para 13.

\textsuperscript{80} \textit{Novartis AG v. Union of India}, W.P. Nos.24759 and 24760 of 2006 decided on 06.08.2007 (Madras High Court), para 13.

improvements—such as derivatives of known substances of the type listed in Section 3(d)—would help Indian industries to grow\textsuperscript{82}.

However, in adopting patentability standards development interests, which include the physical well-being and health of its people, should be an equally strong concern for every country, along with concern for industrial development. Therefore, allowing patent protection for incrementally modified drugs, even for the sake of encouraging the development of the indigenous industry, may be outweighed by the need to provide access to pharmaceuticals at an affordable cost. It may be noted that there also are studies in the U.S and Europe that support the approach of avoiding patenting of incremental innovations, at least in these fields, and that suggest that high patentability standards are desirable\textsuperscript{83}.

The crux of the matter is 3(d), which states, the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant. This can be further clarified with the following explanation appended to the section:

For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

These are early days for 3(d) – and as it is unique to India, there isn’t directly applicable case law to reflect upon. Further, as the provision is technologically neutral, it would help that a cautious and reticent approach is taken by the judges in parsing out 3(d). To an extent, the lower courts have provided some useful parameters that could be reiterated. For one, ‘efficacy’ will necessarily be dependent on the technological sector; thus, prohibits the possibility of a general / quantifiable rule. It may itself have a


temporal dimension – in that as science and technology develop and stabilize along particular pathways, particular technological achievements are considered mundane rather than inventive. The lower courts have also pronounced that for pharmaceutical products the idea of efficacy is necessarily therapeutic. It makes full sense for this to be reasserted. No doubt, a number of developments around a given substance, as in the case of Glivec, are important and add to the product. For instance, improved absorption, better storability, etc.; however, these, as the IPAB concluded, are “presentational” and do not render a significant change in the efficacy of the drug. To elaborate, one of the aspects of ever-greening in pharmaceutical is to pursue a spectrum of pathways to incrementally modify a single drug; thus, deepening the patent thicket and delaying generic entry. While some of these incrementally modified drugs may be ‘better’ – they rarely are therapeutically ‘better’.

The patent law contains several substantive safeguards to check ever-greening of patents. Section 3 of the Indian Patents Act, 1970, enumerates lists out what are not considered “inventions” and therefore cannot be granted a patent. Firstly, section 3(d), even before the 2005 amendment, excluded mere discovery of new properties or new uses of known substances from patentability. Thus, second medical uses of known substances cannot be patented in India. Second, section 3(d), as amended in 2005, states that discoveries of new forms of known substances are not inventions, unless there is a significant enhancement in the known efficacy of the known substance. For example, if a patent applicant wishes to patent a polymorph of a known salt (A), the patent applicant must show that the particular polymorph is significantly more efficacious than the known efficacy of the known salt (A). The explanation to section 3(d) clarifies that salts, esters, ethers, polymorphs, combinations, etc are deemed to be new forms of known substances.

Third, section 3(e) of the Patents Act, 1970 disallows patenting of admixtures, which result merely in the aggregation of the properties of the

---

84 Section 3(d) of the Patents Act, 1970, as it now stands, reads as follows: “The following are not inventions within the meaning of this Act.—(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substances, unless they differ significantly in properties with regard to efficacy.” (emphasis supplied).
Interestingly, India also amended the definition of inventive step to make it more stringent. Section 2(1)(ja) of the Patents Act, 1970 requires a patent applicant to show that the invention constitutes technical advance or economic significance or both and it is not obvious to a person skilled in the art. Thus, the Indian patent law has certain provisions that can prevent frivolous patents from being granted. It remains to be seen whether the Indian Patent Office applies the patentability standards in a strict manner to ensure that the public health interest is safeguarded. However, the spate of patents granted to pharmaceuticals in India raises questions as to how public health safeguards are being implemented.

5.3.3 Flexibilities in the TRIPs are not sufficient to meet the requirements of the Indian People

The effects of compulsory licensing are to increase competition, to supply the market, and possibly to reduce prices. It is considered, in certain cases, that access to the invention should have priority over the private interest of the patent-holder and his exclusive right to exploit it. In developing countries, the patent has a marginal effect in terms of encouraging innovation, with extremely negative consequences for social well-being.

The analysis of the costs and benefits of compulsory licensing is essential to use it as an instrument to create public policies by developing countries. Discouraging innovation is regarded as the main risk caused by compulsory licensing. The prospect that profits obtained from exploiting the patent could suddenly disappear would reduce the incentive to invest in innovations. It would be more beneficial to profit from investments made by third parties than perform one’s own research to develop a new product or productive process. It is also stated that inventors have little incentive to patent their inventions, and would rather keep them as industrial secrets.

85 Section 3(e) of the Patents Act, 1970 reads as follows: "The following are not inventions within the meaning of this Act,— ...(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance." (emphasis supplied).

86 Section 2(1)(ja) of the Patents Act, 1970 reads as follows: "2(1) In this Act, unless the context otherwise requires—...(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art" (emphasis supplied).

The foresee ability of compulsory licensing can affect investments in markets of great importance. However, there will be reduced impact on innovation if royalties are paid according to the existing criteria for the licensing of products on the market. Non-predictable compulsory licensing may affect a company’s decision to invest, but the licensing may occur too late for the company to change its behavior. Another frequent argument refers to the potential negative effects of compulsory licensing on the attraction of foreign investment. So far there have been no conclusive studies showing a link between the level of protection of intellectual property and the amount of foreign resources entering a country. Choices of investment are in fact influenced by the analysis of the potential for economic growth of a country and by the soundness of its institutions. High levels of protection of intellectual property do not in themselves guarantee the transfer of technology to developing countries. To reduce the risks of abuse, developing countries should use compulsory licensing in the specific circumstances defined by already existing laws. The use of compulsory licensing as a strategy to create public policies should be linked to a framework which ensures reasonable remuneration for the patent-holder. This would attenuate the effects of compulsory licensing on technological progress. Article 31(h) of the TRIPs Agreement requires that the patent-holder receive adequate remuneration, established case-by-case according to the value of the concession. When compulsory licensing is conceded to repress anti-competitive conduct, the remuneration may receive special treatment, in the terms of article 31(k). It has already been suggested that this norm would allow the payment of reduced royalties, or even the free concession of the license. The main problem involving the concession of compulsory licensing lies in the value of the remuneration to be paid to the patent-holder. The payment of royalties similar to those paid to the patent-holder in the case of voluntary licensing would prevent, in practice, the fulfillment of the objectives of compulsory licensing.88

The situation changes when the issue is compulsory licensing conceded to repress anti-competitive conduct. The establishment of high royalties for the compulsory licensing of medicines would have extremely negative effects on the poorer sectors of the population. On the other hand, the establishment of royalties at

88 Bárbara Rosenberg, Patentes de medicamentos e comércio internacional: os parâmetros do TRIPs e do direito concorrencial para a outorga de licenças compulsórias, a doctorate thesis presented at the University of São Paulo, 2004, page 176.)
low levels would enable the market to be supplied, thus contributing to raising the level of social welfare. Compulsory licensing is not widely used by developing countries to encourage access to medicines. Greater use of compulsory licensing in developing countries requires the existence of high levels of the protection of patents in developed countries. This factor would make it possible to adopt different prices according to the specific needs of each market. The granting of compulsory licenses would increase competition and decrease the prices of pharmaceutical products in developing countries. On the other hand, the price of medicines would tend to rise in the market of developed countries.

Lamentably India has not availed of these flexibilities. As highlighted earlier the provisions of compulsory licensing as incorporated in the Indian patent law is hardly sufficient to prevent abuse of patent monopoly. These flexibilities in the TRIPs allow us to incorporate a stricter and foolproof compulsory license provision that shall be better able to deal with the abuses if any. Further the criterion for patenting can be made more austere so that ‘ever greening’ of patents may be prevented. Again a maximum time limit must be fixed within which the patent holder should grant a license on reasonable terms. A violation of this period should be severely punished. Moreover these flexibilities in the TRIPs may be used beneficially to find and plug loopholes which might allow the abuse of the patent monopoly in any form.

In practice it is difficult for developing countries to make use of these flexibilities. To start with, a variety of burdensome administrative tasks have been created to limit the potential for compulsory licensing. According to 20 civil society groups, WTO took a 52-word mechanism endorsed by the EU in 2002 and created a 3200-word maze of red tape ‘plainly designed to frustrate and undermine the

---


objective of protecting public health and promoting access to medicines to all. Developing countries are furthermore subjected to enormous economic and political pressures not to use the TRIPs flexibilities. These pressures include threats of litigation by companies and trade sanctions by governments.

The US government, for example, has used bilateral trade agreements, the threat of sanctions, and associated diplomatic and political pressures to undermine countries that produce generic medicines and/or consider importing them. This clearly shows how “International law only for weaker states” is applied in stricter sense. The harsh truth is that the U.S interprets the 1963 Vienna Convention on Consular Relations restrictively at home but liberally overseas so as to shield even the spies and contractors it sends. A just rule based international order has long been touted by powerful states as essential for international peace and security. But there is a long history of major powers using international law against other states but not complying with it themselves, and even reinterpreting or making new multilateral rules to further their geopolitical and economic interests.

5.3.4 Findings

Confronted with this new framework, which constitutes a reinforcement of the legal patent system the world over, India is witnessing a reappraisal of its industry and as a corollary, of patients’ access to medicines. The problematic of self-sufficiency in healthcare has resurfaced with the danger of India once again becoming dependant on foreign products, which are themselves fortified by guarantees granted at the international level. It is the main stance taken by some developing countries, which would like the WTO to acknowledge the priority of patient care over drug manufacturers. In other words, these countries would appreciate it if the WHO logic is given more evident and effective weight, for it is a logic that recommends healthcare for all and the recognition of health as a global public good for this new millennium.

94 Bramha Challeney, article, The Hindu, Friday, December, 20, 2013.
95 92 AJWH ( VOL. 2:65)
96 See Carlos M. Correa, supra note 56, at 331; see generally Jeffrey D. SACHS, Macroeconomics and Health: Investing in Health for Economic Development (2001).
More precisely, many provisions may undermine the recourse to TRIPs flexibilities, prevent the supply of generic drugs and finally damage drugs accessibility in developing countries. Among others, efforts are made to broaden the scope of patentability so that new forms and new therapeutic uses can be patented; data protection is ensured for five years, even ten years; and provisions governing Compulsory Licenses and Parallel Imports proved to be more restrictive compared to the ones in the TRIPs agreement. To sum up, these provisions could well strengthen in a more than a reasonable manner the interests of the MNCs by ensuring the protection and the extension of monopolistic positions in developing countries.

In practice, however, the question remains whether TRIPs is flexible enough to allow developing countries to address public health issues. In other words, does TRIPs strike a fair balance between public health and patent rights? This question still generates a great deal of controversy. Hence, TRIPs flexibility regarding patent rights has been repeatedly challenged. Hence we can clearly make out a conclusion that there is conflict in product patent protection and protection of public health. This ongoing debate and controversy about patent rights and public health embodies an underlying controversy between developed countries and developing countries regarding the nexus between IP rights protection and public health care. Whereas developed countries seek a very narrow interpretation of the flexibilities recognized within TRIPs, developing countries tend to adopt a broad interpretation of the exceptions to patent rights.


98 Cynthia M. Ho, A New World for Addressing Patent Rights and Public Health, 82 Chicago-Kent Law Review, 1469, [2007], Ibid. p. 1470, see also, Frederick M. Abbott and Jerome H. Reichmann, The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions, 10, Journal of International Economic Law, 921, December 2007, p. 7. As pointed out by Abbott and Reichmann, “Although the decolonisation process saddled many (if not most) developing countries with membership in the Paris Convention for the Protection of Industrial Property of 1883, the provision of that agreement concerning patented inventions dealt mainly with rules of priority and national treatment. It otherwise left states free to devise and implement their own patent systems and, as many chose to do, even deny any patent protection for pharmaceutical products at all”. The examples of Switzerland and Italy which provide patent protection respectively in 1977 and 1978 are given.

99 It is worth to note that though developed countries often claim that TRIPs flexibilities should be interpreted narrowly, they don’t hesitate to adopt a broad interpretation when facing health issue. For instance the United States considered using compulsory licence in the anthrax “crisis”.
Patent rights and public health involve also different rationales and values that are not necessarily reconcilable, such as trade and human rights. Although a supportive international framework for the right to health exists through the different United Nations declarations, and the Millennium Development Goals, the balance is still in favor of patent rights, favored by a binding enforcement mechanism. Moreover, patent protection is getting stronger with the tendency of some developed nations, especially the United States, beside the multilateral framework, to “impose” stronger patent standards in bilateral agreements. These bilateral agreements, generally referred to as “TRIPs-plus”, coupled with insidious political pressure, as well as the threat of the “Special 301” of the US Trade Act on countries willing to legally enforce their rights from the TRIPs flexibilities, as illustrated by the Thai case, leads ineluctably to a drastic hindrance of TRIPs flexibilities.

5.4 THE PRODUCT PATENT REGIME IN THE FIELD OF MEDICINES AND DRUGS HAS A NEGATIVE IMPACT ON PUBLIC HEALTH POLICY

Granting Patents to the drug itself under the product patent regime especially the pharmaceutical sector has raised the prices of the drugs not only in India but all over the world. The reason for the drug priced at high rates is due to the exclusive rights to the patent holder who fixes the price at his whims and fancy stating that there is a huge investing in Research and Development of a particular drug. Drug prices play

---

100 See for instance, United Nations, Report of the High Commissioner of the Human Rights Commission on Economic, Social and Cultural Rights, The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, UN Doc, E/CN.4/Sub.2/2001/13, at 14. The argument is made in this study that access to medicine is a Human Right and TRIPs should be interpreted in a way to facilitate access to medicine. See also, Alan O. Sykes, ‘TRIPs, Pharmaceuticals, Developing Countries, and the Doha “Solution”’, 3, Chicago Journal of International Law, 47, Spring 2002, at p. 5.


102 Cynthia M. Ho, A New World for Addressing Patent Rights and Public Health, 82 Chicago-Kent Law Review, 1469, [2007], Ibid. p. 1470, see also, Frederick M. Abbott and Jerome H. Reichmann, The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions, 10, Journal of International Economic Law, 921, December 2007, p. 7. As pointed out by Abbott and Reichmann, “Although the decolonisation process saddled many (if not most) developing countries with membership in the Paris Convention for the Protection of Industrial Property of 1883, the provision of that agreement concerning patented inventions dealt mainly with rules of priority and national treatment. It otherwise left states free to devise and implement their own patent systems and, as many chose to do, even deny any patent protection for pharmaceutical products at all”. The examples of Switzerland and Italy which provide patent protection respectively in 1977 and 1978 are given. p 1485.
a significant role in the access to medicines, health service provision and financing particularly in low income countries dominated by the private sector and with weak to absent social health insurance systems. From a position of high drug prices in the pre-1970s era in India, rapidly growing domestic drug companies aided by effective drug policies are now capable of indigenously producing both bulk drugs and formulations, to a large extent. This has resulted in a situation in the country, where relatively speaking, drug prices are presently among the lowest in the world. However, policy changes in the 1990s reduced the coverage of drug price control from about 90% of the market in late 1970s to about 10% of the market in 1995.\(^{103}\)

Taking advantage of lax regulations on drug pricing, the pharmaceutical industry has been able to reap high margins through complex price setting activities. It has been observed that the price of a therapeutically similar drug could vary around 1000% between the most expensive and the cheapest brands.\(^ {104}\) Further, the variation between the market and procurement price of similar drugs could range anywhere between 100% to 5000%.\(^ {105}\)

5.4.1 Variation of Drug Prices – Evidence of Profiteering

Currently the prices of only 74 drugs are controlled by the Government in contrast to the prices of 342 drugs being under price control in 1979. Further, since the list of these 74 drugs was drawn up in 1995, the importance of many of these has declined.\(^ {106}\)

Studies in the past few years have clearly demonstrated the effectiveness of price control\(^ {107}\) reported a nearly 40% increase in all drug prices between the period of 1996 and 2006. During the same period, the price of controlled drugs rose only by 0.02% while the price of EDL drugs (Essential Drug List) rose by 15%. In contrast, the price of drugs that were neither under price control nor under the EDL grew by 137%. The price decontrol policies of the 1990s have contributed to an


\(^{107}\) Sengupta et al. (2008)
enormous price increase during the last 15 years. Drug prices have shot up phenomenally, as shown in the table and have widened vis-à-vis general price trends during 1993-94 to 2003-04. The current practice of drug price control is based on cost-plus pricing. This can be an effective mechanism if the government is able to obtain cost data accurately.

Table 3: Comparative Price Variations in Medicines for Various Therapies

<table>
<thead>
<tr>
<th>Drug Therapeutic</th>
<th>Category</th>
<th>Top Selling vs. Cheapest (%)</th>
<th>Most Expensive vs. Cheapest (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albendazole – 400 mg. tablet</td>
<td>Anti helminthes</td>
<td>300.00</td>
<td>320.00</td>
</tr>
<tr>
<td>Alprazolam – 0.5 mg tablet</td>
<td>Tranquiler</td>
<td>555.56</td>
<td>555.56</td>
</tr>
<tr>
<td>Amikacin Inj. 250 mg</td>
<td>Antibiotic</td>
<td>188.99</td>
<td>339.08</td>
</tr>
<tr>
<td>Amitriptyline – 10 mg tablet</td>
<td>Anti psychotic</td>
<td>700.00</td>
<td>700.00</td>
</tr>
<tr>
<td>Amlodipin – 10 mg</td>
<td>Cardio vascular</td>
<td>423.20</td>
<td>792.00</td>
</tr>
<tr>
<td>Amoxy+Clavulanic Acid 625 mg tabs</td>
<td>Antibiotic</td>
<td>195.47</td>
<td>203.63</td>
</tr>
<tr>
<td>Atorvastatin – 10 mg tablets</td>
<td>Lipid lowering agent</td>
<td>500.00</td>
<td>500.00</td>
</tr>
<tr>
<td>Azithromycin 250 mg tablets</td>
<td>Antibiotic</td>
<td>181.64</td>
<td>552.97</td>
</tr>
<tr>
<td>Beclamethasone Inhaler 100 mcg x 200 doses</td>
<td>Anti-asthamatic</td>
<td>100.28</td>
<td>126.25</td>
</tr>
<tr>
<td>Cefepime – 500 mg injection</td>
<td>Antibiotic</td>
<td>432.81</td>
<td></td>
</tr>
<tr>
<td>Cefotaxime - 1 gm. Injection</td>
<td>Antibiotic</td>
<td>106.06</td>
<td>264.48</td>
</tr>
<tr>
<td>Cefuroxime 250 mg tabs</td>
<td>Antibiotic</td>
<td>262.66</td>
<td>745.78</td>
</tr>
<tr>
<td>Ceftrizine 10 mg tablet</td>
<td>Anti allergic</td>
<td>384.62</td>
<td>461.54</td>
</tr>
<tr>
<td>Ciprofloxacin 500 mg tab</td>
<td>Anti infective</td>
<td>301.68</td>
<td>301.68</td>
</tr>
<tr>
<td>Cllopidroge 75 mg tabs</td>
<td>Cardio vascular</td>
<td>219.90</td>
<td>817.28</td>
</tr>
<tr>
<td>Diclofenac sodium – 50 mg tabs</td>
<td>Pain killer</td>
<td>551.43</td>
<td>551.43</td>
</tr>
<tr>
<td>Domperidone 10 mg tabs</td>
<td>Anti emetic</td>
<td>250.00</td>
<td>330.00</td>
</tr>
<tr>
<td>Efavirenz – 600 mg tablet</td>
<td>HIV AIDs</td>
<td>102.08</td>
<td>138.89</td>
</tr>
<tr>
<td>Enalapril - 10 mg tab.</td>
<td>Cardiovascular</td>
<td>350.00</td>
<td>394.17</td>
</tr>
<tr>
<td>Ethambutol 800 mg tabs</td>
<td>Anti T.B.</td>
<td>320.00</td>
<td>320.00</td>
</tr>
<tr>
<td>Fluconazole - 150 mg capsule</td>
<td>Anti Fungal</td>
<td>496.15</td>
<td>584.62</td>
</tr>
<tr>
<td>Fluoxetine 20 mg caps</td>
<td>Anti depressant</td>
<td>168.42</td>
<td>168.42</td>
</tr>
<tr>
<td>Gatifloxacin 400 mg tab</td>
<td>Anti infective</td>
<td>177.32</td>
<td>607.03</td>
</tr>
<tr>
<td>Glibenclamide 5 mg tab</td>
<td>Anti diabetic</td>
<td>173.68</td>
<td>231.58</td>
</tr>
<tr>
<td>Ibuprofen 400 mg tabs</td>
<td>Pain killer</td>
<td>125.00</td>
<td>227.50</td>
</tr>
<tr>
<td>Isosorbide mononitratre 20 mg tab</td>
<td>Anti anginal</td>
<td>291.67</td>
<td>302.50</td>
</tr>
<tr>
<td>Lamivudine 100 mg tablet</td>
<td>Anti HIV-AIDS</td>
<td>100.00</td>
<td>451.61</td>
</tr>
<tr>
<td>Lansoprazole 30 mg Caps</td>
<td>Anti ulcerant</td>
<td>154.29</td>
<td>168.57</td>
</tr>
<tr>
<td>Levofoxacin 500 mg Tabs</td>
<td>Anti infective</td>
<td>207.10</td>
<td>349.11</td>
</tr>
<tr>
<td>Metclopropamide 10 mg Tabs</td>
<td>Anti emetic</td>
<td>366.67</td>
<td>366.67</td>
</tr>
<tr>
<td>Nimesulide 100 mg tabs</td>
<td>Pain killer Pain killer</td>
<td>800.00</td>
<td>800.00</td>
</tr>
<tr>
<td>Ofloxacin 400 mg tabs</td>
<td>Anti infective</td>
<td>359.18</td>
<td>1084.69</td>
</tr>
<tr>
<td>Omeprazole 20 mg Caps</td>
<td>Anti ulcerant</td>
<td>470.00</td>
<td>530.00</td>
</tr>
<tr>
<td>Tadalafil 10 mg</td>
<td>For erectile dysfunction</td>
<td>270.83</td>
<td>288.19</td>
</tr>
<tr>
<td>Tinidazole 500 mg Tabs</td>
<td>Anti amoebic</td>
<td>190.00</td>
<td>289.47</td>
</tr>
</tbody>
</table>

However, it is nearly impossible to get accurate cost data from companies, as it is not mandatory for them to provide such data. In the absence of precise cost data, pharmaceutical companies tend to project a higher base cost in the initial period, in addition to higher margins charged by manufacturers, wholesalers, stockiest and retailers.
For ex: When the list of medicines under price control is limited and close substitutes are not price controlled, companies find ingenious ways to circumvent price control.

Glaxo Smith Kline (GSK), for instance, markets ‘Actified,’ a drug used for cold and cough in India. While Glaxo Smith Kline uses the active pharmaceutical ingredient pseudoephedrine in its global product ‘Active,’ in India it uses Phenylpropanolamine (PPA). PPA enhances the risk of cerebro-vascular accidents and has been banned in several countries, while pseudoephedrine is under price control in India.\textsuperscript{108} Inspite of being under price control they are still highly priced.

Figure-1: TRENDS IN PHARMACEUTICAL AND ALL COMMODITY PRICE INDEX\textsuperscript{109}

5.4.2 Comparision of Generic drugs and brand-name drugs

Generic drugs, which are the drugs that are usually produced when a branded drug loses its patent, approximately 20 years after the drug patent application was registered, can tremendously increase the availability, affordability and efficient use of medicines. Price appears to be the real difference between most brands and generic drugs since generic drugs are held to the same quality standards for safety and performance as the brand names, yet can sell for 30-80% less, and in fact on an average, most generic drugs are approximately half the price of their brand name counterparts. However, prices of even the generic drugs are being manipulated by larger drug companies which have been acquiring smaller generic


\textsuperscript{109} Source: HLEG Secretariat, Aggregated data from Respective Monthly Bulletin of Reserve Bank of India, Mumbai quoted in chapter 3 Access to medicines,Vaccines and Technology.
companies, and keeping the generic drugs prices high to discourage their use. These changes result in reducing the price difference between branded and generic products, thus keeping their sale and profits of former intact and letting them earn more even from generic drug sales, leading to disproportionate profiteering by them, while the people may not get the benefit of savings through use of generic drugs despite the end of patent on them. It is extremely important that the generic drugs be protected from price manipulations and also that they be used in public health care system as it would drastically bring down the drug expenditure of government, allowing more money to be spent on other areas of healthcare that would otherwise be neglected with the higher price of medicine. The comparative prices table will clearly show how there is a difference in the prices of generic and branded versions of the same medicines manufactured by different companies.

Table-4: Price variation of Generic Drugs (G) and Brand (B) Drugs

<table>
<thead>
<tr>
<th>Name of the medicines drug/capsule</th>
<th>Cipla</th>
<th>Cadila</th>
<th>Blue cross</th>
<th>Generic</th>
<th>Branded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roxithromycin(150 mg)</td>
<td>4.41</td>
<td>9.75</td>
<td>4.46</td>
<td>10.90</td>
<td>--</td>
</tr>
<tr>
<td>Omeprazole(20 mg)</td>
<td>1.77</td>
<td>3.60</td>
<td>--</td>
<td>1.33</td>
<td>3.50</td>
</tr>
<tr>
<td>Norfloxacin (400 mg.)</td>
<td>4.70</td>
<td>--</td>
<td>1.31</td>
<td>--</td>
<td>4.50</td>
</tr>
<tr>
<td>Cetrizine (10 mg.)</td>
<td>2.50</td>
<td>--</td>
<td>0.27</td>
<td>0.74</td>
<td>2.10</td>
</tr>
<tr>
<td>Ciprofloxacin(500 mg)</td>
<td>2.45</td>
<td>7.89</td>
<td>2.50</td>
<td>6.63</td>
<td>--</td>
</tr>
<tr>
<td>Nimesulide(100mg)</td>
<td>0.45</td>
<td>--</td>
<td>1.99</td>
<td>0.32</td>
<td>1.82</td>
</tr>
</tbody>
</table>

Table-5: Price (Generic) Variation of the Same Drug Manufactured by Different Companies

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Nimesulide</th>
<th>Omeprazole</th>
<th>Sparfloxacin</th>
<th>Ciprofloxacin</th>
<th>Cetrizine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cipla</td>
<td>0.45</td>
<td>1.77</td>
<td>11.03</td>
<td>2.45</td>
<td>2.50</td>
</tr>
<tr>
<td>Cadila</td>
<td>1.99</td>
<td>--</td>
<td>--</td>
<td>2.50</td>
<td>0.27</td>
</tr>
<tr>
<td>Torrent</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>2.55</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>--</td>
<td>--</td>
<td>22.50</td>
<td>8.47</td>
<td>--</td>
</tr>
<tr>
<td>Blue Cross</td>
<td>0.33</td>
<td>1.33</td>
<td>--</td>
<td>--</td>
<td>0.74</td>
</tr>
<tr>
<td>Glaxo</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>2.67</td>
</tr>
<tr>
<td>Panacea Biotec</td>
<td>2.90</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Mankind</td>
<td>0.99</td>
<td>1.99</td>
<td>--</td>
<td>3.49</td>
<td>0.55</td>
</tr>
<tr>
<td>Dr Reddy</td>
<td>--</td>
<td>3.95</td>
<td>--</td>
<td>--</td>
<td>2.72</td>
</tr>
<tr>
<td>Sun Pharma</td>
<td>--</td>
<td>--</td>
<td>25.75</td>
<td>--</td>
<td>2.61</td>
</tr>
<tr>
<td>Alembic</td>
<td>--</td>
<td>--</td>
<td>26.00</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

110 Promoting Rational Drug Use Need for an Nrhm Sub-Mission, Published by National Health Systems Resource Centre(NHSRC), a technical support body set up under the National Rural Health Mission for strengthening public health systems in India. August, 2009. pps6 -7
Table-6: Highs and Lows in Cancer Drug Prices\textsuperscript{111}

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Highest Price</th>
<th>Firm</th>
<th>Lowest Price</th>
<th>Firm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letrozole 2.5 mg (10 tablets)</td>
<td>1,986</td>
<td>Novartis</td>
<td>60</td>
<td>Hetero</td>
</tr>
<tr>
<td>Imatinib 400 mg (10 tablets)</td>
<td>41,152</td>
<td>Novartis</td>
<td>3,000</td>
<td>Glenmark</td>
</tr>
<tr>
<td>Nozolamide 250 mg (5 capsules)</td>
<td>22,282</td>
<td>Dr Reddys</td>
<td>4,485</td>
<td>Sun</td>
</tr>
<tr>
<td>Pemetrexed 500 mg (vial)</td>
<td>73,660</td>
<td>Eli Lilly</td>
<td>11,990</td>
<td>Glenmark</td>
</tr>
<tr>
<td>Exemestane 25 mg (30 tablets)</td>
<td>4,315</td>
<td>Pfizer</td>
<td>1,290</td>
<td>Natco</td>
</tr>
</tbody>
</table>

5.4.3 There is a Poor Access to Pain-relieving Cancer Drugs in India due to High Prices\textsuperscript{112}

Untreated cancer pain has become a global pandemic. Pain can affect as many as 64% of patients with metastatic, advanced or terminal phase disease, 59% of patients on anti-cancer treatment and 33% of patients after curative treatment.

\textsuperscript{111} Source: “NPPA Study Finds Huge Gap in Cancer Drug Prices”, Joe C Mathew in Business Standard, New Delhi, 31 October 2010.

\textsuperscript{112} Kounteya Sinha, TNN Oct 1, 2012, 02.24AM IST
However, a global survey conducted between December, 2010 and July, 2012, that came up with 156 reports submitted by experts in 76 countries and 19 Indian states has revealed that several countries, including India, have failed to ensure adequate access to pain-relieving drugs.

The researchers found that very few countries provided all seven of the opioid medications that are considered to be essential for the relief of cancer pain. Those essential medications include codeine, immediate and slow release oral morphine, oral oxycodone and transdermal fentanyl.

In many countries, fewer than three of the seven medications are available. In many of the countries, the medications that are available are either unsubsidized or marginally subsidized by government, and the availability is often limited. In addition, many countries have highly restrictive regulations that limit entitlement of cancer patients to receive prescriptions, limit prescriber privileges, impose restrictive limits on duration of prescription, restrict dispensing, and increase bureaucratic burden of the prescribing and dispensing process. The Union health ministry is working on amending the “draconian and restrictive” Narcotic and Psychotropic Act, 1985, that severely restricts availability of morphine the cheapest and most effective painkiller, for fear of misuse. Dr. M.R. Rajagopal, Chairman of Pallium India and also part of the committee, says at least 20 lakh people need morphine but aren’t getting it.

Commenting on the study, Dr. Carla Ripamonti from the National Cancer Institute of Milan said, “Despite published guidelines and educational programs on the assessment and treatment of cancer-related pain, unrelieved pain continues to be a substantial worldwide public health concern in patients with solid cancers and hematological malignancies.”

“According to the World Health Organization, the incidence of cancer was 12,667,470 new cases in 2008 and based on the projections it will be more than 15 million cases in 2020. These statistics suggest that cancer-related pain may be a major issue of healthcare systems worldwide.”

The Indian pharma formulations industry is characterized by wide-ranging prices for the same product and high profits, apart from marketing and selling unnecessary combinations. Analysis showed that more than 60% of the top-selling 300 drugs which accounted for nearly 80% of the retail sales are not to be found in
the national essential drug list. There are also other ironic consequences due to susceptible users making decisions in distress and out of ignorance. Often, these decisions are taken on the “advice” of prescribers, and due to the “marketing” efforts of companies – called asymmetry by our economists. As a result, the costlier versions of the same drugs are bought more, and irrational combinations sell more because the doctor prescribes them. Collectively it qualifies as a market failure – in the sense that much of the intended clientele is left impoverished after buying India’s modern medicines, or worse cannot afford to buy the medicines prescribed, illustrating the classic Indian descriptive metaphor (also witnessed in the food sector) – “sitting on the banks of the Ganga, yet thirsty”. It is not a failure if one compares these prices to international prices of medicines, especially the HIV-related medicines\(^\text{113}\). In fact international civil society acolytes of India’s pharmacy prowess see the low prices of HIV medicines here as a triumph of the market. The collateral fallout is an interesting phenomenon: local predators are viewed as saints abroad. Whenever such discourse takes the Indian Drug Manufacturers Association offers to supply all the medicines required by the state and central governments free or at the TNMSC prices.

**Table-7: Unaffordable Drugs Price-Retail and Procurement Price**

<table>
<thead>
<tr>
<th>Disease Conditions</th>
<th>Therapeutic drug</th>
<th>Formulation</th>
<th>Strength and no</th>
<th>Retail Price</th>
<th>TNMSC Price</th>
<th>Price Difference (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>Cytosaphamide</td>
<td>Endocan-N</td>
<td>50mg:10</td>
<td>36.35</td>
<td>13.28</td>
<td>63%</td>
</tr>
<tr>
<td>Cancer</td>
<td>Flurouracil</td>
<td>Fluracil</td>
<td>5ml</td>
<td>11.67</td>
<td>1001</td>
<td>1166</td>
</tr>
<tr>
<td>Child infectious disease</td>
<td>Chloramphenicol</td>
<td>Chloloromycin</td>
<td>250mg:10</td>
<td>30.76</td>
<td>4.4</td>
<td>699</td>
</tr>
<tr>
<td>Child health</td>
<td>Phenoytoin Sodium</td>
<td>Dilantin</td>
<td>100mg:10</td>
<td>131.55</td>
<td>9.75</td>
<td>1349</td>
</tr>
<tr>
<td>COPD, Asthma</td>
<td>Betamethasone</td>
<td>Walacort</td>
<td>0.5mg:10</td>
<td>3.55</td>
<td>1.043</td>
<td>340</td>
</tr>
<tr>
<td>CVD</td>
<td>Verapamil</td>
<td>Verapamil</td>
<td>40mg:10</td>
<td>5.02</td>
<td>4.392</td>
<td>114</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Gilbenamide</td>
<td>Duonil</td>
<td>5mg:10</td>
<td>6.60</td>
<td>4.54</td>
<td>445</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Insulin NPH</td>
<td>Actrapid</td>
<td>10ml</td>
<td>129.28</td>
<td>86.85</td>
<td>449</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>Pyramzimamide</td>
<td>PZA-GBa</td>
<td>50mg:10</td>
<td>42.46</td>
<td>5.188</td>
<td>818</td>
</tr>
<tr>
<td>Malaria</td>
<td>Chloroquine</td>
<td>Melubrin</td>
<td>250mg:10</td>
<td>4.36</td>
<td>2.233</td>
<td>95</td>
</tr>
<tr>
<td>Maternal Health</td>
<td>Ferous Sulphate</td>
<td>Ferrochelate-Z</td>
<td>150mg:10</td>
<td>19.94</td>
<td>0.495</td>
<td>4028</td>
</tr>
</tbody>
</table>

Source: Retail price –monthly index specialities, India, August 2004, Available at URL: http://www.tnmsc.com/system.html

The *quid pro quo* is “non-interference” especially in matters of pricing. However, this will not work because

(a) it is difficult to regulate, manage and morally justify such vastly different prices in the same country to the middle class constituency, who may have to buy the medicines or to justify it before the judiciary, if nobody else,

\(^{113}\) Economic and Political Weekly EPW June 11, 2011 vol xlvi no 24
(b) it would in effect translate and be perceived as “sarkari” medicines for the poor; and costly, quality medicines for those who can afford or have access to insurance schemes, etc. Indeed one can see government doctors advising patients to buy “better” medicines from the nearest retail pharmacy, and

(c) This would therefore negate the basic premise of equity in health and postpone by a long measure the goal of universal access and same quality of healthcare for all. Its passage through Parliament will also be difficult since MPs would want to know what happens if the private players renege or if the low prices agreed upon do not turn out to be feasible down the line or even within the contracted period.

Survey shows People with chronic diseases requiring lifelong treatment has greater problems of affordability\(^\text{114}\) and lack of supply of medicines in Health care centers of the Government.

Affordability for chronic combination treatment of cancers and hypertensive diabetics who require both oral hypoglycaemics (e.g. metaformin) and angiotensin-converting enzyme (ACE) inhibitors for high blood pressure (e.g. captopril) involves high cost of treatment. Even for the oral hypoglycaemic alone, a 1-month supply of the lowest-priced treatment regimen using generics costs over a day’s wages in the majority of countries for which data are available. In the United Republic of Tanzania, for example, this treatment would cost the lowest-paid unskilled government worker the equivalent of over 5 days’ wages. The combined therapy, the oral hypoglyacemics and ACE-inhibitor, would cost the lowest-paid government worker over 2 days’ wages in all countries except Fiji and the Islamic Republic of Iran, and as much as 15 days’ wages in Ghana. In many low- and middle-income countries, medicine prices are high, treatments are unaffordable and availability is unreliable .At best the situation could be described as worrying, as low availability of medicines is likely to lead to poor disease control. Where out-of-pocket expenditure on medicines is high, the combination of high prices and low availability of medicines is a cause for serious concern, leading as it does to indebtedness or people having to go without the treatment they need. A patient in the Philippines described the reality of her illness in a recent interview, “I cannot accept that I have diabetes… I am scared of losing all properties just because of

diabetes. I know that it is expensive to have a disease like this. The same persists as well in India.

Countries depend on different methods, such as, taxes, user charges, social insurance, and private insurance, to finance health care. Method of financing is an important determinant of whether people are financially affected after illness. For instance, evidence from various countries suggests that government subsidies, social insurance and community based insurance help to reduce financial burden of illness on households. On the other hand, heavy reliance on user charges or out-of-pocket (OOP) health expenditure increase financial burden on households.

**Figure 2: Projected Proportions of Public and Private Out-of-Pocket Expenditures**

Many developing countries still depend on OOP health expenditure. For instance, in India, around 70% of the total health care expenditure is OOP health expenditure. Therefore, for such economies, it is important to analyze OOP health expenditure and effect of illness on economic wellbeing of households.

---


Historically, the commitment of Indian government to health development has been guided by two principles-health care constitutionally State’s responsibility and free medical care for all (not merely to those unable to pay).118

Retrospectively, from this point of time when 71% of the health budget is contributed by private sector of which households alone spend 69%, one can remark that Indian state has failed badly in its aim that was reiterated in the forms of “health for all” in 1980”s. The frail political commitment of the country is also revealed by the fact that the draft of Right to Health Bill, 2009, prepared by the Ministry of Health and Family Welfare (MOHFW) four years ago, is still in the pipeline. This delay only reveals government’s lax attitude toward public health, whereas affordable and accessible health care is still a mirage for a major chunk of the population in the country.

It was observed that there was poor availability of surveyed medicines in the public sector due to government’s inability to procure life saving medicines as a result of high prices of medicines. WHO and HAI has set a benchmark of 80% for medicine availability as good against which it was found that medicines for acute, chronic, and for children were suboptimal. 119 Availability of essential medicines was found to be poor in other low- and middle-income countries120. Availability of two medicines for hypertension, amlodipine and atenolol was good (>80%) in all the public sectors. Availability of medicines for other chronic diseases, like asthma, psychiatric conditions, and hyperlipidemia was very poor. Earlier surveys conducted in other states of India have also shown poor availability of essential medicines in the public sector.121 Budesonide and salbutamol inhalers were on the Delhi state EML but they were not in the procurement list of other two agencies. It is reported earlier that inhalers were not on the procurement list of other Indian

states like Haryana, Karnataka, Maharashtra, Tamil Nadu, and West Bengal\textsuperscript{122}. Antidepressants agents studied, amitriptyline and fluoxetine were on the Delhi state EML and are also on the National EML 2011\textsuperscript{123} but not on the procurement list of MCD. However, the availability of psychiatric medicines was very poor for Delhi state and for central (federal) government run facilities\textsuperscript{124}. Studies from other low- and middle-income countries have shown poor availability of medicines for chronic diseases\textsuperscript{125}. Dispersible zinc tablet was not procured by any agency though WHO recommends this medicine for treatment of acute diarrhoea in children.\textsuperscript{126} The second and third generation antibiotics like cefuroxime, ofloxacin, cefixime, amoxicillin+clavulanic acid were available at primary healthcare facilities.

In India a few essential medicines are under price control, for most of the medicines government does not fix the price. It is believed that free market forces will keep the prices of medicine in-check. Findings from the private sector indicate that the free market competition does not seem to be driving medicine prices as low as possible. Brand loyalty, marketing strategies do not allow ‘real’ competition in free pharmaceutical market\textsuperscript{127}. As the free market competition is not working to lower medicine prices, the free market rules need to be modified by the Department

\begin{itemize}
\item Anitha Kotwani : Psychiatric medicines in India: why public healthcare facilities and a thriving generics industry cannot assure access and affordability. *Internl Psychiatry* 2012, 9:34-36.
\end{itemize}
of Pharmaceuticals\textsuperscript{128} or government must intervene and regulate the prices of essential medicines or provide subsidy for certain formulations that are expensive.

With the lowest daily wage of government worker Indian Rupees 247 (USD $5.5 2011) per day, treatments were not so affordable, e.g., adult respiratory pneumonia if treated with amoxicillin will cost 0.8 days salary and if treated with amoxicillin+clavulanic acid will cost 2.3 days of salary with highest-priced generic. Purchasing one inhaler each of budesonide and salbutamol costs 1.4 days’ wages for the lowest paid government worker. However, a large proportion of India’s population earns less than this. According to World Bank Report, the Gross National Income per capita for the year 2011 in India is $1420/annum or USD $3.89 per day\textsuperscript{129}. It is reported that about 320 million people in India are working in unorganized sector and around 300 million people are unemployed\textsuperscript{130}. According to Horton and Das World Bank definition of poverty (an income of less than USD $1.25 a day) is more sensitive, embracing 42% of India’s people\textsuperscript{131}. Medicines for chronic diseases are often unaffordable as they require lifelong treatment with multiple medications\textsuperscript{132}. Further, the need for other mandatory expenditure like food, housing, and other family members living on the salary will change the affordability estimate. Affordability can be severely affected by multiple illnesses in the family or if the earning member is one to fall ill. Therefore, the information on affordability is to be interpreted with caution and should not impact on the potential for taking policy decisions for medicine prices in India.

India stands at 119\textsuperscript{th} position in the world in terms of human development and it is a harsh reality that the health situation in the country is worse than many developing nations in the subcontinent. Although, a baby born in present India can expect to live two times more than his great-grandfather did and the infant mortality


rate has been halved\textsuperscript{133}. It is still a very high rate and “in 2001, people continue to die for the same reasons they did when India became independent in 1947: infectious diseases”\textsuperscript{134}. Health outcomes in any settings are directly linked to quality health care services available to the population and these are not in good condition in India, particularly for the poor and deprived masses.

It is surprising to know that Professor B.M. Hegde\textsuperscript{135}, who has made an important information public in his article “Inventing diseases to sell drugs” in his article who has made the following observation and findings has made public of the fact known of many tricks of the trade of the pharmaceutical lobby. when one opens any newspaper or journal there are articles on a recent disease in children by name ADHD (Attention Deficit Hyperactivity Disorder) and our pediatricians bend over backwards to make the diagnosis and start our children on dangerous chemical drugs at that tender age. American psychiatrist, Dr. Leon Eisenberg (87), made a statement to a German magazine, Der Spiegel, a couple of months before his death that ADHD is a fictitious disease which they put together for the benefit of drug companies in the new disease classification in the American Psychiatry Association’s DSM (Diagnostic and Statistical Manual of Mental Diseases).

In his book, Inventing Diseases, Professor Jerg Blech, another German, gives a graphic description of hypertension having been discovered as a disease needing drug treatment through the German plan of Well Man clinics in nice air-conditioned vans, with beautiful nurses, parked around Church squares and shopping malls to give people a free check-up, a dangerous activity when one feels healthy and happy.

Any one that walks in becomes a patient. There is no proof or test to find out exactly what chemicals are “out of balance” in the brain for ADHD or any other disorder. Most of those drugs are unnecessary as they are known to provoke suicide and homicide. “Since that DMS conference in 1968, Dr. Eisenberg’s contribution to mental disease by invention and committee consensus has resulted in drugging


\textsuperscript{135} The Hindu, Opinion » Open Page October 7, 2013 Updated: October 7, 2013 15:05 IST, href="http://www.thehindu.com /opinion/open-page/inventing-diseases-to-sell-drugs/article5209896.ece?textsize=largeandtest=1" title="Large Text Size"
millions of children from preschool age through high school. It is currently estimated that up to 20 percent of children from nursery school and kindergarten through high school and in foster homes have been prescribed Ritalin. Commonly prescribed for kids “diagnosed” or better still, labelled with ADHD, Ritalin was tested a little over a decade ago by the Brookhaven National Laboratory (BNL). The BNL study determined that Ritalin is pharmacologically similar to cocaine with perhaps even worse brain damaging potential”. Dr. Irwin Savodnik, Assistant Clinical Professor of Psychiatry at the UCLA School of Medicine, was of the opinion that “the very vocabulary of psychiatry is now defined at all levels by the pharmaceutical industry.” This racket has been going on ever since and has been able to get even health insurance to cover their dark deeds.

Vaccination is another fertile ground for the industry where most of what it sells has dubious value. Lead researcher, Dr. Diane Harper, who was instrumental in creating Gardasil, and Cervarix, admitted back in 2009 that the vaccines were essentially useless and more dangerous than the very conditions they were hailed as preventing and treating? A 2009 article published by CBS News, in fact, which is still available online, reveals the truth about these vaccines. One particular quote, which was pulled out, using the Wayback Machine, reveals that both Gardasil and Cervarix do nothing to prevent cervical cancer, which is their primary claim to fame. “The rate of serious adverse events from Gardasil is on a par with the death rate of cervical cancer,” admitted Dr. Harper at that time, refuting a pro-Gardasil piece published by Slate. “Gardasil has been associated with at least as many serious adverse events as there are deaths from cervical cancer developing each year.”

Dr. Harper dropped a bombshell when she told reporters that the public health benefit of getting vaccinated with Gardasil “is nothing,” adding the vaccine has led to “no reduction in cervical cancers.” Dr. Harper went on to admit that deaths from Gardasil had been underreported by the U.S. Center for Disease Control and Prevention (CDC), which has given the illusion that the vaccine is somehow safe. The vast majority of HPV infections resolve themselves on their own within a year and nearly all of them within two years. She also admitted that an extremely small number of people experience symptoms from infection. Millions of young girls and now even boys, some as young as nine years old, have received the vaccine since 2006.
Recently, Dr. Puliyal from New Delhi, an expert in this field, exposed the myth of another childhood vaccine, the pentavalent vaccine. Some people wanted me to retract an article of mine on polio dangers for malnourished children, which information had, by then, even entered the British Pharmacopoeia.

We can go on and on till the cows come home on the fraud in medical research but I highly recommend the following article in the Atlantic Magazine of November 20th, 2010 by Davis Freedman on the important topic: Lies, Damned Lies and Medical Research. The article is a result of a long interview with Professor John PA Ioannidis of Stanford University, who has been pioneering the work to expose these frauds successfully. He is a much respected member of the American medical scene. 136

It can be clearly made out that those inventions in the IT era in the fields of Pharmaceuticals are mostly made not for the welfare of the people in curing the diseases but to extract money from highly priced medicines, where patients have no choice but to purchase the medicines, as mute spectator, which are prescribed to them on the contrary the doctors blame the patients for their negligence they themselves have worsened their health.

In the news paper ‘Vijay Karnataka’ made a report about the fact that ‘Cancer medicines are not for Indians: Bayer’ 137 which reported that tablet ‘Nexavar’ was not available at low prices in a stricter sense this shocked ‘medicines San Frontiers’. This statement by Bayers was in response to the direction made by Indian Controller General of Patents who permitted Natco Company to manufacture tablet Nexavar. Bayer is the German company manufacturing Nexavar. Innovations and granting patents have become a curse instead of a blessing as it is an admitted fact that most of the medicines are un-necessary prescriptions according to the WHO most of the medicines are irrationally prescribed only for the reason that it benefits the drug manufacturing companies.

5.4.4 Findings

Due to product patent regime and arbitrary high pricing of the patented medicines has a negative impact on public health policies as the government is

---

136 The writer is a cardiologist and former Vice-Chancellor of Manipal University. His email: hegdebm@gmail.com
incapable to meet the requirements of the general public with regard to supply of costly medicines to the poorer sections. When we compare the pricing of different drugs available in the market we can come to a conclusion that the same drug having the same content is being marketed under different companies having different prices. But nobody can explain why such a difference in pricing strategies of different company differs in case of generics. But there are other certain medicines which are basically used for non-communicable diseases or lifestyle diseases which requires administration of drugs and medicines which are very costly and unaffordable when we analyze and compare the prices of the medicines this is mainly due to the reason of Patents Act that has given an exclusive rights to fix an exorbitant prices to cure life threatening diseases on the contrary a person having a low income forces him to curtail the treatment and die helplessly seeking the help from the government in the name of the almighty god. Therefore the conclusion with regard to the second hypothesis is in the affirmative. As the government has not made adequate provisions in its budget for the treatment of life style diseases and supply of medicines in the government hospitals are rarely found. One can get surprised to know the fact that for rabies injection, blood supply, dialysis, the government charges money. Most of the government hospitals do not have anti-venom injection for the poorer classes. Most of the patented drugs do not have a place in the list of essential medicines and are not freely supplied due to the reason of high cost of patented medicines.

5.5. THE PRODUCT PATENT REGIME IN THE FIELD OF MEDICINES AND DRUGS HAS INCREASED THE NON-AFFORDABILITY OF THE LIFE SAVING DRUGS FOR COMMON MAN DUE TO HIGH TENDENCY OF MONOPOLY

The Comparison of Prices of Patented Drugs with that of other Brands would clarify what the granting of patent does have an impact on the prices of the patented product. At the same time the existence of the competitor in the market will have an automatic check on the pricing policy of the companies on their patented products this analysis can be made by going through the following table comparing the patented medicines and the same medicines produced by other manufacturers.
Table 8: Comparison of Prices of Patented Drugs with that of other Brands\textsuperscript{138} License to Natco

<table>
<thead>
<tr>
<th>Innovator Brand MRP</th>
<th>Natcos Brand MRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nexavar 2,80,000 / 120’s</td>
<td>Sorafenat 200 mg 8800 / 120’S</td>
</tr>
<tr>
<td>Iressa 33,263 / 10’s</td>
<td>Gefitinat 250 mg 3400 / 10’s</td>
</tr>
<tr>
<td>Tarceva 40,300 / 10’s</td>
<td>Erlonat 150 mg 25,000 / 30’s</td>
</tr>
<tr>
<td>Velcade 60360 / 3.5mg</td>
<td>Bortenat 3.5 mg 17640 / vial</td>
</tr>
<tr>
<td>Alimta 100 mg 18235 / vial</td>
<td>Pennat 100 mg 4900 / vial</td>
</tr>
<tr>
<td>Alimta 500 mg 75960 / vial</td>
<td>Pennat 500 mg 19800 / vial</td>
</tr>
<tr>
<td>Glivec 100 mg 10,288 / 10’s</td>
<td>Veenat 100 mg 950 / 10’s</td>
</tr>
<tr>
<td>Glivec 400 mg 41,152 / 10’s</td>
<td>Veenat 400 mg 3450 / 10’s</td>
</tr>
<tr>
<td>Temodal 100 mg 34,590 / 5’s</td>
<td>Temonat 100 mg 9450 / 5’s</td>
</tr>
<tr>
<td>Temodal 250 mg 80,000 / 5’s</td>
<td>Temonat 250 mg 23100 / 5’s</td>
</tr>
<tr>
<td>Aromasin 25 mg 4315 / 15’s</td>
<td>Xtane 25 mg 1290 / 30’s</td>
</tr>
<tr>
<td>Fludara 10 mg 35,470 / 20’s</td>
<td>Lymfuda 10 mg 5775 / 5’s</td>
</tr>
<tr>
<td>Zometa 4 mg 15123 / vial</td>
<td>Zoldonat 4 mg 2990 / vial</td>
</tr>
</tbody>
</table>

The reason usually given to explain why medicine prices are so high is that the development of new drugs is an expensive business. People in the multinational pharmaceutical industry claim that a new drug can cost anything from US$800 million to US$1.5 billion which includes R and D to trials and final approval for consumption to the patients. But many independent experts dispute these figures, saying that the figure is more in the range of US$50–100 million for each newly developed drug.

The pharmaceutical industry continues to rely on the inflated figures to justify high prices for new medicines as being inevitable. Without the ability to charge these high prices, they argue, they would not be able to spend the money required to develop new medicines. But upon analysis it appears that many of the costs of what is called “research and development” (RandD) are in fact marketing costs\textsuperscript{139}. Central to the RandD of new medicines in any market-driven system is the creation of incentives to stimulate investment in drug development – in other words, making sure that drug companies have a financial reason to bring new medicines to the market. In the modern world, this is largely achieved through patent protection\textsuperscript{140}.

\textsuperscript{138} The Face Off: Patented Drugs vs Indian Challengers. Cancer Therapy... Business Standard http://www.business-standard.com/content/general_pdf/032912_03.pdf
\textsuperscript{139} For more detail on drug costs and related issues, see Angell, The Truth about the Drug Companies: How They Deceive Us and What to Do about It, 2004.
\textsuperscript{140} Access to essential medicines, Health and Democracy, p. 439.
Table-9: Comparison of Prices of Patented Drugs with that of other Brands\textsuperscript{141}
License to Natco. Figures next to MRP represent number of tablets.

<table>
<thead>
<tr>
<th>Cancers</th>
<th>Therapy</th>
<th>Innovators Price (INR)</th>
<th>Natco’s Price (INR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Small cell lung cancer</td>
<td>Gefitinib</td>
<td>99,789 / month</td>
<td>10,353 / month</td>
</tr>
<tr>
<td>Chronic Myeloid Leukemia</td>
<td>Imatinib</td>
<td>123,456 / month</td>
<td>10,560 / month</td>
</tr>
<tr>
<td>Multiple Myeloma</td>
<td>Bortezomib</td>
<td>241,440 / cycle</td>
<td>50,752 / cycle</td>
</tr>
<tr>
<td>Myelodysplastic Syndrome, MM</td>
<td>Lenalidomide</td>
<td>297,000/cycle (Not marketed in India)</td>
<td>12,852 / cycle</td>
</tr>
<tr>
<td>Non-Small cell lung cancer</td>
<td>Pemetrexed</td>
<td>130,665 / cycle</td>
<td>34,500 / cycle</td>
</tr>
<tr>
<td>Gliomas</td>
<td>Temozolomide</td>
<td>311,310 / month</td>
<td>87,615 / month</td>
</tr>
<tr>
<td>Non-Small cell lung cancer</td>
<td>Erlotinib</td>
<td>120,000 / month</td>
<td>25,000 / month</td>
</tr>
<tr>
<td>Non-Hodgkin’s Lymphoma</td>
<td>Rituximab</td>
<td>80,000 / month</td>
<td>40,000 / month (Dr Reddy’s)</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>Fulvestrant</td>
<td>25,573 / month</td>
<td>17,600 / month</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>Letrozole</td>
<td>5950 / month</td>
<td>25,000 / month</td>
</tr>
<tr>
<td>Metastatic Bone Disease</td>
<td>Zoledronic acid</td>
<td>15,213 / cycle</td>
<td>2990 / cycle</td>
</tr>
<tr>
<td>Metastatic Bone Disease</td>
<td>Ibandronate</td>
<td>14,550 / cycle</td>
<td>2762 / cycle</td>
</tr>
<tr>
<td>Chronic Lymphocytic Leukemia</td>
<td>Bendamustine</td>
<td>3,45,600 / cycle (Not marketed in India)</td>
<td>27,800 / cycle</td>
</tr>
<tr>
<td>HCC and RCC</td>
<td>Sorafenib</td>
<td>280,000 / Month</td>
<td>8800 / Month</td>
</tr>
</tbody>
</table>

Drugs, a “decisive technology”, constitute 20-60% of total health care expenditure in developing countries\textsuperscript{142}, About 85% of India’s total health expenditure is financed by household out-of-pocket expenditure\textsuperscript{143}. A major portion of the private health care spending goes to drugs and per capita private drug spending in India is estimated as US $ 16. In other words, expenditure on drugs imposes a major financial burden on households, especially when it is met from out-of-pocket expenditure due to total lack of health insurance and risk protection. This is further compounded by the fact that majority of government health care institutions including those in rural areas lack critical inputs such as drugs\textsuperscript{144}. As a result, drug prices act as a strong barrier to seeking effective health care in India, as they are high and people lack purchasing power\textsuperscript{145}.

Health is a fundamental right guaranteed by the Constitution of India. Unfortunately the health services are not able to cope up and extend all the health

\textsuperscript{141} The Face Off: Patented Drugs vs Indian Challengers. Cancer. Therapy... Business Standard http://www.business-standard.com/content/general_pdf/032912_03.pdf

\textsuperscript{142} Abel-Smith 1994, WHO/WTO 2001

\textsuperscript{143} Government of India 2002

\textsuperscript{144} Government of India 2002a

\textsuperscript{145} Mr. S K Godwin and Dr D. Varatharajan Drug Price Differentials across Differentials retail Market settings An analysis of retail prices of 12 commonly used drugs, chapter 10, Health Administrator Vol : XIX Number 1: 41-47.
facilities to the ever growing population, 25% of which earns below a dollar a day\textsuperscript{146}. 10% of illness episodes remain untreated in India. Approximately 60% of the rural and 70% of the urban population utilize private facilities for health care and their per capita annual health care expenditure of an household is Indian rupees 334\textsuperscript{147}. The out of pocket (OOP) payments comprise 80% of the total expenditure on health in India. Health insurance in India is in nascent stage, so most of the population ends up paying for their own treatment. The share that goes in medicines is 74.72% due to greater prevalence of self medication in economically poor and particularly rural societies in which access to health services is constrained by income and distance. Thus medical expenditures can be impoverishing\textsuperscript{148}.

Due to this catastrophic impact of health care expenditure on families, the World Health Organization (WHO) and the Health Action International (HAI) are attempting to generate data on availability and pricing of different types of medicines from different countries, so that policy makers are informed and can suitably intervene. This data is collected by using a standardized methodology across countries and their regions. This study also is a part of several international surveys on medicine availability and pricing using a standardized WHO-HAI methodology of data collection on 30 core medicines of specified strength, dosage and formulations for common conditions. It was previously conducted in the state of Rajasthan followed by two studies including this in Maharashtra, West Bengal, Chennai in Tamil Nadu, Haryana and Karnataka\textsuperscript{149}.

Affordability was measured in terms of number of days worked by the lowest paid unskilled government worker to purchase a standard treatment regimen. The range of daily wage of the lowest paid unskilled government worker in six survey states was INR 120-144 ($3). Table \textsuperscript{1} below shows the availability of a particular medicine in public sector and the number of days a lowest pain government worker have to work to purchase a treatment from private sector. Medicines chosen are commonly used essential medicines that are procured by all state government public

\textsuperscript{146} World Bank Report 2004 www.worldbank.org/poverty/inequal
\textsuperscript{148} Doorslaer E. Paying out-of-pocket for health care in Asia: Catastrophic and poverty impact. May 2005, EQUITAP working paper # 2.)
\textsuperscript{149} Archana Patel, Vijay Thawani, Kunda Gharpure, Medicine Pricing, Availability and Affordability Report of Four Regions, Clinical Epidemiology Unit\textsuperscript{1}Indira Gandhi Government Medical College, Nagpur Maharashtra, India. Health Action International and World Health Organization.
sectors. This table shows that if a patient visit public sector and in case of non availability of the medicine how much money it will cost to purchase the medicine in terms of number of days’ wages of lowest government worker\textsuperscript{150}.

**Table-10: Affordability of medicine for a few treatments* in private sector and availability of related medicine in public sector in six areas surveyed\textsuperscript{151}**

- *Treatments
  - Diabetes (glibenclamide tab 5 mg x 2 for 30 days)
  - Hypertension (atenolol tab 50 mg daily for 30 days)
  - Pediatric Respiratory Infection (co-trimoxazole susp 10ml daily for 7 days)
  - Gonorrhoea (ciprofloxacin 500mg tab x 1)
  - Pneumonia (Amoxicillin 250 mg x 3 for 7 days)
- (Mean daily wage of an unskilled government worker – INR 134)

<table>
<thead>
<tr>
<th>State/City</th>
<th>State/City Income</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Public</td>
</tr>
<tr>
<td>Diabetes - Glibenclamide</td>
<td></td>
</tr>
<tr>
<td>% Availability</td>
<td>95</td>
</tr>
<tr>
<td>Affordability</td>
<td></td>
</tr>
<tr>
<td>Hypertension - Atenolol</td>
<td></td>
</tr>
<tr>
<td>% Availability</td>
<td>83.3</td>
</tr>
<tr>
<td>Affordability</td>
<td></td>
</tr>
<tr>
<td>Adult ARI - Amoxicillin</td>
<td></td>
</tr>
<tr>
<td>% Availability</td>
<td>100</td>
</tr>
<tr>
<td>Affordability</td>
<td></td>
</tr>
<tr>
<td>Child ARI - Co-trimoxazole</td>
<td></td>
</tr>
<tr>
<td>% Availability</td>
<td>15</td>
</tr>
<tr>
<td>Affordability</td>
<td></td>
</tr>
<tr>
<td>Gonorrhoea - Ciprofloxacin</td>
<td></td>
</tr>
<tr>
<td>% Availability</td>
<td>42.1</td>
</tr>
<tr>
<td>Affordability</td>
<td></td>
</tr>
<tr>
<td>(Mean daily wage of an unskilled government worker – INR 134)</td>
<td></td>
</tr>
</tbody>
</table>

*Source: Anita Kotwani, Medicine price and availability with special reference to price components in India*  

Only a small proportion of the population is employed in the government sector, and wages are very low in the unorganized sector. Thus the affordability of medicines for the poor and unemployed is severely challenged. According to a World Bank report, 34.7%, or 35 million Indians live on less than U.S. $1 per day. As a result, affordability of medicines is often beyond the reach of a majority of the population. However, these costs only accounts for the price of medicine, consultation fees of the doctor and diagnostic tests may lead to a considerably

\textsuperscript{150} Poverty matters blog http://www.theguardian.com/global development/poverty matters  
\textsuperscript{151} Anita Kotwani, Medicine price and availability with special reference to price components in India: insight for policymakers Department of Pharmacology, V. P. Chest Institute, University of Delhi, Delhi, India.anitakotwani@yahoo.com. P5.
higher total cost for the patient in private sector. It was not possible to obtain detailed price component information in the private sector, though discussions with wholesalers and retailers suggest mark-ups are variable and may be high. Price components could not be obtained in spite of the best efforts. From few survey areas data collectors reported that there was no transparency in the supply chain from manufacturer to the wholesaler and to the retailer and they did not complete this part of the survey.

Table-11: Cost of Treatment with Biotechnology-based Drugs\textsuperscript{152} and Cancer Drugs

<table>
<thead>
<tr>
<th>Drug/Price Component</th>
<th>Cost (Rs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abciximab (antianginal, Eli Lily)</td>
<td>39,480 for a 60 kg man per day</td>
</tr>
<tr>
<td>Epoetin alfa (Wepox/Wockhardt, Treatment of anemia of chronic renal failure)</td>
<td>10,200 for 8 weeks for a 60 kg man AND 1912 to 11475 per week for a 60 kg man thereafter</td>
</tr>
<tr>
<td>Interferon alpha-2a (Roferan-A/Nicholas Piramal)used in types of leukemia: Initial therapy costs of Rs. 43,552 then maintenance therapy costs of Rs. 1,06,158- Rs.3,18,474 (6-18 months it cost)</td>
<td></td>
</tr>
<tr>
<td>Etanercept (Enbrel/Wyeth) –in severe arthritis:</td>
<td>18,131 per week of therapy which has to be taken long term.</td>
</tr>
<tr>
<td>Price of Glivec, an anti-cancer drug</td>
<td></td>
</tr>
<tr>
<td>Novartis:</td>
<td>Rs 1, 30,000 per month</td>
</tr>
<tr>
<td>Price of Indian generic equivalents:</td>
<td>Rs 10,000 per month still unaffordable</td>
</tr>
</tbody>
</table>

Price components are a concern for all those involved in public health and access to medicines, whether the government, nongovernmental organizations (NGO), a social insurance plan, the prescribers or the patients. Price components come from a variety of sources, including: government-collected tariffs; markups collected by middlemen to meet their overheads and distribution expenses; and inefficient procedures in procurement. Price component is a very important aspect to be studied in-detail and the data can be used to develop national pharmaceutical policies, such as creating tax and tariff exemptions, controlling mark-ups and establishing government-recommended selling prices, which aim to increase access to essential medicines.

Table-12: Comparison of Prices of LOCOST Baroda, a Small Scale Schedule M Certified Manufacturer and the Market.

<table>
<thead>
<tr>
<th>Name of the Drug</th>
<th>Use</th>
<th>LO cost Selling prices per Tab</th>
<th>Market selling prices per tab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albendazole 400 mg</td>
<td>For worms</td>
<td>Rs. 1.10</td>
<td>Rs. 9 to 12</td>
</tr>
<tr>
<td>Amlodipine 5 mg</td>
<td>In high blood pressure and as antianginal</td>
<td>Rs. 0.25</td>
<td>Rs. 1.40 to 5.00</td>
</tr>
<tr>
<td>Atenolol 50 mg</td>
<td>In high blood pressure and as antianginal</td>
<td>Rs. 0.20</td>
<td>Rs. 4 to 22</td>
</tr>
<tr>
<td>Enalapril 5 mg</td>
<td>In high blood pressure mild to moderate</td>
<td>Rs. 0.30</td>
<td>Rs. 1.60 to Rs. 2.30</td>
</tr>
<tr>
<td>Fluconazole 150 mg</td>
<td>Anitallergic</td>
<td>Rs. 0.20</td>
<td>Rs.0.50 to Rs. 3.00</td>
</tr>
</tbody>
</table>

Source of Prices: Circa 2008 from MIMS / CIMS et al.

Medicines are the only commodity in which the end-user (the paying patient) does not decide what to buy and at what cost. The doctor prescribes and the patient pays. In addition, in India every doctor decides on his/her own which brand of which medicine to prescribe. There is no choice for the consumer in the medicines market. Unlike in case of other commodities the purchaser of medicines is extremely vulnerable at the time of making a decision to purchase a medicine he or she is seeking immediate relief from suffering. These asymmetries in information that is unequal information that does not help the patient in making an informed, considered choice - in the doctor-drug company interface as much as in the doctor patient and drug company-patient, is what leads to market failure. This special nature of the pharma sector is the reason why even in market economies, all issues related to medicines including their prices are the subject of regulation by their Governments.

The only exception is the USA – even in the USA the prices of medicines are indirectly regulated by health maintenance organizations negotiating prices to be paid on prescription costs. (The Government’s own committees have reported that even in the so called free market countries there is price control of some kind or the other.) Pharma is the only sector in India (and probably in the world) where government tender procurement prices are 1-3% of the retail market prices! This if anything indicates the level of overpricing. An example: for the Tamil Nadu Government, a drug company bids to supply Albendazole 400 mg tablets, a medicine for worms, at a mere 35 paise per tablet, while brands of this drug sell for Rs.12/- in the market. India’s pharma markets are full of unnecessary, unscientific and therapeutically useless drugs.
### Table 13: A Glimpse of the ‘Free’ Market of Branded Medicines - What happens when there is no Price Regulation?\(^\text{153}\)

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Name of the Drugs</th>
<th>Drug under Price Control</th>
<th>Lowest Price of Branded Brand in Rupees/Brand Name Manufacturer</th>
<th>Highest Price of Brand in Rupees/Brand name Manufacturer</th>
<th>Highest Price Brand/Lowest Price Brandx100</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ofloxacin</td>
<td>No</td>
<td>200 mg Rs. 3.20/Zo/FDC</td>
<td>Rs.31.00/Tarvid/Aventis</td>
<td>969%</td>
</tr>
<tr>
<td>2</td>
<td>Levofloxacin 500 mg</td>
<td>No</td>
<td>Rs. 6.82/Levofox/Cipla</td>
<td>Rs.95.0/Tavanic/</td>
<td>1392%</td>
</tr>
<tr>
<td>3</td>
<td>Ciprofloxacin</td>
<td>Yes</td>
<td>Rs.3.90/ Zoxan/FDC</td>
<td>Rs.8.90/ 500 mg Cifran/Ranbaxy</td>
<td>228%</td>
</tr>
<tr>
<td>4</td>
<td>Azithromycin 250 mg</td>
<td>No</td>
<td>Rs.8.50/Zathrin, FDC</td>
<td>Rs.39.14/Vicon/pfizer</td>
<td>460%</td>
</tr>
<tr>
<td>5</td>
<td>Zidovudine 100 mg</td>
<td>No</td>
<td>Rs.7.70/Zidovir/Cipla</td>
<td>Rs.20.40/Retrovir/GSK</td>
<td>265%</td>
</tr>
<tr>
<td>6</td>
<td>Amlodipine 5 mg</td>
<td>No</td>
<td>Rs.1.51/Amlodac Zydus Cadila</td>
<td>Rs.6.00/Amlogard/Pfizer</td>
<td>397%</td>
</tr>
<tr>
<td>7</td>
<td>Atenolol 50 mg</td>
<td>No</td>
<td>Rs.0.40/Ziblo/FDC</td>
<td>Rs.2.45/Tenormin/Nicholas Piramal</td>
<td>612%</td>
</tr>
<tr>
<td>8</td>
<td>Valsartan 80 mg</td>
<td>No</td>
<td>Rs.5.90/Valzaar /</td>
<td>Rs.41.00/Diovan/Torrent Novartis</td>
<td>694%</td>
</tr>
<tr>
<td>9</td>
<td>Pioglitazone 15mg</td>
<td>No</td>
<td>Rs.0.99/Pio/Systopic</td>
<td>Rs.6.00/Piozone/Nicholas Piramal</td>
<td>606%</td>
</tr>
<tr>
<td>10</td>
<td>Glimepride 1Mg</td>
<td>No</td>
<td>Rs.0.80/Glimestar/Discovery / Mankind</td>
<td>Rs.5.30/Amaryl/Aventis</td>
<td>696%</td>
</tr>
<tr>
<td>11</td>
<td>Tamoxifen 10 mg</td>
<td>No</td>
<td>Rs.2.70/Tamodex/Biochem</td>
<td>Rs.20.00/nolvadex/ICI</td>
<td>741%</td>
</tr>
<tr>
<td>12</td>
<td>Letrozole 2.5 mg</td>
<td>No</td>
<td>Rs.9.90/Oncolet/</td>
<td>Rs.181.50/</td>
<td>1833%</td>
</tr>
<tr>
<td>13</td>
<td>Risperidone 2 mg</td>
<td>No</td>
<td>Rs.1.69/Respidon/Torrent</td>
<td>Rs.27.00/Risperdal/Ethnor</td>
<td>1598%</td>
</tr>
<tr>
<td>14</td>
<td>Risedronate 35mg</td>
<td>No</td>
<td>Rs.50.12/Risofos/Cipla</td>
<td>Rs.500.00/Actonel/Aventis</td>
<td>997%</td>
</tr>
<tr>
<td>15</td>
<td>Leflunomide 10mg</td>
<td>No</td>
<td>Rs.8.00/Rumalet/Zydus</td>
<td>Rs.44.00/Arava/Cadila Aventis</td>
<td>550%</td>
</tr>
</tbody>
</table>


\(^{154}\) OMS Medicines survey, Measuring medicine prices, availability, affordability and pricecomponents2ND EDITIONWHO/PSM/PAR/2008.3
The results of the surveys confirm that in many countries access to essential medicines is hindered by low availability and unaffordable prices. To quote For example, salbutamol inhaler – an important medicine used to treat asthma – is virtually unavailable in the public sector of many countries (where medicines are generally cheaper or even free) and when purchased from the private sector, can cost the lowest-paid, unskilled government worker several days’ wages. As Figures illustrates, people are paying high prices for many medicines. The price of originator brand atenolol 50 mg tablets is over 20 times the international reference price in all the countries except India (where it is still high at 5 times the reference price) and Kazakhstan. Even the lowest-priced generic is very expensive in all countries, and there are some huge brand premiums, e.g. in Uganda the originator brand is about 13 times the price of the generic. The same exists in India also.

The irrational and highly priced prescription leads to further market distortion and market failure apart from adding to the cost of prescriptions and complications in health recovery. We need to immediately weed out all these medicines by allowing only medicines\textsuperscript{155}. If one studies the ORG-Nielsen list of top-selling 300 medicines accounting for more than Rs. 35,000 crores sales (almost 90 percent of the retail market), atleast 60 percent of the top-selling 300 medicines are not in the National List of Essential Medicines (NLEM). Therefore 2/3 of medicines sold in India are not essential medicines by the Government’s own definition\textsuperscript{156}.

Changes in price due to the introduction of product patent regime are starting to be experienced in India. This is because the first set of drugs under patent monopoly has entered the Indian market. The price levels of these patented medicines are very high. Peg interferon alphas used in the treatment of Hepatitis C and some cancers are patented in India – both versions alpha 2a and alpha 2b are patented by Roche and Schering- Plough respectively and are excessively high. Third line AIDS medicines patented in India such as raltegravir are expensive even at discounted rates, cost a person living with HIV Rs. 1,20,276 ($2672 USD) per year. Patented cancer drugs are equally expensive. According to data from the Drug Controller General of India’s office, Dasatinib (IN203937) is Rs. 2761 per 50mg

\textsuperscript{155} WHO essential drug list. March 2007
tablet. Sunitinib (IN20251) is Rs. 4357 per 25mg capsule. As patients and developing countries watch what India will do to reduce prices, including whether it will support CL applications that open up generic competition, an Indian pharmaceutical company, NATCO has applied for a CL to manufacture a affordable generic version of sorafenib tosylate – the anti-cancer drug for which Bayer has obtained a patent IN215758 in India in 2008, which will expire in 2020. To view CL application dated 28th July 2011 US and EU FDA approval for use in the treatment of advanced renal cancer 2005 – 2006. The recommended dosage for advanced renal cancer is 400 mg twice daily. Current availability of sorafenib tosylate at health centers is not provided. ‘India does not provide expensive cancer treatment under the public health programme’. Patients have to pay themselves but Bayer currently markets the drug at a high price of approximately Rs. 2, 80,000 per patient per month157. Cipla filed a post grant opposition on the sorafenib tosylate patent and applied for marketing approval with the Indian FDA. Bayer however delayed the market registration of the generic version by filing a case against the Indian FDA to prevent it from registering a generic version of sorafenib tosylate. The Indian courts rejected Bayer’s attempt to link registration of medicines to their patent status (patent linkage), following which, Cipla launched at risk the medicine in the Indian market at Rs. 28,000 per patient per month – 1/10th the cost of the patented version. Bayer has now filed an infringement suit against Cipla in the High Court of Delhi. The matter is listed as Bayer Corporation ANR vs. Cipla Ltd, CS(OS) 523/2010.

In July 2011, NATCO filed a CL application proposing to market the same drug at Rs. 8,800 per patient per month if the patent office grants it a compulsory license. This is 31 times cheaper than Bayer’s sorafenib tosylate or 3% of the price at which Bayer sells the drug in India. Even the health systems of developed countries have found the drug too expensive. In the UK, the National Institute for Health and Clinical Excellence (NICE) the body that provides guidance on the use of new drugs by the National Health Service, decided that NHS could not pay for

157 India – prices of patented medicines and compulsory licence test case Posted on October 10, 2011 by don’t trade our lives away update on Application U/S 84 OF The Indian Patent Law for Generic production of Patented Cancer Drug - Sorafenib Tosylate Don’t trade our lives away Theme: Twenty Ten Blog at WordPress.com
the drug as the price being asked by Bayer was too high. The drug was just too expensive\textsuperscript{158}.

By the end of 2007, over 50 surveys had been undertaken across the globe, from Cameroon and the Cook Islands to El Salvador, South Africa and the Syrian Arab Republic. They have generated reliable evidence showing, for the first time, some startling facts about the affordability and availability of medicines. The results of these surveys revealed that in many low- and middle-income countries:

1. Medicine prices are high, especially in the private sector (e.g. over 80 times an international reference price);
2. Availability can be low, particularly in the public sector (including no stocks of essential medicines);
3. Treatments are often unaffordable (e.g. requiring over 15 days’ wages to purchase 30 days’ treatment);
4. Government procurement can be inefficient (e.g. buying expensive originator brands as well as cheaper generics);
5. Mark-ups in the distribution chain can be excessive; and
6. Numerous taxes and duties are being applied to medicines.

India’s drug policies over the years have created an environment of duality. The country not only produces enough drugs to meet domestic consumption, but as one of the largest exporters of generic and branded drugs, is also known as the ‘global pharmacy of the south.’ India exports life-saving drugs to developing countries and also supplies quality drugs to the rich nations at affordable prices. Despite this seemingly commendable performance, millions of Indian households do not have access to drugs\textsuperscript{159}. This results from both financial (lack of the necessary purchasing power) and physical (lack of public health facilities) barriers. Evidence from large sample surveys of households over the last 25 years suggests that the impediments to access of medicines have become steeper. During the mid 1980s, approximately a third of the drugs prescribed during hospitalization were

\textsuperscript{158} See BBC News: Liver drug too expensive
supplied for free. This declined sharply to only about 9% by 2004. Free drug supply for out-patient care has fallen from 18% to about 5% over the same period.

During the same period, the number of hospitalization episodes in which an ailing population paid out-of-pocket (OOP), has risen dramatically from about 41% to close to 72%. As far as out-patient care is concerned, the proportion of drugs fully purchased by households decreased from as high as 80% in the mid 1990s to 65% in 2004. The above table shows that since medicines have started becoming unaffordable since the mid-1990s, by 2004, in over one-fourth of out-patient episodes, patients did not receive medicines because they could not afford them.

5.5.1 Trends in Access to Medicines in India

Table-14: Trends in Access to Medicines in India 1986-87, 1995-96 & 2004-05\(^{160}\)

<table>
<thead>
<tr>
<th>Period</th>
<th>Free Medicines</th>
<th>Partly free</th>
<th>On Payment</th>
<th>Not received</th>
<th>Total in %</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Patient</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1986-87</td>
<td>31.20</td>
<td>15</td>
<td>40.95</td>
<td>12.85</td>
<td>100</td>
</tr>
<tr>
<td>1995-96</td>
<td>12.29</td>
<td>13.15</td>
<td>67.75</td>
<td>6.80</td>
<td>100</td>
</tr>
<tr>
<td>2004</td>
<td>8.99</td>
<td>16.38</td>
<td>71.79</td>
<td>2.84</td>
<td>100</td>
</tr>
<tr>
<td>Out Patient</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1986-87</td>
<td>17.98</td>
<td>4.36</td>
<td>65.55</td>
<td>12.11</td>
<td>100</td>
</tr>
<tr>
<td>1995-96</td>
<td>7.21</td>
<td>2.71</td>
<td>79.32</td>
<td>10.76</td>
<td>100</td>
</tr>
<tr>
<td>2004-05</td>
<td>5.34</td>
<td>3.38</td>
<td>65.27</td>
<td>26.01</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: Health data extracted from National Sample Survey Rounds 60, 52, and 42\(^{161}\) 3-5.

The Figures in the above table shows how heavily the Indian population is dependent on private chemists. The availability of free or partially free drugs in out-patient care is extremely low. This highlights the limited protection offered by the government and the preponderance of private players in drug prescription and dispensing. The HLEG study shows that people in some of the southern states appear to have relatively better access to medicines than in the other states. The success of the Tamil Nadu Medical Services Corporation (TNMSC) model is clearly reflected in the proportion of people able to obtain medicines free/partially free from public health facilities. The Tamil Nadu figure is close to 25% in the case of Tamil Nadu, followed by Karnataka, Kerala and Delhi. The lower percentage share in other states indicates higher reliance on private chemists\(^{162}\).

---


The UN High Commissioner for Human Rights, Mary Robinson says that “The right to health does not mean the right to be healthy, nor does it mean that poor governments must put in place expensive health services for which they have no resources. But it does require governments and public authorities to put in place policies and action plans which will lead to available and accessible health care for all in the shortest possible time. To ensure that this happens is the challenge facing both the human rights community and public health professionals.”

Further, the Committee interpreted the right to health as an inclusive right extending not only to timely and appropriate health care but also to the underlying determinants of health, such as access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions and access to health-related education and information, including on sexual and reproductive health.

The General Comment sets out four criteria by which to evaluate the right to health:

(1) **Availability.** Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity.

(2) **Accessibility.** Health facilities, goods and services have to be accessible to everyone without discrimination, within the jurisdiction of the State party. Accessibility has four overlapping dimensions:
   a) Non-discrimination;
   b) Physical accessibility;
   c) Economic accessibility (affordability);
   d) Information accessibility.

(3) **Acceptability.** All health facilities, goods and services must be respectful of medical ethics and culturally appropriate, sensitive to gender and life-cycle requirements, as well as designed to respect confidentiality and improve the health status of those concerned.

(4) **Quality.** Health facilities, goods and services must be scientifically and medically appropriate and of good quality.

It was found that most of the patients avoided treatment due to the reason of the cost involved in the treatment especially for cancers, diabetic nephropathy and other such diseases as the treatment required is for a longer duration the disease is
cured if initiated at the beginning of the first stage once this stage is passed it is very difficult to control the disease which at a later stage becomes life threatening these diseases were believed to be the rich men’s diseases but due to food habits and lifestyles they are even the commonest mans diseases the only difference is rich men can manage by controlling the diseases but poor people are helpless and leave hope of getting the disease cured as the price of diagnosis and treatment is not within the reach of poor persons they say for themselves “let’s save money and loose the life instead of losing both money and life” at least the future generations can lead a proper life. According to the report of “The State of Health of Mumbai” July 2013, by Praja Foundation the observation made by them was astonishing according to it Malaria cases in 2012-2013 were 21,939, deaths reported 230, Dengue cases were 4,867 deaths reported were 74, tuberculosis reported were 36,417 deaths were 6,921, deaths due to Diarrhoea were 245. As per the Doctor Deepesh Reddy who states the programme’s failure for the past ten years he was critical of the attention and resources spent on tackling malaria whereas a serious disease like tuberculosis has been ignored. Another Doctor Zarir Udwadia, Chest Physician at Hinduja Hospital says “The fact that nine per cent of deaths in a shining metropolis are caused by an ancient, preventable disease is scandalous”. This clearly shows even in such a developed city the working of public health policies have failed to deliver causing deaths of innocent people. The Independent citizen survey of over 24,694 households conducted by Hansa Research had got surprising revelations. The survey showed that the incidence of malaria was highest in the high income group -139 as compared to 44 in the lowest income group. Similarly, incidence of dengue, diabetes and cancer was high in this section as compared to other sections. Oommen Chandy\textsuperscript{163} opined that India needs the Right to Health he gave an example, of a 30 year old suffering from a serious illness, waiting outside a hospital, but unable to afford the cost. But then an 80 year old person goes in, pays lakhs, gets his treatment done and extends his life by a few years. How will the youth and their family members react? This can turn a major social issue. This is where the government has to work in such a way that health facilities should be made available within the reach of the common man at least cost.

\textsuperscript{163} In a recent interview by the “The Week” in September 29, 2013, issue correspondent Ajish P. Joy of Chief Minister of Kerala.
and affordable prices especially for medicines as they form the major costs in the treatment and due to which the disease can be cured only by taking the medicines.

From the table below we can clearly make out that most of the people are dependent on out of pocket costs as to the taking of the treatment is concerned as many of the medicines are not freely available except the generic versions and that too for communicable diseases. As to the Non-communicable diseases are concerned the availability of medicines are not made available in most of the government hospitals due to shortage of funds in procurement of drugs and medicines required by the needy people. Even the budgets allocated are not properly utilized as the funds earmarked are higher than what actually allocated it means the amount spent is less than that of the budgeted fund.

Table-15: Percentage of Households Facing Catastrophic Expenditure on Health, 2009-10 (>10% of HH Spend)\textsuperscript{164}

<table>
<thead>
<tr>
<th>Quantile Groups</th>
<th>OOP Expenditure</th>
<th>Inpatient Expenditure</th>
<th>Outpatient Expenditure</th>
<th>Drug Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poorest</td>
<td>7.656</td>
<td>1.082</td>
<td>6.329</td>
<td>4.523</td>
</tr>
<tr>
<td>2\textsuperscript{nd} Poorest</td>
<td>9.875</td>
<td>1.980</td>
<td>7.394</td>
<td>6.012</td>
</tr>
<tr>
<td>Middle</td>
<td>12.237</td>
<td>2.770</td>
<td>8.848</td>
<td>7.392</td>
</tr>
<tr>
<td>2\textsuperscript{nd} Richest</td>
<td>16.197</td>
<td>4.496</td>
<td>10.979</td>
<td>9.591</td>
</tr>
<tr>
<td>Richest</td>
<td>22.456</td>
<td>7.954</td>
<td>16.207</td>
<td>14.852</td>
</tr>
<tr>
<td>All</td>
<td>13.684</td>
<td>3.656</td>
<td>9.951</td>
<td>8.474</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>States</th>
<th>2008-09 (Actuals)</th>
<th>2009-10(RE)</th>
<th>2010-11(BE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assam</td>
<td>5.7</td>
<td>5.6</td>
<td>5.0</td>
</tr>
<tr>
<td>Bihar</td>
<td>6.3</td>
<td>5.9</td>
<td>7.0</td>
</tr>
<tr>
<td>Gujarat</td>
<td>6.5</td>
<td>4.9</td>
<td>7.6</td>
</tr>
<tr>
<td>Haryana</td>
<td>8.6</td>
<td>6.8</td>
<td>5.5</td>
</tr>
<tr>
<td>Kerala</td>
<td>10.6</td>
<td>10.4</td>
<td>12.5</td>
</tr>
<tr>
<td>Maharashtra</td>
<td>9.6</td>
<td>5.2</td>
<td>5.2</td>
</tr>
<tr>
<td>Madhya Pradesh</td>
<td>9.1</td>
<td>10.1</td>
<td>9.3</td>
</tr>
<tr>
<td>Punjab</td>
<td>1.1</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Rajasthan</td>
<td>3.0</td>
<td>1.9</td>
<td>1.5</td>
</tr>
<tr>
<td>Uttar Pradesh</td>
<td>6.9</td>
<td>4.8</td>
<td>5.3</td>
</tr>
<tr>
<td>Jharkhand</td>
<td>2.9</td>
<td>2.3</td>
<td>3.4</td>
</tr>
<tr>
<td>West Bengal</td>
<td>9.2</td>
<td>6.8</td>
<td>6.8</td>
</tr>
<tr>
<td>Andhra Pradesh</td>
<td>7.3</td>
<td>6.8</td>
<td>10.0</td>
</tr>
<tr>
<td>Karnataka</td>
<td>8.0</td>
<td>7.2</td>
<td>6.3</td>
</tr>
<tr>
<td>Tamil Nadu</td>
<td>11.2</td>
<td>9.3</td>
<td>12.2</td>
</tr>
<tr>
<td>Himachal Pradesh</td>
<td>4.5</td>
<td>2.3</td>
<td>1.9</td>
</tr>
<tr>
<td>J and K</td>
<td>6.5</td>
<td>5.2</td>
<td>4.3</td>
</tr>
</tbody>
</table>

Source: Government Expenditure on Drugs (%) morbidity, Health care and the condition of the aged NSSO 600\textsuperscript{th} round (January-June -2004) National Sample Survey Organization Ministry of Statistics and Programme Implementation Government of India, March 2006, Report No. 507 (60/25.0/1).

\textsuperscript{164} Source Budget documents of the Central and State governments, Annual Report of 2010-11 released by RBI on 25-Aug- 2011: Appendix Table 15 on Key Fiscal Indicators as a percent to GDP. For State finances, budget numbers are Budget Estimates for 2011-12 and RE for 2010-11.
The Budgeted fund is not fully utilized. This is where India is lagging behind due to improper planning and lack of awareness of the people. Since non-communicable diseases are usually treated as lifestyle diseases as many of the diseases are attracted due to stress, addiction to alcohol and tobacco. The News Channel India TV reported that In Punjab alone every year new cases are added to the list of cancer patients due to overuse of fertilizers, pesticides and adulterated food and are forced to live without medications due to huge cost of medicines.

Table-16: Pricing Comparisons that Market Leaders are Price Leaders\textsuperscript{165}

<table>
<thead>
<tr>
<th>Name of the Medicine</th>
<th>Manufacturers (Number)</th>
<th>Market Leaders</th>
<th>Most Expensive</th>
<th>Least Expensive</th>
<th>TNMSC Prices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-diabetic Human Insulin (40IU-pack size)</td>
<td>10</td>
<td>128.1 Abbot</td>
<td>147.8 Eli Lilly</td>
<td>101.5 Biocon</td>
<td>47.84</td>
</tr>
<tr>
<td>Glibenclamid 5mg-packsize 10</td>
<td>11</td>
<td>7.1 Sanofi Avantis</td>
<td>7.1 Sanofi Avantis</td>
<td>3.7 Lupin</td>
<td>NA</td>
</tr>
<tr>
<td>Cardiovascular System Atenolol (50mg-packsize 10)</td>
<td>46</td>
<td>26.3 Zydyus</td>
<td>31.3 Torrent</td>
<td>4.0 Unison</td>
<td>1.20</td>
</tr>
<tr>
<td>Atrosastatin (10mg-packsize 10)</td>
<td>58</td>
<td>68 Ranbaxy</td>
<td>68 Ranbaxy</td>
<td>9.1 Hetro</td>
<td>2.77</td>
</tr>
<tr>
<td>Antibiotics Cefixime (200mg-packsize 10)</td>
<td>51</td>
<td>79.1 FDC</td>
<td>305.7 Admac</td>
<td>64.6 Laborate</td>
<td>NA</td>
</tr>
<tr>
<td>Gastor Intestinal System Omeprazole (20mg- packsize 10)</td>
<td>79</td>
<td>39.7 Zydyus</td>
<td>75.2 Dolphin</td>
<td>2.5 Medley</td>
<td>2.4</td>
</tr>
</tbody>
</table>

Table-17: Market Share for Fixed Dosage Combinations involving Essential Medicines

<table>
<thead>
<tr>
<th>Drug Market</th>
<th>All Dosages (Rs in Crores)</th>
<th>NLEM Dosages (Rs in Crores)</th>
<th>NLEM to All Dosages (Rs in Crores)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti Diabetic Human insulin 40 IU</td>
<td>508</td>
<td>274</td>
<td>53.93</td>
</tr>
<tr>
<td>Glibenclamide 2.5 and 5 mg</td>
<td>384</td>
<td>264</td>
<td>68.7</td>
</tr>
<tr>
<td>Antibiotics Cefixime 200mg</td>
<td>357</td>
<td>331</td>
<td>92.7</td>
</tr>
<tr>
<td>Gastor Intestinal System Ranitidine 150mg</td>
<td>208</td>
<td>174</td>
<td>83.6</td>
</tr>
<tr>
<td>Gynaeceology Methylergometrine 0.125 mg</td>
<td>24</td>
<td>24</td>
<td>100</td>
</tr>
<tr>
<td>Analgesic- antipyretic Paracetomol 250 mg</td>
<td>131</td>
<td>84</td>
<td>64.1</td>
</tr>
</tbody>
</table>

\textsuperscript{165} Source: Based on IMS Health, 2008, database figures
5.5.2 Findings

1. Medicines are overpriced and unaffordable in India.
2. Medicines constitute 50 to 80 percent of health care costs in India.
3. Health care is the second-most leading cause of rural indebtedness, after dowry.
4. There is no universal health insurance in India; even if there were, regulation of prices would result in considerable savings.
5. Because of a crumbling public health system, the first choice of patients is a private practitioner which means more out of pocket expenditures apart for loss of wages etc.

On the analysis made by comparing the pricing of different medicines both common generics and the patented medicines we can clearly make out that the pricing pattern varies from companies to companies for the same drug and combination the reason for such a difference is not known or clearly explained. On pricing the patented medicines they are costly it is said that the companies or a patent holder has incurred huge amount on research and development to bring out a medicine hence a pharmaceutical product which is patented need to be priced at a higher rate this is what the justification is made by the patent holders. Patented drugs are priced at a very high prices and hence they are not easily accessible by common man even the governments have expressed their inability to provide free medicines especially patented medicines to the poor at free of cost due to high procurement cost patent on medicines is a very major contributor for non affordability of medicines. The companies avail many tax benefits from the government where it is established for example provisions in income tax laws, the companies claim deductions on the innovations made by them either as recurring expenditure or by capitalizing it later on amortizing it. The Patent holder claims depreciation on intangible assets created by the companies. The companies are benefitted both sides taking deductions on expenditure incurred on innovations and innovations converted into intangible assets and depreciation and amortizations are claimed and pricing their innovated drugs at a higher range which becomes unaffordable in the hands of the common man. There are no proper mechanisms for fixing the patented products price. The prices are fixed arbitrarily and the companies are not under obligation to disclose exactly what cost was incurred in
inventing the product. Hence the arbitrary price fixed by the innovators has increased the unaffordability of patented drugs and medicines. Ellen ’t Hoen from Médecines Sans Frontières’ Access to Essential Medicines Campaign on “Patents and Access to Essential Medicines”, said that 30 to 50 per cent of the population in developing countries do not have access to essential medicines. This is especially so in India and in African countries.

Access to essential medicines depends on many factors. Patent is not the only factor. For instance, there are the regulatory, quality, production, supply and rational use factors. At the end of the day all of these factors must be addressed. The future holds both concerns and opportunities.

5.6 PRIORITY TO THE HEALTH IS NOT GIVEN IN INDIAN PATENTS ACT IN UTILIZING THE FLEXIBILITIES TO REGULATE THE EFFECT OF PRICES OF PRODUCT PATENTS IN THE FIELD OF MEDICINES AND DRUGS AFTER ITS AMENDMENTS IN 1999, 2002 AND 2005.

The Patent Act speaks much more about the procedures and protection of Patent rights and has very few provisions such as the flexibilities which are insufficient to cover health care aspects no specific provision speaks about the price fixation and accessibility of the medicines to the poor so right to health is not given much importance.

5.6.1 Flexibilities which India can use under its Patents Law

Within the scope of TRIPs, the following are the main flexibilities which developing countries can use them:

1. Provide exemptions from grant of patents in certain cases
2. Provide exceptions to product patent rights in certain cases
3. Limit data protection
4. Provide for government use and
5. Provide compulsory licenses to non-patentees.

Under Article 27(1) of TRIPs, patents will have to be provided for inventions, which are “new, involve an inventive step and are capable of industrial application” The agreement however does not define these terms. This provides some flexibility. It has been suggested that a developing country can interpret these
terms so as to restrict the number of patents\textsuperscript{166} in fact has warned that if the patentability standards are too broad, so that the terms “new”, “inventive” are defined to include all the new forms of the same New Chemical Entity, then effectively the patent life can be extended beyond the 20-year period. WHO has advised governments to exercise discretion in this regard\textsuperscript{167} has pointed out that there is no compulsion under TRIPs for the developing countries to follow the liberal patent standards of developed countries. The aim should be to ensure that patents are granted for true technical contributions and not for blocking innovation and legitimate competition by generic producers\textsuperscript{168}.

Chapter II (Sections 3 to 5) of the Patents Act, 1970 deals with “inventions not patentable.” It was hoped that the third amendment would provide the qualification that product patents will be granted only for new drugs which represent significant therapeutic advances. that patents may not be granted for “a new molecular modification or a salt or ester or a derivative or a formulation or dosage form of a known new chemical entity having the same or similar pharmaceutical activity” or new uses or new combinations of existing NCEs\textsuperscript{169}.

But as the NIHCM in its study shows that, most of the new drugs are unnecessary combinations of existing drugs or simple modifications of existing drugs, which represent practically no therapeutic advance. There is no reason why developing countries should subsidize such wasteful expenditure by providing patents for these products.

Before 1\textsuperscript{st} January, 2005, when mailbox applications were accepted, new uses of a drug were excluded from patentability because under the then existing Section 3 of Patents Act, 1970, “new use for a known substance” was not a patentable subject matter. The Patent Ordinance has amended Section 3(d) by replacing the words “new use” by “mere new use.” This widens the scope of patentability by providing an opportunity to an applicant to patent a new use even when the substance is known\textsuperscript{170}.

But the new Section 11a (7) of the Patent Ordinance has spelt out that for mailbox applications, patent rights will accrue only from the date of grant of patent

\textsuperscript{166} Correa 2000; Abbott 2001; CIPR 2002, WHO 2001
\textsuperscript{167} CIPR (2002, p. 49) Correa 2000, p. 110
\textsuperscript{168} Correa, Carlos 'IntellectualProperty Rights, the WTO andDeveloping Countries, The TRIPS Agreement and Policy Options, ZedBooks: London and New York.2000, p. 110
\textsuperscript{169} Peoples’ Commission on Patent Laws in India 2003, pp. 62, 76
and that patent infringement cases cannot be filed before the grant of patent. Thus Indian generic companies will not be required to immediately suspend production and will not face any penalty for their past manufacturing and marketing activities\textsuperscript{171}. But they will have to suspend production in future, if and when the mailbox applications are processed and patents granted.

The Ordinance lists 11 grounds on which a patent can be opposed, but only after the patent has been granted. Before the grant of the patent, opposition is restricted to only two grounds: “(a) Patentability, including novelty, inventive step and industrial applicability or (ii) non-disclosure or wrongful mentioning in complete specification, source and geographical origin of biological material used in invention and anticipation of invention by the knowledge, oral or otherwise available within any local or indigenous community in India or elsewhere”\textsuperscript{172}. Moreover, the Patent Rules\textsuperscript{173} issued to implement the Ordinance specify time limits on entertaining such opposition.

Representation for opposition will have to be made within three months of the date of publication of the patent application. The applicant will have to reply to the notice, if issued by the Controller within one month. The Controller of Patents will have to decide about the refusal or grant of patent ordinarily within one month from the completion of proceedings, which may include hearing, if requested\textsuperscript{174}. Thus unlike as under the Patents Act, 1970, a patent can be granted even when it is not convincingly settled that it can be granted this obviously will speed up the process of grant of patents and that seems to be the objective\textsuperscript{175}. But this favours the patentees.

The following three are the most significant and common exceptions which the national laws in many countries provided when TRIPs came into effect:

\textsuperscript{171} It has been said that since India’s Patent Offices lack adequate resources and expertise, there may be a delay in processing mailbox applications. And since the generic companies can continue to produce till the patent is granted, this goes against the interests of the mailbox applicants. But because of the inadequacies in the patent offices, patentees may also gain - a patent may be granted wrongly and in that case the generic companies will have to suspend production even though they are not supposed to do so. In such cases it is only after a lengthy and difficult legal process that the generic companies can get back their rights.

\textsuperscript{172} Section 25 of the Indian Patents Act, 1970.

\textsuperscript{173} The Patent Rules 2003 were updated on December 28, 2004 through a notification. Text of the Rules accessed from www.patentoffice.nic.in.

\textsuperscript{174} Rule 55, of the Patents Act, 1970

\textsuperscript{175} It was stated in the “Statement of Objects and Reasons” of the Patents (Amendment) Bill, 2003 (on which the Patent Ordinance is based) that “While considering amendments to the Act, efforts have been made to make the law not only TRIPs compliant but also to simplify and rationalize the procedure governing grant of patents so as to make the system more user-friendly.” The text of the Bill was accessed from www.patentoffice.nic.in.
1. Early working
2. Parallel imports and
3. Research and experimental use\textsuperscript{176}
4. Compulsory Licensing

Countries have some flexibility in interpreting these terms and incorporating some exceptions to exclusive rights of the patentees in national patent laws. But under TRIPs, in the absence of clear guidance, any such use by a country (for example Canada can be contested by any other country and in that case the former cannot use it unless the dispute is resolved in its favor.

\textbf{1. Early Working}

The “early working” provision is popularly referred to as the “Bolar” provision or exception, as it is known in USA. The Bolar provision is very important for generic entry. It permits generic entry soon after the patents expire and hence allows the consumers to benefit from competition and lower prices without delay. In the absence of it, generic companies will have to wait till the patents actually expire before they can start the tests necessary for getting regulatory approval. During the several months or even years it may take to get such approvals, the patentee will effectively enjoy monopoly status even though there are no legal barriers to entry. The amended patents Act in India provides for Bolar exception. Under Section 107A (a), use of a patent for development and submission of information for regulatory approval will not be considered as an infringement of the patent right. Thus in the new patent regime, as innovator companies introduce new drugs in India and enjoy exclusive patent rights, such Bolar provisions can be used to introduce generics immediately after the expiry of patents.

\textbf{2. Parallel Imports}

Under Article 28 of TRIPs, the patent owner has the exclusive right to prevent others not only from making, using or selling the invented product or process in the country, but also importing from other countries. This is however subject to Article 6 on “exhaustion.” What it basically means is that the patent holder in a country cannot legally stop imports of patented products offered for sale in another country. Such imports of patented products without the consent of the patent holder in the importing

\textsuperscript{176}See, UNCTAD-ICTSD 2004, p. 95.
country are known as parallel imports. The underlying justification of allowing parallel imports is that since the innovator has been rewarded through the first sale of the product, its patent rights have been “exhausted” and hence it should have no say over the subsequent re-sale. Under Article 6 of TRIPs as clarified by the Doha Declaration (paragraph 5(d)), each country is “free to establish its own regime for such exhaustion without challenge”\textsuperscript{177}.

Under the original 1970 Act, importing was not mentioned as an exclusive right. This has been amended (in Section 48) to conform to TRIPs. But unlike Article 28 of TRIPs, Section 48 of India’s amended Patents Act provides no qualification about exhaustion of patent rights. Instead another section \{107A (b)\} has been inserted which says that “importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product shall not be considered as an infringement of patent rights.” This does permit parallel imports but only in some cases. As the Indian Drug Manufacturers Association (IDMA)\textsuperscript{178} has pointed out, the phrase “duly authorized by the patentee” may cause delay and difficulty. In accordance with the spirit of Article 28 of TRIPs, any import from any legitimate source even if not specifically authorized should be permitted.

3. Research and Experimental Use

Section 47 of the Patents Act, 1970, which has not been deleted in the recent amendments, provides other exceptions. The patented product/process may be made or used by any person for the “purpose merely of experiment or research including the imparting of instructions to pupils.” As UNCTAD-ICTSD\textsuperscript{179} has pointed out, the exception can not only be for scientific research with no commercial intent. It is also possible to exempt acts of experimentation even if made with commercial purposes. To avoid any ambiguity, it should be clearly understood that the non-patentees can experiment with the patented product and develop their own processes of manufacturing for commercial purposes, (though they may not be able to actually use these unless they are authorized to do so). As the Doha Declaration has affirmed, “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”. Such possibilities of experimentation will help realise the objectives

\textsuperscript{177} See Correa 2000, pp. 71-80 for a discussion on the theory and practice of parallel imports.
\textsuperscript{178} Letter to Secretary, Ministry of Industrial Policy and Promotion, 28 July, 2003, p. 25
\textsuperscript{179} UNCTAD-ICTSD 2002 (p. 101)
mentioned in Article 7, viz., promotion of technological innovation and transfer and dissemination of technology. This is also important for maintaining and developing efficient alternatives to protect public health and to prevent patentees from abusing patent rights. RandD is a continuous process. If the indigenous sector is asked once in a while to develop a process, it is possible that they may not be able to do so. The opportunity of using the patented product for RandD purposes will enable the indigenous firms to be ready with efficient processes and use these whenever they are permitted to do so. Article 66.2 obliges the developed countries to provide incentives to developing countries to promote technology transfer. A number of studies have shown that the single most important factor determining the success of technology transfer is the existence of indigenous technological capacity.

India’s Drug and Cosmetics Act, 1940, which regulates the marketing approval of new drugs as well as the Patents Act, 1970, the three amendments including the Ordinance of 2004 carried out till date to comply with TRIPs do not contain any provisions relating to test data protection. Thus India has been able to use an important TRIPs flexibility with positive implications for generic competition and prices. But India has been under tremendous pressure from MNCs and the US government to introduce data exclusivity provisions. Government officials admit that it is not a TRIPs obligation but feel that a re-consideration by India may be necessary. In the USTR 2004 report, India has been targeted as a “priority watch list” and points out that “…the United States is encouraged by the Indian Government’s recent statements concerning implementation of data exclusivity regulations…” It is significant to note that in a public speech few days after the Patent Ordinance was issued, the Commerce and Industry Minister has announced that the government is looking at the possibility of enacting a “holistic” piece of legislation on data protection.

---

180 Article 8 on Principles of TRIPs Agreement.
181 Article 66.2 of TRIPs Agreement.
182 CIPR 2002, p. 11.
183 Director, Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, told Express Pharma Pulse that “the magnitude of pressure on India is such that even though the government want to exploit all flexibilities under TRIPs, we cannot predict anything now.” See Express Pharma Pulse (a pharmaceutical weekly), 3 October, 2002 (accessed from www.Expresspharmacapulse.com). See also “Govt to consider data protection”, in The Economic Times, 29 November, 2003 (accessed from www.economictimes.indiatimes.com).
4. Compulsory Licenses

In fact as WHO and WTO\textsuperscript{186} point out, compulsory licensing is one of the ways in which TRIPs attempts to strike a balance between promoting access to existing drugs and promoting RandD into new drugs. International NGOs such as Medecins Sans Frontieres/Doctors without Borders (MSF), Consumer Project on Technology, Health Action International have been drawing attention to compulsory licensing provisions of TRIPs to enhance access\textsuperscript{187}. After analysing the costs and benefits of the patent system, what Penrose\textsuperscript{188} concluded more than fifty years back is valid and relevant even today.

TRIPs do not use the term “compulsory license.” Article 31 refers to “use without authorization of the right holder,” and includes both use by third parties (what is usually referred to as compulsory licenses) and use by government.

Article 31 of TRIPs dealing with compulsory licensing\textsuperscript{189}, does not place any restriction on the grounds under which a compulsory licenses can be given. In case there was any doubt, the Doha Declaration has made it clear that “Each member has the right to grant compulsory license and the freedom to determine the grounds upon which such licenses are granted.” The problem is that certain conditions listed in the Article will have to be satisfied. These include: (i) that authorization of such use will have to be considered on its individual merits, (ii) that before permitting such use (except in such cases as situations of national emergencies, extreme urgency, public non-commercial use), the proposed user will have to make efforts over a reasonable period of time to get a voluntary license on reasonable commercial terms, (iii) that the legal validity of the compulsory licensing decision and the remuneration will be subject to judicial or other independent review, (iv) the compulsory licenses can be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur.

\textsuperscript{186}WTO , 2001, p. 99
\textsuperscript{189} As Scherer and Watal, have pointed out, compulsory licenses can be also be granted under Article 40 of TRIPs in case of an adverse impact on competition in the relevant market. 2002, p. 915
### 5.6.2 Compulsory Licensing in India’s Patent Act General Provisions

The Patents Act, 1970 had a clear strategy – to eliminate the monopoly of the MNCs and remove the bottlenecks in the previous regime which prevented the indigenous firms from producing patented drugs. And it was done through a very simple process of abolishing product patent protection in drugs. The Act of 1970 also had provisions for compulsory licensing for pharmaceutical processes. In fact under Section 87 of the 1970 Act, any process patent related to pharmaceuticals were to be endorsed with the words “Licenses of right” within three years of the sealing of the patent. In such cases, anyone could ask for a license from the patent owner to use the patented process on mutually agreed terms. But a compulsory license was redundant in the previous regime. Being free to produce the patented drugs, the indigenous firms could develop their own processes and they indeed did so, as we have mentioned above. But in the product patent regime has been introduced in India, the indigenous firms cannot produce a patented drug even if they develop the processes of manufacturing it, unless they get a compulsory license. Hence it is of fundamental importance to have a simple and easy to administer compulsory licensing system. TRIPs do not prohibit this as we have mentioned above and the Canadian experience shows how it is possible to have such a system.

Patented Medicine Prices Review Board (PMPRB) of Canada Created in 1987, under the Patent Act, as an independent quasi-judicial tribunal, the PMPRB limits the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure they are not excessive. As an independent quasi-judicial body, the PMPRB carries out its mandate independently of other organizations, such as Health Canada, which approves drugs for safety and efficacy; and public drug plans, which approves the listing of drugs on their respective formularies for reimbursement purposes. This agency is unique in the sense that it was set up exclusively to monitor the prices of patented drugs. Besides it also analyses the therapeutical contribution of the patented drugs and documents the pharmaceutical R&D investment in Canada. Though the data provided by this agency are rich, the PMPRB’s area of operation is restricted to the patented medicines marketed or distributed under voluntary licenses. It does not regulate the prices of generic drugs and
prices charged by wholesalers or retailers. Thus PMPRB regulates the price of each patented product on the first and last month of every year.\footnote{Source: http://www.pmprb-cepmb.gc.ca/english/06_e/06ann01_e.htm.}

The price of a patented product in Canada can at no time exceed the highest price for the same drug in countries such as France, Germany, Italy, Sweden, Switzerland, the UK and the US. Sale of patented drugs accounted for 67 percent of total sales in 2001 as compared to 43 percent in 1990. Of the 933 patented drugs reviewed by this body till 2001, 827 drugs have been within the price guidelines. This may imply that the PMPRB does keep the prices of patented drugs under control.

Lexchin\footnote{Generally see T.A. Faunce and J. Lexchin, “Linkage in pharmaceutical evergreening in Canada and Australia”, \textit{Australia and New Zealand Health Policy}, vol. 4, (2007), p. 8, referring to the two following sources: Government of Canada. Canada Gazette Part II Regulations amending the patented medicines (notice of compliance) regulations 2006, 140 (21): 1503-1525; \textit{AstraZeneca Canada Inc. v. Canada (Minister of Health)}, 2006 SCC 49.} observes that the prices of drugs, which had voluntarily surrendered patents, were above the prices of patented medicines. Once this was brought to the notice of PMPRB, the rules were changed and now, even if companies voluntarily surrender their patents, such products still come under the scrutiny of PMPRB until the expiry of patents.

Canadian regulators have ordered the local subsidiary of US-based ICN Pharmaceuticals to cut the price of its Virazole, anti-infection, drug by almost 90 percent, and pay a C$1.2mn (US$876,000) penalty for excessive pricing. It found ICN had sold Virazole at “an excessive price” since January 1994, and ordered the company to reduce the price of a 12-hour dose from C$1540 to about C$200.\footnote{Source: Sawtee newsletter, August- December, 1996}

But this has not been done in case of India. The basic problem with the amended Act is that it lacks any positive strategy. It appears that adequate attention has not been devoted to design the law to take advantage of the flexibilities which TRIPs provides. The entire amendment has been carried out very mechanically. It starts with the relevant text of the Patents Act, 1970 and then makes some changes to make it TRIPs compliant. This has been done by deleting some clauses of the 1970 Act for example abolition of special license of right compulsory licensing provisions relating to pharmaceutical processes and lifting some clauses from TRIPs and inserting these in the amended Act. In the process many negative aspects have remained in the amended Act, which could have been tackled without violating TRIPs,
As Article 1 of TRIPs has made it clear, member countries are “not obliged to implement in their laws more extensive protection than is required by this Agreement ...” But the government has adopted a stricter compulsory licensing regime than what is required under TRIPs. In the amended Act, an application for a compulsory license can be made under two sets of circumstances: under Section 84, three years after the sealing of the patent and under Section 92, anytime after the sealing of the patent with respect to a patent notified by the government as eligible for a compulsory license. The amended Act has elaborate provisions on compulsory licensing in Chapter XVI (Sections 82 to 94). The “general principles” sound very impressive. In fact these are more elaborate than what we find in the Act of 1970. The general principles note that patents are granted to encourage inventions and to make the benefit of patented invention available at “reasonably affordable prices to the public,” to secure that these are worked in India, and not to enable patentees to enjoy monopoly power by importing. That the patent right is not abused by the patentee and the patentee does not “resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology”\(^\text{193}\) Entire Article 7 of TRIPs agreement on Objectives and the entire Article 8 on Principles are listed. Para 4 of the Doha Declaration relating to the right of the governments to take measures to protect public health, is also incorporated here. The Amended Act also specifies the “general purposes” to be followed while granting compulsory licenses, for example that “the patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable”\(^\text{194}\).

An application for a compulsory license can be made under Section 84 on the following grounds: that the “reasonable requirements of the public” have not been satisfied, or that the product is not available at a “reasonably affordable price”, or that the patented invention is “not worked in the territory of India”. Thus under the Indian law, if a patentee does not exploit locally the patented inventions, then compulsory licenses can be asked for. For a similar feature in the Brazilian patent law, USA lodged a complaint with the WTO. USA withdrew its complaint later. But Brazil has agreed to hold talks with USA before using such a provision. It remains to be seen how Brazil, India or any other country will or can use this provision.

\(^{193}\) Section 83 of the Indian Patents Act, 1970.
\(^{194}\) Section 89 of the Indian Patents Act, 1970.
As CIPR,\textsuperscript{195} for example has stressed, what is often crucial for an effective compulsory licensing system is to have straightforward, transparent and fast procedures. A patent holder will naturally be opposed to any compulsory licenses. The pre-1993 Canadian experience shows how the practice and the procedures can be such that the patentees have no opportunity to delay or prevent the grant of compulsory licenses. But in India that has not been the case. The wording of the grounds for granting compulsory licenses in Section 84 is not amenable to easy interpretation and is not operationally useful and the procedure specified is cumbrous. The procedure is open-ended without any time limit imposed for the grant of compulsory licenses. The copy of the compulsory licensing application will have to be advertised in the official gazette, though this is not required under TRIPs. The patentee or any other person may oppose the application and will have to be given adequate time for doing so\textsuperscript{196}. The Controller will decide only after giving both the parties an opportunity to be heard\textsuperscript{197}.

A compulsory license granted by the Controller can be opposed. Such appeals will be considered by an Appellate Board before a compulsory license is ultimately permitted. Whether a patent is worked in India or not, can perhaps be objectively assessed. But the grounds of “reasonable requirements of the public” or “reasonably affordable price” can easily be challenged by the patentees. Then arguments and counter-arguments will follow. After all these are heard by the Controller and then by the Appellate Board,\textsuperscript{198} in case of an appeal, it may take years before a compulsory license is granted. The entire process is excessively legalistic and provides the patentees the opportunity to buy time through litigation. The huge

\begin{footnotesize}
\begin{enumerate}
\item The Patent Rules, 2003 (Chapter XIII (98)) issued for administering the amended act specifies a time limit of two months. Time limit has not been specified at any other stage. (The text of the Patent Rules, 2003 accessed from www.patentoffice.nic.in).
\item TRIPs does not prevent governments from specifying the maximum time permissible at each stage. Peoples’ Commission on Patent Laws for India (2003, pp. 120-24) has suggested: that under Section 84, before applying for a compulsory license, an applicant may not wait for more than 150 days to get a voluntary license from the patent holder and that under Section 87(4), the Controller of Patents may not take more than 100 days to hear the opposition to the grant for a compulsory license and decide the case.
\item One change introduced in the amended Act is that the appeals will be referred to a separate Appellate Board rather than to High Courts as was done under the Acts of 1970 and 1911. But the structure is basically judicial. It is possible that compared to High Courts, the specialized Appellate Board may take less time in disposal of appeals. But considering the procedure prescribed, it is doubtful to what extent it will be able to take quick decisions. As we have mentioned above, India had the option to adopt a simple administrative process. But that has not been done.
\end{enumerate}
\end{footnotesize}
legal expenses involved in fighting the MNCs holding the patents may dissuade the
generic companies from applying for licenses in the first place. These are not mere
theoretical possibilities. This is precisely what happened in India under the Patent and
Designs Act of 1911, which was in force till the Patents Act, 1970 replaced it.\(^{199}\) It
may not be irrelevant here to refer to the experience under the Act of 1911.

The Patent and Designs Act of 1911, which provided product patent
protection, also had elaborate provisions for compulsory licensing. But during the
British rule not a single compulsory license was granted\(^ {200}\). Attempts were made to
improve the situation after India attained independence in 1947. The Patents Enquiry
Committee (1950) found that the foreign patentees did misuse or abuse their rights,
for example by importing the patented product rather than manufacturing it in India,
fixing the prices at high levels, not allowing others to manufacture the product even
when it was not itself engaged in manufacturing. But, the provisions regarding
compulsory licensing were “wholly inadequate to prevent misuse or abuse of patent
rights, particularly by foreigners”.\(^ {201}\) The compulsory licensing provisions (Sections
22 and 23) were amended in 1950 and in 1952, an entirely new Section (23CC)
dealing specifically with drugs and food and few other products was added. But the
procedure specified in Section 23D of the 1911 Act was very elaborate and
cumbersome. The patentees could oppose grant of compulsory licenses and if
granted, appeal against such decisions and indefinitely delay or prevent the actual use
of compulsory licenses. Because of the hazards of obtaining a compulsory license
which include legal battles, till 1972, i.e., when the 1970 Act came into force, only
five applications were made for compulsory licenses. It was granted in only two cases
and refused in one case. The applications were ultimately withdrawn in the remaining
two cases. It is the same procedure which the 1970 Act inherited for products other
than pharmaceuticals and now the amended Act has retained and made applicable for
all the products including pharmaceuticals. Hence the experience under the Act of

\(^{199}\) Chaudhuri, Sudip, “Indigenous Firms in Relation to the Transnational Corporations in the Drug
\(^{200}\) The Panel on Fine Chemicals, Drugs and Pharmaceuticals (1947), appointed by the government also
reported it was because of the wording of the relevant provisions that not even a single compulsory license
could be obtained (p.15).
\(^{201}\) The Patents Enquiry Committee (1950) p. 172.
1911 would be a rough guide to what is likely to happen in India unless some corrective actions are taken.\textsuperscript{202}

1. Government use

Article 31 of TRIPs dealing with compulsory licensing provides for special provisions “in the case of national emergency or other circumstances Public use of patents or “government use” is a standard feature of patent laws in many countries. Under 28 USC Sec 1498 of the US patent law, the US government can use a patent or authorize third parties to use patents for virtually any public purpose and the government has actually made good use of it as it was mentioned above. For any such use, the government is not required to negotiate with the patent owner. Nor is the latter provided any injunctive relief. All that it can expect is payment of compensation for the use.\textsuperscript{203}

Following the British patent law, the Indian patent law also provided for government use of patents and much of these have been retained in the recent patent amendments. The central government or anyone authorized by it may use (i.e., “make, use, exercise or vend”) an invention or acquire an invention for the purpose of the central government, state Governments or a government undertaking on payment of adequate remuneration or compensation (Sections 99 to 103)\textsuperscript{204}.

Except in circumstances of national emergencies, extreme urgency or public non-commercial use, the government need not even inform the patentee about such use. The patent owner however can challenge such a use or the terms of such use. Any such disputes are required to be judicially settled at the level of the High Court. Under the Act of 1970, the right to use included “the right to sell the goods.” In the amended Act, the right of the government is restricted to the “right to sell, on non-commercial basis.” This is an important difference. But still, in the amended Act, the government has wide ranging powers to make drugs more affordable. If the

\textsuperscript{202} For a discussion of the ineffectiveness of the compulsory licensing regime for non-pharmaceuticals under the Act of 1970, see Bagchi et al. Bagchi, Amiya Kumar, Banerjee, Parthasarathi and Bhattacharya, Uttam Kumar, “Indian Patents Act and Its Relation to Technological Development in India: A Preliminary Investigation,” \textit{Economic and Political Weekly}, February 18, 1984.


\textsuperscript{204} The government also has the power to revoke patents if the patentee has “without reasonable cause failed to comply with the request of the central government” to use the patent (Section 64(4)) or if the patent and the way it is exercised is “mischievous to the State or generally prejudicial to the public” (Section 66).
patented drugs are too expensive, then the government can produce or authorize others to produce and distribute these through public clinics. As the World Bank has pointed out, even if the government recovers the cost of such drugs fully or partially, such an arrangement will be consistent with TRIPs so long as the government does not seek to make a profit out of it.

In the absence of product patent protection in pharmaceuticals in the previous patent regime, government was not required to and in fact did not use such special provisions. As a result unlike in USA, there is no history of such use. The ability of the government to use such provisions to enhance affordability of drugs will crucially depend on whether proper administrative and judicial systems are put in place. If as in the case of compulsory licenses discussed above, any patent holder can oppose such a use by government and can indefinitely delay or prevent the use, then obviously such provisions will remain ineffective. Moreover, as Abbott has pointed out, the US government did not face any internal or external pressure when it tried to invoke “government use” to tackle the anthrax crisis. But if a government of a poor country tries to do anything close to it, they would put to intense diplomatic and economic pressures from developed countries, even if the public health crisis is more severe and extensive. Government use will ultimately depend on how such pressures are tackled.

2. Compulsory licensing applicable in cases of national emergency or other circumstances of extreme urgency

Any time after the sealing of the patent, an application for a compulsory license can also be made under Section 92 for a patent notified by the Central Government in the official gazette. Such a notification can be made when the Central Government is satisfied that in circumstances of national emergency, extreme urgency, or public non-commercial use, it is necessary to grant a compulsory license for such a patent. The procedure mentioned above for the grant

---


of compulsory licenses will have to be followed for these applications too, except that the applicant will not be required to first approach the patentee and try to get a voluntary license. The procedure, however, may not be followed in certain circumstances of emergency or extreme urgency or public non-commercial use “including public health crises relating to Acquired Immune Deficiency Syndrome, human immunodeficiency virus, tuberculoses, malaria or other epidemics.” (Section 92 (c). This special provision for exempting the usual procedure in public health crises was not there in the Bill recommended by the Joint Committee (2001)\textsuperscript{207}. It was incorporated in the last minute\textsuperscript{208}. This is a positive provision. But the benefit of this provision will very much depend on how this is implemented. The “Rules” for administering the amended Act could have elaborated on a simple and easy to use procedure. This has not been done.\textsuperscript{209} It is important to note that though the usual procedure is not applicable, any decision by the Controller here too can be challenged and referred to the Appellate Board. As we have mentioned above, the patent holders will obviously oppose any such compulsory licenses. If it takes a long time for such disputes to be settled, and in particular, if the patent holders can get injunction against any such use till such cases are finally disposed off, then such special provisions will effectively be of limited use. As listed below, some simple administrative steps can be taken to avoid such delays and hurdles.\textsuperscript{210}

Under Section 92, rather than adopting a case by case approach, the Central Government may notify the list of medicines eligible for compulsory licenses in public health crises. The list should be prepared in consultation with health experts and may be revised from time to time. Any relevant new drug should be added to the list. Both Para 5(c) of the Doha Declaration and Section 92 (3) of the amended Act have only given examples of public health crises, for example AIDS, tuberculosis, malaria. Public health crises should be interpreted in broad terms. The list may be prepared bearing in mind the specific situation in the country, such as the disease pattern, the need for drugs and the present availability. It is well known

\textsuperscript{207} For a critique of the Bill recommended by the Joint Committee, see Zaveri 2002.

\textsuperscript{208} The inclusion of Section 92(3) was agreed upon in the previous evening when a delegation from the Indian pharmaceutical industry met the Minister in charge (interview, Mumbai, 9 October, 2003 with N B Zaveri, a member of the delegation).

\textsuperscript{209} After the Second Amendment in 2002, Patent Rules were revised on 2 May, 2003 (text accessed from www.patentoffice.nic.in).

that majority of the Indian people living in rural areas and in urban slums have no or little access to modern drugs. Medicines necessary to take care of the health needs of these people may be included in the list. As Para 5 (c) of the Doha Declaration has clarified, individual countries have “the right to determine what constitutes a national emergency or other circumstances of extreme urgency.” The inclusion of any drug in the list cannot be a ground for opposition and appeal. There is nothing in TRIPs or the amended Act to suggest that it should be so.

Following the examples of Germany and Canada, guidelines may be issued for the royalty to be paid to the patent holders in case of compulsory licenses. Germany has used rates varying between 2% and 10%. In Canada, the rate used to be 4%. Both UNDP\(^\text{211}\) and the patent experts who appeared before the Peoples’ Commission on Patent Laws for India 2003, have recommended that royalty rates may vary depending on the therapeutic value of the product and whether public funds have been used in R&D for developing the drugs. The patent experts suggested that 5% royalty may be paid for drugs with significant therapeutic benefit or less if the benefits are not significant. Where the drug is particularly innovative with higher than average R&D investment incurred, an additional royalty of up to 3% may be awarded.\(^\text{212}\)

For any drug in the public health list, the Controller may immediately after receiving an application, grant the compulsory license, fixing a royalty rate using the royalty guidelines. Any opposition or appeal against the grant of a compulsory license in this case can only relate to the royalty rate fixed. The patentees should not have the right to object to the inclusion of any drug in the list. The opposition to the rate fixed should not hold up the use of compulsory license. While this is being adjudicated, the non-patentee could begin to use the patent on the basis of an undertaking that the royalty rate finally decided will be paid in full.

Such a simple administrative structure does not contravene TRIPs, but speeds up the use of compulsory licenses. Two important TRIPs conditions which are often considered to stand in the way of fast use of compulsory licenses are that any grant of compulsory licenses must be (i) considered on individual merits


\(^{212}\)Report of the Peoples’ Commission for Patent Laws for India 2003, pp. 71-72
(Article 31 (a) and (ii) subject to review by higher authorities (Article 31(h and j)). As Watal\textsuperscript{213} has clarified, consideration of individual merits does not mean patent-by-patent consideration. In fact while TRIPs was being negotiated, USA did not want the phrase, “each case” to be mentioned because that would have gone against her own law and practice. In the procedure suggested, the merits of each case would be the consideration of the royalty rates payable. Again the requirement that any compulsory licensing decision would be subject to review, does not mean that the actual use should be held up till all disputes are settled. TRIPs do not require governments to grant injunctive relief to patent holders (Article 44 (2)).\textsuperscript{214} The consideration of any opposition to the royalty rate proposed would satisfy the requirement of review of the compulsory licensing decision.

3. Compulsory licenses for export to countries with no manufacturing capacities

A country can issue a compulsory license not only for manufacturing drugs in the country but also for importing drugs. Before 1\textsuperscript{st} January, 2005, patented drugs could be imported by countries with insufficient or no manufacturing capacities\textsuperscript{215} from countries such as India which had manufacturing capacities but did not grant product patent protection in pharmaceuticals. Now with the introduction of product patent protection under TRIPs, such supplies will dry up. Generic manufacturers from India will no longer be permitted to produce new patented drugs unless they are specifically authorized to do, for example by getting a compulsory license. But a major limitation of any compulsory license that a drug manufacturer in India may get is that under Article 31(f) of TRIPs, production will have to be “predominantly for the supply of the domestic market of the member authorizing such use,” (unless the compulsory license were issued to remedy anticompetitive practices under Article 31(k)). In other words, a compulsory license cannot be granted in countries with manufacturing capacities exclusively or mainly to export to countries with no manufacturing capacities. Thus under TRIPs, a country with manufacturing capacities can resort to compulsory licensing to manufacture drugs to tackle problems such as public health needs. But the compulsory licensing provisions of


\textsuperscript{215} Balance, Pogany and Forstner 1992 lists more than 60 countries (such as Bhutan, Chad, Congo, Oman, Swaziland) which have no pharmaceutical industry. The situation has not changed much since then.
TRIPs cannot be used by a country with no manufacturing capacity to import drugs to take care of her health needs. The Doha Declaration recognized this major lacuna of TRIPs and instructed TRIPs Council to find an expeditious solution to this problem and to report to the General Council before the end of 2002.\textsuperscript{216}

Even after several rounds of formal meetings and informal discussions, a consensus could not be arrived at by the deadline of December 2002. The delay was basically because of the differences between the developed countries and the developing countries over the scope of the solution, including the diseases and the medicines to be covered, the countries to be eligible to import and the procedures to be followed. Ultimately a compromise was reached on 30 August, 2003. The agreement was in the form of a decision adopted by the General Council to be implemented in the light of the “shared understandings of Members regarding the Decision” as contained in the Statement read out by the Chairperson in the General Council \textsuperscript{217}. The solution takes the form of a temporary waiver (pending the amendment) of the obligation under Article 31(f) of TRIPs that compulsory license can be granted predominantly for the supply of the domestic market. The decision permits countries producing patented drugs under compulsory license to export these to the countries with no manufacturing capacities.

But several conditions have been attached to the Decision which raises serious doubts about the extent to which it can be used at all. Rather than facilitating exports of drugs to countries which urgently require them, unnecessary procedural complications and limitations have been introduced\textsuperscript{218}. India as a low cost producer of drugs has particular significance from the point of view of supplies to countries with no manufacturing capacities. But in line with the 30 August, 2003 decision, no attempts have been made in the patent amendments to facilitate such exports. The Patent Ordinance has simply inserted a new section (92A) permitting compulsory licenses to these countries provided compulsory licenses have also been obtained there. The lack of concern is reflected in that the Ordinance does not even clarify that in the 50 odd least developed countries (LDCs)\textsuperscript{219}, as permitted by the Doha

\textsuperscript{216} For a discussion on the background of the paragraph 6 problem, see Correa 2002(b), pp. 19-20.
\textsuperscript{217} For a discussion on the background of the paragraph 6 problem, see Correa 2002(b)
\textsuperscript{219} ibid
Declaration, pharmaceutical product patents are not mandatory till 2016 and now 2023, hence the question of getting compulsory licenses there does not arise.

5.6.3. Findings

1. **Priority to health is not given in the Indian Patents Act as regard to public health policy is concerned since the provisions relate only to the method of utilizing the flexibilities with few sections which are not clear as to the use of compulsory license as number of cumbersome conditions have been put forth for the implementation of any type of flexibilities provided under the Indian Patents Act which is subject to various interpretations and clarifications.**

2. **There are no clarifications on what constitutes national emergency, the requirement to disclose the amount of investment of Research and Development and cost to bring up the product along with audited report to be submitted along with the patent application to justify the prices that would be fixed in future to market the product patented and related matters are not included in the TRIPs nor Indian Patent Act.**

3. **A provision for health impact fund should also be created as advocated by Thomas Pogge, so that a part of the fees collected by the patent office should include some money as a contribution for this fund and sales revenue as a percentage of profit should be charged till the patent is in force from the patent holder which could be used for the welfare of the patients particularly on medicines patents.**

4. **User friendly provisions are sought at the international level for providing an effective means for utilizing the flexibilities doubting the efficacy of various sections included in the Patent Act various member countries questioned the stand taken by India. India is one of the member countries in the perspective of other international countries which is lacking behind in the strict implementation of the Patent Law. As many of the members have posed question to India as to its efficacy of various provisions included in the Indian Patent Act is concerned at the WTO meeting. In spite of several requests made by the WHO which has put efforts to show that Patent law particularly extending to pharmaceutical products is harsh and the whole world is suffering due to governments inability to supply medicines to the needy persons as the government have no sufficient means to fund in health sectors instead of making provisions for public health issues the**
WTO has been ignorant to make sufficient provisos at the international level to minimize the effect of the product patent on prices.

5. Even the Indian government is least bothered to keep its view in including the provisions of health related issues in incorporating certain provisos to give priority to health sectors and making the patent holder to be lenient in his stand for the purpose of a social cause the large scale manufacturing companies should strive hard to benefit the general public rather than making profits at the cost of poor patients. As there are many examples of rich persons who at the end realized that life as a human being is not for making profits but for attaining enlightenment and the bounded duty of every human living being is social welfare and welfare of the society. Those who have deviated from this path have either lost all the wealth that they have earned by discrimination and exploitation due to the curse of the people who are sufferers at their hands or they have committed suicide. Hence many companies run foundations helping others who are in need of the help by providing funding for the welfare of the people. For example Napoleon who conquered the world wanted to show the world that at the end of his life he is going empty handed which means nothing comes along with but the man is remembered for his values and good deeds.

6. The government should bring necessary changes to the Patent Act such as provisions for fixing the price, expenditure incurred on Research and Development, transparency in fixing the profits in the price of the product, making the companies shoulder certain obligations to disclose sales turnover and the profits made by selling the product not only in India but elsewhere in the world should be disclosed to the world at large. A kind of a social responsibility should be imposed for the supply of free medicines at least 10% of the sales made in a particular country to the needy persons.

5.7 DISEASE SUFFERER’S RIGHT TO HAVE ACCESS TO MEDICINES AND DRUGS IS INEFFECTIVELY ADDRESSED UNDER THE EXISTING LAWS SUCH AS INDIAN PATENTS ACT AND DRUG PRICE CONTROL POLICY (DPCI) OF GOVERNMENT OF INDIA

In real life we talk about right to life under various provisions of law both at the national level and at the international level but when the question of right to life is spoken in terms of right to health the law becomes silent as the right to health is not directly recognized as the right to life. In a country like India we come across
many persons who are suffering from serious diseases and need to be treated. But for one or the other reasons they become helpless due to financial constraints in taking the treatment. Say for example a person having Cancer or acute renal failure requires continued intake of medicines for life which is accustomed to a daily routine the day he stops taking medicines the countdown to die begins for this reason they resort to take help from others by making an advertisement in the newspapers, electronic media, asking the general public to come to their rescue and seek monetary help from those who are willing to help the needy.

These needy persons are forced to live like a slave at the mercy of others. They even dare to take harsh steps to die by attempting suicides. At present Indian laws do not recognize the mercy killing what is called as “euthanasia” so that they can get rid of their difficulties and die peacefully. But unfortunately it is not possible in India. On the other side the government has not taken sufficient steps to overcome the problems of the poor patients to meet their needs of access to health.

Different scholars and philosophers have assigned different duties to the state. For example Kautilya in Arthashastra has advised that the protection of the life, property and dignity of “Praja” (citizens) is the prime duty of the King. In Leviathan\(^\text{220}\), Thomas Hobbes, who otherwise believed in the absolute power of the ruler, too does not allow the king to violate the right of an individual to have life. According to Locke state existed only to protect natural rights of individuals i.e. right to life, property and liberty\(^\text{221}\). Besides them Rousseau, Montesquieu, Kant, Thomas Pain, Mill, Bentham, Karl Marx and John Rawls have been the protagonists of the rights that a state has to protect and maintain. To Harold J. Laski a state is known by the rights it maintains\(^\text{222}\). According to him the very purpose of the existence of state is to recognize and protect the rights of individuals. Thus, it can be concluded that man created state for the protection and maintenance of his rights. The history of evolution of the systems of governance also manifests that any system if not able to protect the rights of the citizens, was rejected and changed. In modern times Human Rights have become a movement. International organizations, governments and nongovernmental agencies have continuously been

\(^{220}\) *Leviathan* is a book written in 1651 by Thomas Hobbes. It is one of the most famous and influential books of political philosophy.

\(^{221}\) John Locke has discussed his concept of Natural Rights in his book, *Two Treatises of Government*, Published anonymously in 1689.

\(^{222}\) Laski, H.J., *A Grammar of Politics*, p.89
exploring the dynamics of human rights and have been working to evolve such mechanisms which could safeguard the rights of human beings.

The widely acceptable definition of health is that given by the WHO in the preamble of its constitution, according to which, “Health is a state of complete physical, mental and social wellbeing and not merely the absence of disease.” In recent years, this statement has been amplified to include the ability to lead a ‘socially and economically productive life’. Through this definition, WHO has helped to move health thinking beyond a limited, biomedical and pathology-based perspective to the more positive domain of “well being”. Also, by explicitly including the mental and social dimensions of well being, WHO has radically expanded the scope of health and by extension, the role and responsibility of health professionals and their relationship to the larger society.

5.7.1 Right to Health under Indian Constitution

Right to health is not included directly in as a fundamental right in the Indian Constitution. The Constitution maker imposed this duty on state to ensure social and economic justice. Part four of Indian constitution which is DPSP imposed duty on States. If we only see those provisions then we find that some provisions of them has directly or indirectly related with public health. The Constitution of India not provides for the right to health as a fundamental right. The Constitution directs the state to take measures to improve the condition of health care of the people. Thus the preamble to the Constitution of India, inter alia, seeks to secure for all its citizens justice-social and economic. It provides a framework for the achievement of the objectives laid down in the preamble. The preamble has been amplified and elaborated in the Directive Principles of State Policy. Indian Constitution presciently anticipated many of the ideals enshrined in the watershed international human rights agreements that followed it. While not explicitly delineating a right to health, the Indian Constitution enshrines the right to life as a

---

223 Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19–22 June 1946; signed on 22 July 1947 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100); and entered into force on 7 April 1948

224 Kumar Avanish, “Human Right to Health”, satyam law international 2007 at 21

fundamental right in Article 21\textsuperscript{226}, and the Indian Supreme Court has expansively construed the right to life to encompass a right to health\textsuperscript{227}. For example, the Indian Supreme Court has interpreted the constitutional Right to life The Fundamental Rights and Article 21 Right to Life with Dignity forms the basis of Right to Health. Article 21 of the Indian Constitution, a fundamental right reads: “No person shall be deprived of his life or personal liberty except through procedure established by law.” the courts, by and large, had interpreted ‘life’ literally i.e. right to exist- right not to be killed\textsuperscript{228}.

In the Indian Constitution, Article 21 refers to the right to life\textsuperscript{229} but there is no right to health, so the developments that have taken place in Indian are really remarkable. The first event took place in 1987 when the Supreme Court in a far reaching order said that public health is a priority that the State must switch to indigenous production and that the poor should get medicines at affordable prices. In 1995, the Supreme Court declared the right to health and the right to health care as a fundamental right. In 1996, the Supreme Court said that government hospitals are duty bound to preserve and protect life but more importantly they said that when a poor person goes to a hospital and needs drugs that they need to look after that person, financial inability cannot be pleaded in questions related to drugs and medicines for the poor. These are the three landmark judgments of the Supreme Court.

In 2006, the government of India proposed to deregulate the pricing of drugs. That immediately affected people suffering from malaria, hypertension, diabetes, leprosy, tuberculosis, and so on. The Human Rights Law Network filed a case in the Supreme Court saying that if the poverty line in India is one third of dollar per day then cost of the medicines for treating tuberculosis far exceeds the income of most people in the country and on that basis challenged the government’s notification of the deregulation of the prices of drugs. The government replied saying that under the WTO system governments are obliged to let companies sell drugs at market values and those market values would ultimately result in a stabilization of prices and that competition results in a decrease of prices. A study was done that showed that as far as

\textsuperscript{226} Indian Constitution, Art. 21 (“No person shall be deprived of his life or personal liberty except according to procedure established by law.”).

\textsuperscript{227} See, e.g., Consumer Educ. and Research Ctr. v. Union of India, A.I.R. 1995 S.C. 636, 636(holding that “[t]he right to health . . . is an integral fact of [a] meaningful right to life”).


\textsuperscript{229} Colin Gonsalves, Litigating the Right to Medicines in India, Human Rights Law Network, India, p. 20.
pharmaceuticals are concerned; this principal does not apply at all. In fact, they found that the highest selling drugs were the most costly, even those consumed by poor people. On this basis, the Supreme Court gave an order saying that the government should guarantee that all the drugs in the essential list would be available and affordable for people that are below the poverty line. As a consequence, the government will shortly release a new pharmaceutical policy.

The next case was the hemophilia case which came up in the High Court. The claim was that people living with hemophilia cannot even get the drugs they need in the country and when they can find it, it is extremely expensive. The High Court, in a remarkable intervention, directed government to form a special committee, and ultimately the government agreed to provide the anti-hemophilic factor free to people below the poverty line and substantially subsidized to people above the poverty line.

The third case presented was the HIV case pending in the Supreme Court, where a number of parties are involved. In 2002, the government decided they would only focus on prevention not on treatment so they would not provide antiretroviral drugs. So many groups presented their case to the Supreme Court taking many countries in Latin American as an example where the antiretroviral drugs are provided for free. There has been some success in that the government is now doing something and the hope is that in the future they will do more.

The next case is the vaccine case where several multinational companies came in promoting all kinds of different vaccines. The Ministry, under the globalization regimen, is collaborating with multinational corporations by closing down vaccine production. The argument for this is that there have to be certain standards that need to be maintained for hygiene. So instead of raising the standards, the ministry took a short cut by closing the production, and today national manufacturers say that India must have indigenous production of vaccines. The current stance of the world as it stands today in its “highly developed and advanced era” where the right to essential medicines is recognized as an innate part of the human right of right to health. Since time immemorial, millions of people have lost their lives to life threatening diseases. Earlier society did not have the capabilities or the technology to produce the necessary medicines

to protect it. Today, the only difference is that, though we have all the resources and medicines necessary to cure most diseases, majority of the population does not have access to such essential medicines. The United Nations Development Group defines “access” in this context as “having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour’s walk from the homes of the population.” Still today, millions in the world do not have this access to these medicines. The access to essential medicines which is a human right is currently compromised by the high prices charged by pharmaceutical corporations, which are facilitated by the global protection afforded to pharmaceutical patents by Trade Related Intellectual Property Rights (TRIPs).

“Essential medicines”, according to the WHO, are those that “satisfy the priority health care needs of the population” and “are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.” Now it can be said that such essential medicines are present and manufactured today. However this seems to be a futile exercise if such essential Medicines are not within the access of the people.

“...the national constitutions define the fundamental political principles of a country and usually guarantee certain rights to their people. Health is a fundamental human right recognized in at least 135 national constitutions. Access to health care, including access to essential medicines, is a prerequisite for realizing that right. However, only five countries specifically recognize access to essential medicines and technologies as part of the fulfillment of the right to health.”

The formulation of India’s Constitution was certainly influenced by the UDHR and this is reflected in the Fundamental Rights and the Directive Principles of State Policy. Most of the civil and political rights are guaranteed under the Indian Constitution as Fundamental Rights. But most of the Economic, Social and Cultural Rights do not have such a guarantee. The Constitution makes a forceful appeal to the State through the Directive Principles to work towards assuring these rights through the process of governance but clearly states that any court cannot enforce them.231

---

231 Article 37 pertaining to the application of the principles contained in Part IV of the constitution states, “The provisions contained in this Part shall not be enforceable by any court, but the principles therein laid down are nevertheless fundamental in the governance of the country and it shall be the duty of the State to apply these principles in making laws”
The experience of governance in India shows that both Fundamental Rights and Directive Principles have been used as a political tool. While the Fundamental Rights are justifiable, and on a number of occasions citizens and courts have intervened to uphold them, there have also been numerous instances where even the courts have failed either because the ruling government has steamrolled them or the court orders have been ignored. Further, the Directive Principles of State Policy (DPSP), enshrined under Part IV of the Constitution of India, contains provisions regarding the right to health under Articles 39 (e), (f), 42 and 47.

The Directive Principles set out an objective to be taken by the states in the governance of the country; Dr B.R. Ambedkar describes them as the ‘novel feature’ of the Constitution of India. Article 37 says that the directive principles though they are fundamental in the governance of the country and it shall be the duty of the State to apply these principles in making laws, but they are expressly made non-justifiable. On the other hand, fundamental rights are enforceable by the courts (Art 32 and 227) and the courts are bound to declare as void any law that is inconsistent with any of the fundamental rights. In State of Madras Vs Champakam Dorairajan (AIR 1951 SC 228) case the court held that in case of any conflict between Fundamental Rights and Directive Principles the Fundamental Rights would prevail.

In Re Kerala Education bill (AIR 1957 SC 956) the court observed that though the directive principles cannot override the Fundamental Rights, nevertheless in determining the scope and ambit of Fundamental Rights the court may not entirely ignore the Directive Principles but should adopt ‘the principles of harmonious construction and should attempt to give effect to both as much as possible’. Whole part III contains negative injunctions to the state not to do various things. Part IV contains positive commands to the state to promote what may cause a social welfare of the state. G. Austin has described the Fundamental Right and the Directive Principles as the “Conscience of our Constitution”. Fundamental Rights and Directive Principles are meant to supplement one another. The Directive Principles prescribes the goal to be attained and the Fundamental Rights lay down the means by which that goal is to be achieved.

In case of the Directive Principles it is mostly political mileage, which determines which of the principles get addressed through governance. For instance,
Article 46\(^{232}\) has been implemented with a fair amount of seriousness through the policy of reservations for scheduled caste, tribes and other backward castes/classes because it is the most powerful tool for success in India’s electoral politics. But Articles 41, 42 and 47, which deal with social security, maternity benefits and health, respectively, have been addressed only marginally.

The Constitution of India enlists healthcare as a state subject and state governments play major roles in financing and executing plans, whereas union government plays certain roles at policy level and financing a few important national level health programs. Local governments also play some limited roles in financing and execution of health policies and programs. However, India has a giant private sector which constitutes a major share in healthcare services.

The middle and upper classes, which generally live in the urban areas of India, have access to quality medical care. However, the majority of India lives below the poverty line in rural areas and has extremely limited access to medical care. Most rely on homeopathic or cultural remedies. The stark inequality of available healthcare has shaped the current market environment and should always be kept in mind while framing the policies. When we look at right to health and healthcare in the legal and constitutional framework, it is clearly evident that the Constitution and laws of the land do not in any way accord health and healthcare the status of rights. There are instances in case law where, for instance the right to life, Article 21 of the Constitution, or various Directive Principles has been used to demand access to healthcare, especially in emergency situations or references made to the International Covenants.

The Apex Court of the country, through judicial precedents has laid down that right to health is inherently a fundamental right. The Hon’ble Supreme Court, in the case of Consumer Education and Research Centre V Union of India held that right to health and medical aid to protect the health is a fundamental right under Art. 21. The Supreme Court again in Parmanand Katara V Union of India held that right to health and medical assistance is a fundamental right under Art.21. The same ratio was laid down in a number of other cases. Therefore, in India, the Constitution

\(^{232}\) Article 46 - Promotion of educational and economic interests of Scheduled Castes, Scheduled Tribes and other weaker sections: The State shall promote with special care the educational and economic interests of the weaker sections of the people, and, in particular, of the Scheduled Castes and the Scheduled Tribes, and shall protect them from social injustice and all forms of exploitation
elevates the ‘right to health of the highest attainable standards’ to a guaranteed fundamental right, which is enforceable by virtue of constitutional remedy mentioned under Article 32 of the Constitution. The Court has held that the right to live with human dignity enshrined in Article 21 derives its life and breath from the DPSP, particularly Articles 39 (e) and (f), 41 and 42 and would, therefore, include protection of health as envisaged in the directives.

These are exceptional cases, and even if the Supreme Court or the high courts have upheld some decisions as being a right, for instance getting at least first aid in emergency situations from private clinics or hospitals, or access to public medical care as a right in life threatening situations, or right to healthy and safe working environment and medical care for workers etc., the orders are rarely respected in day to day practice unless one goes back to the courts to reiterate the orders. In fact, this is often the case even with Fundamental Rights, which the State has failed to respect, protect, or fulfill as a routine, and one has to go to the courts to demand them. For a population, which is predominantly at the poverty or subsistence level, expecting people to go to the courts to seek justice for what is constitutionally ordained as a right is unrealistic as well as discriminatory. The mere constitutional provision is not a sufficient condition to guarantee a right, and more so in a situation like health and healthcare wherein provisions in the form of services and commitment of vast resources are necessary to fulfil the right.

The Supreme Court gave an expanded meaning to the term ‘life’ appearing in Article 21. Over the years it has come to be accepted that life does not only mean animal existence but the life of a right to life as requiring the State to provide timely medical treatment to preserve human life and as including a right to the protection of health at work and freedom from sexual harassment.

Despite the above, it is still important to have health and healthcare instituted as a right within the Constitution and/or established by a specific Act of Parliament guaranteeing the right. Ruth Roemer discussing this issue writes, ‘The principal function of a constitutional provision for the right to health care is usually symbolic. It sets forth the intention of the government to protect the health of its citizens. A statement of

---

233 See Paschim bangla Khet Samity v. West Bengal, A.I.R. 1996 S.C. 2426, 2426 (holding that the right to life requires the State to provide timely medical treatment to preserve human life).

234 See Vishaka v. Rajasthan, A.I.R. 1997 S.C. 3011, p7 (holding that Art. 21 includes a right to protection of health at work and freedom from sexual harassment).
national policy alone is not sufficient to assure entitlement to health care; the right must be developed through specific statutes, programs and services. But setting forth the right to health care in a constitution serves to inform the people that protection of their health is official policy of the government and is reflected in the basic law of the land”.

5.7.2 Right to Health at International Level

This right to life jurisprudence has gone hand-in-hand with a longstanding tradition in Indian constitutional law to relax standing requirements for cases that implicate the public interest\(^{235}\). By broadening the substantive dimensions of the right to life and liberalizing standing requirements so that “any member of the public” may seek redress for a legal wrong in the public interest, the Indian judiciary has created a uniquely hospitable litigation culture for pursuing legal claims to the right to health\(^{236}\).

With regard to the question of justifiability of international law, like Britain, India follows the principle of dualism. This means that for international law to be applicable in India, it needs to be separately legislated. Since none of the international human rights treaties have been incorporated or transformed into domestic laws in India, they have only an evocative significance and may be used by the Courts or petitioners to derive inspiration.\(^{237}\) Thus on a number of occasions many of these human right treaties ratified in India, have been used by the Indian Courts in conjunction with Fundamental Rights.\(^{238}\) International law has its importance in providing many principles but in India’s case, there is substantial leeway within our own legal framework on right to health and healthcare. The emphasis needs to shift to critical principles as laid down in the directive principles. This is the only way of bringing right to health and healthcare on the national agenda, even as the support of international treaties will play a role in cementing this demand.

The right to health also has an important place within international law. Article 25.1 of the Universal Declaration of Human Rights (UDHR) affirms that

\(^{235}\) See generally Surya Deva, Public Interest Litigation in India: A Critical Review, 28 CIV. JUST. Q.

\(^{236}\) 24 (2009) (describing the long tradition in Indian constitutional jurisprudence to extend standing to “any member of the public” to seek redress for a legal wrong, particularly when the actual plaintiff belongs to a socially disadvantaged class).

\(^{237}\) Nariman, F1: Economic Social and Cultural Rights and the Role of Lawyers, ICJ Review No. 55, 1995

\(^{238}\) In a judgment on sexual harassment at the work place, in which the CEDAW and Beijing Declaration was invoked, the Supreme Court outlined this approach as follows – Any international convention not inconsistent with the fundamental rights and in harmony with its spirit must be read into these provisions to enlarge the meaning and content thereof, to promote the object of the constitutional guarantee (Vishaka v/s State of Rajasthan, writ petition number 666-70 of 1992, quoted in Toebes, 1998).
“everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including . . . medical care and necessary social services.” The right to health has also been elaborated on in a number of binding treaty instruments, including the International Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Elimination of All Forms of Discrimination against Women, and the Convention on the Rights of the Child—all of which have been either ratified or acceded to by India.

Reinforcing its constitutional obligations to promote the right to health, India also ratified the International Covenant on Economic, Social and Cultural Rights (ICESCR) in 1979, which is the foundational treaty agreement recognizing and individual right to health. Inspirational in tone but legally binding nevertheless, Article 12 of the ICESCR obligates States Parties to “take steps” to realize the universal “right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” In May 2000, the Committee on Economic, Social and Cultural Rights adopted General Comment 14, which gave content to the lofty principles set forth in Article 12. General Comment 14 is a thoughtful and pragmatic consideration of the multi-dimensional nature of the right to health in a global landscape where disparate economic, cultural and political conditions preclude a one-size-fits-all approach to realizing each person’s

---

individual right to health. While a detailed exploration of General Comment 14 is beyond the scope of this Note, a brief discussion of what the Committee identified as the “essential elements” to the right to health is useful because it will orient the analysis that follows on how India’s implementation of TRIPs intellectual property requirements in its domestic patent system implicates its domestic and international obligations to promote the right to health. General Comment 14 states that the right to health contains the “essential elements” of availability, accessibility, acceptability and quality. Within these four essential elements are various sub-components, and the Committee devotes particular attention to elaborating the multiple dimensions of the “accessibility” prong, explaining that “accessibility” entails “non-discrimination,” “physical accessibility,” “affordability” and “information accessibility.” How a State goes about fulfilling its ICESCR obligations to promote the right to health depends on its “prevailing” domestic conditions, but the Comment makes clear that a State will not meet its ICESCR duties unless it ensures the availability, accessibility, acceptability and quality of all of the “underlying determinants of health,” which include, among other things, safe and potable drinking water, adequate sanitation facilities and essential medicines. Access to medically acceptable, affordable essential drugs is an integral component to the right to health, and the Committee emphasizes that a State’s Article 12 obligations to fulfill its citizens’ right to health necessarily involves making essential drugs widely available and affordable. The challenges in realizing this level of availability and access without the benefit of high quality, affordable generic versions of essential medicines are especially stark given that nearly forty-three percent of the world’s population lives on less than US$ 2 a day and this dire poverty directly affects the acquisition of health products. As far and away the

---

248 Id. P 12.
249 Id. P 12(a).
world’s largest producer of generic medicines. India’s generic drug industry has played a major role in making affordable, medically acceptable essential medicines available to the global public, which has helped States address one of the key underlying determinants of health identified by the Committee in General Comment 14. Taken together, India’s domestic and international commitments to the right to health bear heavily on how India’s patent system has taken shape following the ascent of globalized IPR standards.

5.7.3 Provisions that is included in Indian Constitution recognizing Right to Health

Dignified human being with all its concomitant attributes that have been specified at international level is more or less included in Indian Constitution. This would include a healthy environment and effective health care facilities.

Fundamental Rights are enforceable by and large only against the State. Fundamental Rights prescribes the duty and the obligations of the State vis-à-vis the citizens. Right to health and health care as a fundamental right we are speaking of the State’s obligation to provide free, subsidized or even cheap treatment. The ‘Right to Health’ is inseparable from ‘Right to Life’, and the ‘Right to Medical Facilities’ as a concomitant of ‘Right to Health’ is also part and parcel of Right to Life. In a welfare state, the corresponding duty to the right to health and medical facility lies with the State.

Part 3 of the Constitution prescribes the Fundamental Rights of the citizens. These rights are enforceable against the State in a Court of law. This Chapter does not anywhere categorically state that the right to health or healthcare is a fundamental right.

Part 4 of the Constitution lists the Directive Principles of State Policy. These are the guiding principles while enacting laws and policies but have traditionally been believed not to be enforceable in courts of law. A citizen cannot go to court for enforcing a claim which is purely based on Directive Principles. The fact that in interpreting Fundamental Rights the Courts can use the Directive Principles so as to interpret these rights as much in consonance with the Directive Principles as is possible. The obligation of the State to provide health care facilities is set out in the

‘Directive Principles of State Policy’. The relevant provisions of the Directive Principles which cast a duty on State to ensure good health for its citizens are:

Article 38: State to secure a social order for the promotion of welfare of people-State shall strive to promote the welfare of people by securing and protecting as effectively as it may a social order in which justice, social, economic and political, shall inform all the institutions of the national life. State shall, in particular, strive to minimize the inequalities in income, and endeavor to eliminate inequalities in status, facilities and opportunities, not only amongst individuals but also amongst groups of people residing in different areas or engaged in different vocations. In other words, no person will be deprived of a healthy life because he cannot afford it. The State must provide facilities that an economically better off person can afford out of his own pocket.

Article 39: Certain principles of policy to be followed by State- The State shall, in particular, direct its policy towards securing that health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength; and Those 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: Duty of State to raise the level of nutrition and the standard of living and to improve public health- 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, in particular, the State shall endeavor to bring about prohibition of the consumption except for medical purposes of intoxicating drinks and of drugs which are injurious to health.

Public Interest Petition for maintenance of approved standards for drugs in general and for the banning of import, manufacturing, sale and distribution of injurious drugs is maintainable. A healthy body is the very foundation of all human activities. That is why the adage “Sariramadyam Khalu Dharma Sadhanam”. In a welfare State, it is the obligation of the State to ensure the creation and sustaining of conditions congenial to good health.\(^{252}\)

\(^{252}\) Vicent Vs UOI, AIR 1987, SC 990
Some other provisions relating to health fall in DPSP. The State shall in particular, direct its policy towards securing health of workers. State organized village panchayats and gave such powers and authority for to function as units of self-government. This Directive Principle has now been translated into action through the 73rd Amendment Act 1992 whereby part IX of the constitution titled “The Panchayats” was inserted. The Panchayat system has significant implications for the health sector.

Article 41 provides right to assistance in case of sickness and disablement. It deals with “The state shall within the limits of its economic capacity and development, make effective provisions for securing the right to work, to education and to public assistance in case of unemployment, Old age, sickness and disablement and in other cases of undeserved want.” Their implications in relation to health are obvious. Article 42 give the power to State for make provision for securing just and humane conditions of work and for maternity relief and for the protection of environment same as given by Article 48A and same obligation impose to Indian citizen by Article 51A (g).

The DPSP are only the directives to the State. These are non-justifiable. No person can claim for non-fulfilling these directives. But the Supreme Court has brought the right to health under the preview of Article 21. The scope of this provision is very wide. It prescribes for the right of life and personal liberty. The concept of personal liberty comprehended many rights, related to indirectly to life or liberty of a person. And now a person can claim his right of health. Thus, the right to health, along with numerous other civil, political and economic rights, is afforded protection under the Indian Constitution.

5.7.4 Judiciary recognizing Right to Life as an inclusive right including Right to Health

The debate surrounding the implementation of the human right to health is fresh and full of possibility for the developing world. In fact, Indian has been able to create a legal mechanism whereby right to health can be protect and enforced. The early of 1970s, witnessed a watershed in human rights litigation with the

253 Article 39(e) of the Constitution of India
254 Article 40 of the Constitution of India
255 Article 41 of the Indian Constitution
Keshwanand Bharti Vs State of Kerla

ushering in an unprecedented period of progressive jurisprudence following the recognition fundamental rights. At the same time standing rules were relaxed in order to promote PIL and access to justice. So there were two developments in 1980s, which led to a marked increase in health related litigation. First was the establishment of consumer courts that made it cheaper and speedier to sue doctors for medical negligence. Second, the growth of PIL and one of this offshoots being recognition of health care as a fundamental right. Through PIL the Supreme Court has allowed individual citizen to approach the court directly for the protection of their Constitutional human rights.

So there were two developments in 1980s, which led to a marked increase in health related litigation. First was the establishment of consumer courts that made it cheaper and speedier to sue doctors for medical negligence. Second, the growth of PIL and one of this offshoots being recognition of health care as a fundamental right. Through PIL the Supreme Court has allowed individual citizen to approach the court directly for the protection of their Constitutional human rights.

The standing doctrine is not, the only generally applicable legal standard for which courts have used human rights arguments to inform their decisions. In 2008, the High Court of Delhi found that the public’s interest in a particular medication must be taken into account when deciding whether to issue a preliminary injunction. After reviewing international precedents, such as the U.S. Supreme Court’s eBay v. Merc Exchange decision, the court concluded that “unlike in cases involving infringement of other products, the Courts have to tread with care [when] pharmaceutical products and more specifically life saving drugs are involved. In such cases, the balancing would have to factor in unknowns such as the likelihood of injury to non parties and the potentialities of risk of denial of remedies.”

The court further explained that, although “India entered into the TRIPs regime, and amended her laws to fulfill her international obligations,”

The Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. Such injuries to third parties are un-compensable. Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be

257 (1973) 4 SCC 225.
258 Kumar Avanish “Human Right to Health” satyam law pub. 2007 at 171
259 Roche v. Cipla case in India.
stifling Article 21 [which protects the right to life] so far as those who would have or could have access to Erloticip are concerned.\textsuperscript{262}

Strategically referencing international precedents that provide “skin deep”\textsuperscript{263} support to its position,\textsuperscript{264} the Indian court managed to weave respect for the right to health into the preliminary injunction standard. Thus, in this case, human rights law became a lens through which the Indian court interpreted legal standards commonly used in patent cases.

1. Public Health is State’s Priority

In one of the earliest instances of public interest litigations - Municipal Council, Ratlam vs. Vardhichand and Ors\textsuperscript{265}, the municipal corporation was prosecuted by some citizens for not clearing up the garbage. The corporation took up the plea that it did not have money. While rejecting the plea, the Supreme Court decided by Justice Krishna Iyer observed that “The State will realize that Article 47 makes it a paramount principle of governance that steps are taken for the improvement of public health as amongst its primary duties.”

2. Right to Health is a Fundamental Right

In 1991, in CESC Ltd. vs. Subash Chandra Bose, (AIR 1992 SC 573,585) the Supreme Court relied on international instruments and concluded that right to health is a fundamental right. It went further and observed that health is not merely absence of sickness and held that:

“The term health implies more than an absence of sickness. Medical care and health facilities not only protect against sickness but also ensure stable manpower for economic development. Facilities of health and medical care generate devotion and dedication to give the workers’ best, physically as well as mentally, in productivity. It enables the worker to enjoy the fruit of his labour, to keep him physically fit and mentally alert for leading a successful economic, social and cultural life. The medical facilities are, therefore, part of social security and like gilt edged security, it would yield immediate return in the increased production or at any rate reduce absenteeism on

\textsuperscript{262} Id. Article 21 of the Indian Constitution state that “No person shall be deprived of his life or personal liberty except according to procedure established by law.” INDIA CONST. art. 21.
\textsuperscript{263} Amy Kapczynski, Harmonization and Its Discontents: A Case Study of Trips Implementation in India’s Pharmaceutical Sector, 97 CAL. L. REV. 1571, 1637 (2009)
\textsuperscript{264} Ibid.
\textsuperscript{265} 1980 Cri LJ 1075
grounds of sickness, etc. Health is thus a state of complete physical, mental and social well being and not merely the absence of disease or infirmity. In the light of Articles 22 to 25 of the Universal Declaration of Human Rights, International Covenant on Economic, Social and Cultural Rights and in the light of socio-economic justice assured in our Constitution, right to health is a fundamental human right to workmen. The maintenance of health is a most imperative constitutional goal whose realization requires interaction by many social and economic factors.”

With the recognition that both the Indian Constitution and the fundamental right of life emphasize human dignity, began to address the importance of health to Indian citizen. In the DPSP, Art.47 declares that the State shall regard the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties. Since DPSP are not enforceable by the court, implementation of the guarantee has remained illusory\(^\text{266}\). However, in a series of cases dealing with the substantive content of the right to life, the court has found that the right live with human dignity including right to good health. In Consumer Education and Research Center v. UOI\(^\text{267}\), the Court explicitly held that the right to health was an integral factor of a meaningful right to life. The court held that the right to health and medical care is a fundamental right under Article 21. The Supreme Court, while examining the issue of the constitutional right to health care under Arts 21, 41 and 47 of the Constitution of India in State of Punjab v Ram Lubhaya Bagga,\(^\text{268}\) observed that the right of one person correlates to a duty upon another, individual, employer, government or authority. Hence, the right of a citizen to live under Art 21 casts and obligation on the state. This obligation is further reinforced under Art 47: it is for the state to secure health to its citizens as its primary duty. No doubt the government is rendering this obligation by opening government hospitals and health centers, but to be meaningful, they must be within the reach of its people, and of sufficient liquid quality. Since it is one of the most sacrosanct and valuable rights of a citizen, and an equally sacrosanct and sacred obligation of the state, every citizen of this welfare state looks towards the state to perform this obligation with top priority, including by way of allocation of sufficient funds. This in turn will not only

\(^{266}\) Bandhua Mukti Morcha AIR 1984 SC 812.  
\(^{267}\) AIR 1995 SC 636.  
secure the rights of its citizens to their satisfaction, but will benefit the state in achieving its social, political and economic goals.

3. Right to Health Care as a Fundamental Right

The Supreme Court, in *Paschim Banga Khet mazdoor Samity and ors v. State of West Bengal and ors*\(^{269}\), while widening the scope of Art 21 and the government’s responsibility to provide medical aid to every person in the country, held that in a welfare state, the primary duty of the government is to secure the welfare of the people. Providing adequate medical facilities for the people is an obligation undertaken by the government in a welfare state. The government discharges this obligation by providing medical care to the persons seeking to avail of those facilities. Article 21 imposes an obligation on the state to safeguard the right to life of every person. Preservation of human life is thus of paramount importance. The government hospitals run by the state are duty bound to extend medical assistance for preserving human life. Failure on the part of a government hospital to provide timely medical treatment to a person in need of such treatment, results in violation of his right to life guaranteed under Article 21. The Court made certain additional direction in respect of serious medical cases:

a. Adequate facilities are provided at the public health centers where the patient can be given basic treatment and his condition stabilized.

b. Hospitals at the district and sub divisional level should be upgraded so that serious cases are treated there.

c. Facilities for given specialist treatment should be increased and having regard to the growing needs, it must be made available at the district and sub divisional level hospitals.

d. In order to ensure availability of bed in any emergency at State level hospitals, there should be a centralized communication system so that the patient can be sent immediately to the hospital where bed is available in respect of the treatment, which is required.

e. Proper arrangement of ambulance should be made for transport of a patient from the public health center to the State hospital.

f. Ambulance should be adequately provided with necessary equipments and medical personnel.

\(^{269}\)(1996) 4 SCC 37.
4. People are entitled to Adequate Health Care

In the case of Mahendra Pratap Singh vs. Orissa State\textsuperscript{270} the petitioner, an ex-sarpanch of Pachhikote Gram Panchayat approached the court for issuance of appropriate writ commanding the opposite parties to take effective measures to run Primary Health Centre at Pachhikote within Korei block in the district of Jaipur by providing all amenities and facilities for proper running of the said health centre. The Government of Orissa decided to open certain primary health centres in different areas in 1991-92 subject to fulfilment of certain conditions, on basis of demands of the local people and public at large.

The conditions fulfilled were as follows:

(i) The local people should provide minimum one acre of land duly pledged in favour of the Panchayat Samiti for the Medical Institution within a period of one month from the date of issue of this order.

(ii) The local people should provide permanent buildings for the medical institutions as well as for the staff within six months from the date of issue of this order.”

The court noted: Great achievements and accomplishments in life are possible if one is permitted to lead an acceptably healthy life. Health is life’s grace and efforts are to be made to sustain the same. In a Country like ours, it may not be possible. To have sophisticated hospitals but definitely villagers of this Country within their limitations can aspire to have a Primary Health Centre. The Government is required to assist people, and its endeavour should be to see that the people get treatment and lead a healthy life. Healthy society is a collective gain and no Government should make any effort to smother it. Primary concern should be the PHC and technical fetters cannot be introduced as subterfuges to cause hindrances in the establishment of health centre.

The judgment stated that the gram panchayat was agreeable to offer of the gram panchayat building for running of the health centre. If the building was still available, the same could be utilised for the purpose of running of the PHC, till the new building was completed. The Government either diverts the staff from Korei or makes suitable arrangement for running of the PHC in the building of Pachhikote Gram Panchayat.

\textsuperscript{270} AIR 1997 Ori 37.
Necessary arrangement would be made within a period of three months from that day. This is perhaps the only judgment commending the right to health for a general population.

The WHO defines essential medicines as those medicines that are necessary to satisfy the healthcare needs of the majority of the world’s population and therefore ought to be available to all individuals, in adequate dosage, and at affordable prices. It estimates that approximately one third of the world’s population lacks access to essential medicines, with the proportion being as high as two thirds in some of the poorest countries in Africa and Asia.

The WHO Essential Medicines List (EML) is a list of medicines to satisfy the majority of healthcare needs in developing countries, making it easier for developing countries to procure affordable, safe medicines. Of the 312 medicines on the list in 2006, only sixteen are newer patented drugs, including fourteen for the treatment of HIV/AIDS. No patented drugs for non communicable diseases, for example, cancer, diabetes, or for ischemic heart disease, are included. This is despite the fact that non communicable diseases are the leading cause of mortality in low-income countries, including in the Pacific region, and that many new drugs offer substantial improvements in their treatment. Some groups argue the EML contains enough varieties of drug, with a few exceptions, to satisfy the majority of health needs in developing countries while others are pushing for modifications. Still others argue that developing countries don’t take full advantage of the WHO EML at present and therefore shouldn’t need to criticize pharmaceutical companies or to raise compulsory licenses that override pharmaceutical patents.

There are multiple determinants influencing access to medicines, globally and in the Pacific. Many originate from outside the health sector, highlighting the complex linkages between health, poverty, development and trade. They include: domestic factors, for example, lack of adequate finance, limited, or no, domestic manufacturing capacity;

---

271 Health Care Case Law in India (CEHAT) And India Centre for Human Rights and Law, Published in August 2007. www.cehat.org
272 Mould, R., Expensive new drugs – do we really need them?, In, Australian Prescriber 27 (6), December 2004. Available at www.australianprescriber.com last accessed on 13th Jan, 2011.
market factors, for example, undisclosed, differential pricing strategies, and trade factors, for example Bilateral Investment Treaties (BITS)\textsuperscript{274}

Debates on universal human rights need to distinguish between legal, political and philosophical human rights perspectives. The practice of shifting seamlessly between these perspectives has been criticized as an unfortunate trait within literature and public discourse.\textsuperscript{275} Evans points out this practice serves to undermine the status of human rights to global politics because it opens the possibility of gaining the moral status that ratifying international human rights law brings, while simultaneously denying socioeconomic rights philosophically and politically TRIPs are established at the international level by a number of treaties including those administered by the World Intellectual Property Organization (WIPO), which is a specialized UN agency, and the WTO. TRIPs especially had an impact after 2000, when the WTO TRIPs Agreement came into force. Under the Agreement, all WTO members are obliged to implement a set of minimum principles and rules, including patents and their enforcement. These rights include the control of production, sale, use and sometimes importation of medicines. TRIPs therefore give pharmaceutical companies near-global monopolies, allowing them to block competition from generic manufacturing companies and to raise the price of patented pharmaceuticals)\textsuperscript{276}

5.7.5 Welfare State has a Duty to Protect its Subjects:

In traditional international law only states are subjects of the law. The duty to promote and protect health as a human right is therefore assumed to lie with the state, although the liberal expectation is that this duty can only be fulfilled progressively\textsuperscript{277}. However, given the conditions of globalization, the changing

\textsuperscript{274} BITS have been signed with a number of PICs. BITS may mean use of public health safeguards eg. those in TRIPs flexibilities could be expropriation and so require compensation from the host government to the investor from the other country in an international tribunal. They are not enforceable through trade sanctions. Some are listed on http://www.unctadsl.org/templates/DocSearch779.aspx and www.paclii.org referred to in a conference presentation by Ms Sanya Reid Smith, Third World Network, Regional High Level Consultation on HIV and the Law April 2007, Auckland NZ on file with the author


\textsuperscript{276} See reference Lofgren, 2007; WHO 2007a WHO (2007a) for a comprehensive description of all of the issues).

contexts of the social determinants of health are becoming increasingly supranational, in turn challenging the notion of national duty-holders. Recent additions to human rights legislation have sought to bind non state actors as duty-holders, especially transnational corporations.\textsuperscript{278}

Furthermore, human rights law is also fundamentally different from world trade law. For neoliberals, socioeconomic claims are legitimate claims, or aspirations, but these can never be legal rights. Such soft law, associated with human rights, versus hard law of the WTO Order, and its dominance in determining the behavior of states, is commented on by Hestermeyer:

“Enforcement of human rights law is further hampered by the fact that, unlike economic law, the most common case of a states’ violation of HR law – namely a violation of the Rights of its own citizens – does not harm other states directly which therefore lack an incentive to complain about the violation… It is a recipe for perplexity; while the claim of normative superiority of human rights has strong emotional (but far less legal) appeal, state behavior will be largely dominated by the tenets of WTO law. The question to be tackled …is whether there is a way to make human rights law count within the WTO system, as it is that system that will determine the behavior of states”.\textsuperscript{279}

Proponents of human rights contend that the dominance of the neoliberal consensus remains the single most important factor hindering the establishment of socioeconomic rights as legitimate claims.

The human rights framework is broad and may be expressed through a wide range of mechanisms from a state’s constitution to national case law. However, a fundamental difference between human rights and trade and development theories is expressed in Article 2 of the Universal Declaration of Human Rights. The Declaration emphasizes ‘universality’ and ‘indivisibility’, and the delivery of rights to ‘all’, rather than accepting that on some occasions, some people may be disadvantaged in order to provide a net benefit to society. For example, having to

\textsuperscript{278} One important step in clarifying these responsibilities was taken in the form of Norms adopted in 2003 by the UN Sub-Commission on the Promotion and Protection of HR which include reference to economic, social and cultural rights. Another example, is the ”Ethical Globalisation Initiative’ which explores with pharmaceutical companies what the right to health and corporate responsibility implies, particularly in relation to patents, pricing and R&D (Robinson, 2004; Hunt 2005). Hunt, P. (2005). The right to health: an interview with Professor Paul Hunt. Essex Human Rights Review (2) 1, pp.57 -61. Available athttp://projects.essex.ac.uk/EHRR/archive/pdf/ File4-Hunt.pdf, last accessed 24/11/07

decide between investing in a school facility or water sanitation may advantage some people, while disadvantaging others, in realizing their right to health and the right to education. The right to the highest attainable standard of health (the right to health) was first reflected in WHO’s Constitution and has been firmly endorsed in a wide range of international and regional human rights instruments\(^{280}\). The most authoritative interpretation of the right to health is outlined in Article 12 of the ICESCR, which has been ratified by approximately 150 countries.

Since its inception the UN has focused on classic civil and political rights, such as the right to a fair trial. However, in 2000, the UN began to address cases of historical neglect when the UN Committee on Economic, Social and Cultural Rights, which monitors the Covenant, adopted a General Comment (14) on the right to health that further clarified the nature, scope and content of the right to health. The General Comment 14 of ICESCR sets out four criteria by which to evaluate the right to health: availability, accessibility (affordability), acceptability (medical ethics) and quality. This Comment acknowledged that health promotion goes beyond the health sector and that coordinated, multi-sector action is necessary to foster greater equity in health, income and social policies. The Ottawa Charter\(^{281}\) provides a common understanding of health promotion internationally which reflect the human rights ideology. It was developed at the first International Conference on Health Promotion meeting in 1986 as a charter for action to achieve “Health for All” by the year 2000 and beyond. The Ottawa Charter built on the progress made through the Declaration of Primary Health Care at Alma Ata, the World Health Organization’s Targets for Health for All document, and debate at the World Health Assembly on moral action for health.

Human rights case law is a good illustration of how the right to health can be formally introduced into the national justice system so that it ultimately leads to

---

\(^{280}\) Most HR and health issues are thoroughly covered at the website of the United Nations Commission on HR available at www.unchr.ch. Health-related information, including explicit references to HR, is available at the website of the WHO (www.who.org). The Francois-Xavier Bagnoud Center available at http://www.hsph.harvard.edu/fxbcenter/international_hhr.htm and Global Lawyers and Physicians for HR have collaborated in the preparation of a ‘Perspectives in Health and Human Rights’ Gruskin (eds) (2005) which is accompanied by a special website containing links to documents, organisations and other references on health and human rights (http://www.glphr.org/resources/appendix.).

The University of Minnesota Human Rights Collection also provides a valuable list of documents on bioethics (see http://www1.umn.edu/humanrts/links/bioethics.html)

\(^{281}\) For a description of the Ottawa Charter see WHO/HPR/HEP/95.1 at www.WHO.int
concrete changes in government policy and to people’s wellbeing. A majority of the right to health case law relates to access to anti-retroviral treatment. The most commonly described case is the Treatment Action Campaign (TAC) v. Minister of Health case in South Africa in 2002; also known as the Nevirapine case. In this case, the Constitutional Court of South Africa held that the Constitution, which protects the right to access healthcare services, required the government to devise and implement a comprehensive and coordinated program to progressively realize the right of pregnant women and their newborn children to have access to treatment in order to prevent mother-to-child transmission of HIV.

Most countries in the world have become States parties to one or more international human rights treaties, thus creating an obligation by the State to its people towards the realization of the right to health, which includes access to essential medicines. But whether such access is enforceable in practice is unknown. The implementation of the ICESCR is monitored by the Committee on Economic, Social and Cultural Rights, which regularly issues authoritative but nonbinding General Comments, which are adopted to assist States in their interpretation of the ICESCR. In General Comment 3, the Committee confirms that States parties have a core obligation to ensure the satisfaction of minimum essential levels of each of the rights outlined in the ICESCR, including essential primary care as described in the Alma-Ata Declaration, which includes the provision of essential medicines.

General Comment 14 of May, 2000, is particularly relevant to access to essential medicines. Here the Committee states that the right to medical services in Article 12.2 (d) of the ICESCR includes the provision of essential drugs “as defined by the WHO Action Programme on Essential Drugs”. According to the latest WHO definition, essential medicines are: “those that satisfy the priority health care needs of the population. Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality.

---


and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.

Most countries in the world have acceded to or ratified at least one worldwide or regional covenant or treaty confirming the right to health. For example, more than 150 countries have become State parties to the ICESCR, and 83 have signed regional treaties. More than 100 countries have incorporated the right to health in their national constitution. Some might argue that social, cultural, and economic rights are not enforceable through the courts, and some national courts have indeed been reluctant to intervene in resource allocation decisions of governments. Yet accountability and the possibility of redress are essential components of the rights-based approach. Being a State party to a human rights treaty that is internationally binding creates certain State obligations to its people.

India has an excellent health care structure that has the potential to reach a large section of the population. Yet, despite this elaborate structure and the rapid advancement of medical sciences, the reality is deplorable. The percentage of population actually covered by the public health care services is reportedly a mere 30 per cent. Although programmes are being constantly reviewed and revised, the problems persist and continue to worsen.

Table-18: Number of Court Cases per Country for Enforcing Right to Health

<table>
<thead>
<tr>
<th>Country</th>
<th>Right to Health Enshrined in the Constitution</th>
<th>International Treaties Enjoy Constitutional Rank</th>
<th>Successful Cases Claiming the right to health (cases referring to international treaties)</th>
<th>Unsuccessful cases claiming the right to health (cases referring to international treaties)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>n</td>
<td>First case</td>
</tr>
<tr>
<td>Argentina</td>
<td>No</td>
<td>Yes</td>
<td>8</td>
<td>(2)</td>
</tr>
<tr>
<td>Brazil*</td>
<td>Yes</td>
<td>No</td>
<td>3</td>
<td>(0)</td>
</tr>
<tr>
<td>Bolivia</td>
<td>Yes</td>
<td>Yes†</td>
<td>1</td>
<td>(0)</td>
</tr>
<tr>
<td>Colombia</td>
<td>Yes</td>
<td>Yes</td>
<td>28</td>
<td>(1)</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>Yes</td>
<td>Yes</td>
<td>7</td>
<td>(5)</td>
</tr>
<tr>
<td>Ecuador</td>
<td>Yes</td>
<td>Yes</td>
<td>1</td>
<td>(1)</td>
</tr>
<tr>
<td>India</td>
<td>No</td>
<td>No</td>
<td>2</td>
<td>(0)</td>
</tr>
<tr>
<td>Nigeria</td>
<td>Yes</td>
<td>No</td>
<td>1</td>
<td>(1)</td>
</tr>
<tr>
<td>Panama</td>
<td>Yes</td>
<td>No</td>
<td>2</td>
<td>(0)</td>
</tr>
<tr>
<td>San Salvador</td>
<td>Yes</td>
<td>Yes</td>
<td>1</td>
<td>(1)</td>
</tr>
<tr>
<td>South Africa</td>
<td>Yes</td>
<td>Yes†</td>
<td>2</td>
<td>(1)</td>
</tr>
<tr>
<td>Venezuela</td>
<td>Yes</td>
<td>Yes</td>
<td>6</td>
<td>(3)</td>
</tr>
</tbody>
</table>

Total 59 (14) 12 (2) *Large number of new cases filed more recently. †Status not fully clear.

285 Hans V Hogerziel, Melanie Samson, Jaume Vidal Casanovas, Ladan Rahmani-Ocorals access to essential medicines as part of the fulfilment of the right to health enforceable through the courts? www.thelancet.com Vol 368 July 22, 2006 305
Access to healthcare is becoming increasingly difficult for a growing number of people because of the continued apathy of the government to recognize health and healthcare as a national priority, along with the legitimization of an unregulated private sector. Firstly, access to healthcare is affected by physical, financial and socio-cultural factors. Further, access to services has to be seen in terms of its coverage, availability of diagnostic facilities, medicines, surgical care and quality. However, cost of care is an important factor that severely affects access to quality health care services. In resource-scarce countries like India, where 27% of the population lies below poverty line, cost becomes a very important issue while accessing quality\textsuperscript{286}.

Under the provision of the Constitution of India, public health is primarily a state subject. National health programmes have been designed with flexibility to permit the state public health administration to create their own programmes according to their needs and depending on the epidemiological profile of the population. The implementation of the national health programmes carried out through the state government has decentralized public health machinery. The centre will play a coordinating role and provide technical and financial support, wherever it is felt necessary.

Poverty constitutes the underlying factor for poor health status among large masses in India. The era of globalization marked by unemployment, depleting wages, rising health care costs, hazardous working and living environment has clear specific impacts. The trend of reduced public investments and expenditures in health care is forcing people to increasingly access healthcare from the private sector. However, while the dominance of the private sector on one hand, is denying access to a large section – particularly the poor, women and other marginalized communities of the society, on the other, it is skewing the balance towards urbanized, tertiary level care with profitability prevailing over equity. It is increasingly pushing the poor to take loans or sell off their assets to spend on private medical care, which is expensive and not always appropriate or rational. Further, the profit oriented corporate health care services with its urban and elite mindset has not only given rise to unethical practices in terms of irrational diagnostic and screening tests, high curative costs, etc., it has also reduced the concentration of trained medical practitioners in the public sector, especially in

\textsuperscript{286} Ghodajkar, Prachin Kumar R., Quality of Health Care Services: Trends and Assessments in Medico Friend Circle Background Papers, 2005
rural areas\textsuperscript{287}. Both these processes have led to further impoverishment of the poor in general and women in particular. More disturbing is the fact that this trend is in a context where the state spends less than 1\% of GDP on health care and the rest is spent by people’s own resources. This translates to only 17\% of total health expenditure being borne by the government an overwhelming 83\% health care expenditure being private. The consequence, of this dismal allocation is a grossly inadequate public health system that is unable to meet health care demands of people and deteriorating quality of services resulting in poor health outcomes. It also makes the health sector in India one of the most privatized in the world.\textsuperscript{288}

Under the provision of the Constitution of India, public health is primarily a state subject. National health programmes have been designed with flexibility to permit the state public health administration to create their own programmes according to their needs and depending on the epidemiological profile of the population. The implementation of the national health programmes carried out through the state government has decentralized public health machinery. The centre will play a coordinating role and provide technical and financial support, wherever it is felt necessary.

5.7.6 Various Policies of the Government in Promoting Health Policies in Support of Right to Health:

The health policies, plans, and programmes in India mostly evolved during the national movement against colonial rule. The British authorities set up a Health Survey and Development Committee, commonly known as the Bhore Committee (1946)\textsuperscript{289} that was also greatly inspired by the aspirations of the national movement.

Some of the key recommendations of the Bhore Committee were:

a) Integration of preventive and curative health services at all administrative levels;
b) Development of primary health centers in two stages;
c) Major change in medical education;
d) Formation of district health board for each district;
e) Laid emphasis on preventive health services;
f) Inter-sectoral approach to health service development.


\textsuperscript{288} Ibid

\textsuperscript{289} The Bhore Committee was constituted by the government in 1940 to prepare a comprehensive proposal for the development of national programme of health services. They submitted the same in 1946. Several National Programmes were developed based on their recommendations.
It also recommended a comprehensive proposal for development of a national programme of health service for the country\(^{290}\). Subsequently in 1948, the Sokhey Committee\(^{291}\) recommended that manpower and services be developed from the bottom upwards. The Committee represented ‘a people centred and pluralistic’ model of development\(^{292}\). However, in the post Independence era, i.e., in the 1950s and 60s, advanced research institutes, medical colleges with tertiary hospitals and primary health centres emerged, while the sub-centres at village level lagged behind. India experienced a crisis in the late 60s, when it went through widespread drought that raised concerns about the ‘development model’, adopted so far. The international community put the onus of this crisis on the rising population growth, which was seen to be a hindrance to India’s growth and development.

A brief review of the government policies and programmes over the last 55 years is a reflection of how the healthcare system responds to health and particularly women’s health. India has never had an explicit policy for women’s health, but a range of policy decisions and measures has directly influenced women’s health. Since independence, several policies and programmatic interventions have been formulated to meet the health needs of people in the country. Besides, the specific policies that were initiated, the five-year plans, are a statement of the sectoral policies and programmes introduced by the Government of India. The progress of the five year plans, from the first introduced in 1951-56 to the tenth five year plan (2002-07), are indicative of the shifts in the government’s priorities and commitment vis-à-vis specific health issues.

The Ministry of Health and Family Welfare (MOHFW) comprises of the Department of Health, Department of Family Welfare and the Department of Indian System of Medicine and Homeopathy. In addition to general health services provided by MOHFW, specific health and nutritional needs of women are provided through the Integrated Child Development Services (ICDS) Programme under the Ministry of Human Resources Development and newly formed Ministry of Women and Child Development, that was only a department under the MOHFW till 2005.

\(^{290}\) Gopalan Dr. Sarala and Shiva Dr. Mira (2000) National Profile on Women, Health and Development, VHAI, New Delhi.
\(^{291}\) National Health (Sokhey) Sub-Committee (called the Sokhey Committee) and was a part of the National Planning Committee constituted by the National Congress in 1940. Its report was presented in 1948.
\(^{292}\) Ritu Priya, , Public Health Services in India: a historical Perspective in in Leena V. Gangolli, Ravi Duggal and Abhay Shukla (ed) Review of Health Care in India,2005
1. National List of Essential Medicines

The National List of Essential medicines (NLEM)\textsuperscript{293} is one of the key instruments in balanced healthcare delivery system of a country which \textit{inter alia} includes accessible, affordable quality medicine at all the primary, secondary, tertiary levels of healthcare. The first National List of Essential Medicines of India was prepared and released in 1996. This list was subsequently revised in 2003. To address the issues of changing disease patterns, treatment modalities, introduction of newer medicines and identification of unacceptable risk-benefit profile as well as therapeutic profile of some medicines, the National List of Essential medicines (NLEM) has now been revised in 2011. The NLEM, 2011, has a total of 348 Medicines (excluding repetitions). The list includes 181 medicines, which fall under the category of Primary, Secondary and Tertiary levels of treatment. 106 medicines fall under the category of medicines for Secondary and Tertiary only, while 61 medicines are categorized as medicines for Tertiary care only.

2. National Health Policy (NHP)

India committed itself to universal health care as indicated in the Bshore Committee Report developed way back in 1946. Subsequent to the Alma Ata commitment, the GOI passed the (NHP) in 1983. The NHP talked about comprehensive primary health care services linked to extension and health education; large scale transfer of knowledge, skills and requisite technologies to ‘health volunteers’; intersectoral cooperation and better utilization and strengthening of traditional systems of medicine\textsuperscript{294}. In 1983, the Government for the first time adopted a National Health Policy, prior to that the actions of the Government in the health sector were guided by the Five Year Plans and recommendations of various committees, and its major recommendations was: “universal, comprehensive primary health care services which are relevant to the actual needs and priorities of the community at a cost which people can afford”.

Then after a period of eighteen years, the Draft National Health Policy 2001 was announced towards the end of 2001 and was adopted by the Central Government in the year 2002. This new National Health Policy (NHP) candidly acknowledges that India’s public health care system is grossly short of defined

\textsuperscript{293} India’s National Essential Medicine List. Available at: http://cdsco.nic.in/nedl.pdf.

\textsuperscript{294} See NHP 2002, 1.2 www.nic.in
requirements, functioning is far from satisfactory, that morbidity and mortality due to diseases that are curable continues to be unacceptably high, and resource allocations are generally insufficient. However, the 1983 NHP’s goal “of providing universal, comprehensive primary health care services” does not even find a mention in this new policy document.

Since then, there have been marked changes in the larger climate and determinant factors relating to the health sector. The NHP 2002 is a continuation of the earlier indicated trends. The new policy deliberates on the need to improve access to health services among all social groups and in all areas, and proposes to do so by establishing new facilities in deficient areas and improving those existing. Recognizing that women and other underprivileged groups are most affected by poor access to health care, it aims at improving such groups’ access to basic services. Most importantly, the central government is to give top funding priority to programmes promoting women’s health. The policy sets forth several time bound objectives including reduction of MMR, IMR, mortality due to TB and malaria by 2010, and zero growth of HIV/AIDS by 2007. The new policy identifies many of the deficiencies plaguing the health care system and proposes a substantial increment in government expenditure on health care. It represents a retreat from the fundamental concept of the NHP 1983 that was committed to the ‘Health for All by 2000’ through the universal provision of comprehensive primary health care services. In contrast, NHP 2002 conveniently omits the concept of comprehensive and universal health care, thus reducing primary health care to primary level care. The silence maintained on village health worker (first contact in the primary health care) and strengthening public referral services exemplify the trend.

It has been strongly argued by many that this new NHP is riddled with confusions and contradictions as it only proposes numerous impressive principles and goals but does nothing to ensure that these are realized on the ground. On the other hand it can also be argued that this new NHP is an attempt towards legitimizing the ongoing privatization of the health care system of the country.

The policy, while on one hand is totally silent and ambiguous on the need for essential drugs, price control and standardized regimens of treatment, regulation of

---

private medical colleges/institutions and medical research, on the other, many of its formulations pave way for greater privatization of the system. Employing user fee in public hospitals, promoting ‘health tourism’ by making provisions for patients from other countries to avail domestic facilities for treatment in India, encouraging ‘setting up of private insurance for expanding the scope of covering secondary and tertiary sector under private health insurance packages’, etc. mark the government’s intention of legitimizing further privatization and departing from providing comprehensive, secondary and tertiary care. Last but not the least, health issues of women and children has been reduced to a section of rhetoric and passing references without specific prescriptions. Neither does it consider the steady decline of the female-male sex ratio over the few decades as a cause of concern, nor does it highlight any measures to prohibit sex selective abortions such as licensing and regulation of prenatal diagnostic centers. It also fails to acknowledge the problem of malnutrition, or suggest strategies and interventions to tackle the issue.

The avowedly stated objective of the new NHP is to achieve an acceptable standard of good health amongst the general population of the country. As mentioned earlier, NHP 2002 is quite explicit in its acknowledgement of the poor state of affairs in the health sector; it also recognizes globalization as a concern with a critical view of TRIPs and its impacts, envisages regulation of the private health care sector, and proposed to increase the expenditure on primary health care. Also, the new policy recommends an increase in public health expenditure from the present below 1% of GDP to 2% of GDP by 2010. Moreover, the policy projects that public expenditure on health by 2010 will be 33% of total health expenditure – up from the present 17%.

However, the mechanisms of how these eminently desirable objectives are to be achieved are not spelt out. Further, there is no analysis of why the goals of NHP-1983 remain unfulfilled, and there is no attempt to explore the linkages between what is happening to some of the major determinants of health like food, water, and sanitation etc. and the important indicators (of health status) in the emerging scenario. Above all, the NHP 2002 remains blissfully innocent as to what can be done to ensure that the commercial vested interest in the private health care sector do not succeed in overshadowing peoples’ needs and patients’ rights.

---

Although a new Drug Policy (Pharmaceutical Policy, 2002) was adopted by the same Government in the same year as this NHP-2002, it is more or less silent about the impact of this Policy on the health sector and does not discuss the consequences of further deregulation of the pharmaceutical sector which it advocates. The new policy has ignored the pressing needs of primary health care, and shows a strong bias towards urban specialist-based health care. It is true that this policy recommends an increase in public expenditure on health from the present level of less than 1% of GDP to 2% of GDP by 2010. But the quantum of increase suggested is grossly inadequate even today, keeping in mind the huge gaps in this sector, and it well below 5% of GDP recommended by the WHO long back. Although the policy is critical of the states for not increasing their investment on health, it does not address the causes behind their inability to do so. We may also note the valid concern expressed by NHP-2002 regarding resource use inefficiencies of various kinds in the running of the programmes sponsored by Central Government, e.g. the wastage on account of vertical disease control programmes, (as the ‘vertical’ implementation structure for the major disease control programmes requires independent manpower for each disease programme which makes these programmes extremely expensive and difficult to sustain), but the document does not have concrete and worthwhile policy suggestions to improve the situation.

As one may expect, the new NHP proposes to strengthen the provision of user fees in public hospitals, with the qualification that it will target those who can pay. In the 1980s, a few states like Rajasthan and West Bengal had introduced charges for diagnostic facilities and other services. In the 1990s, several other states followed suit. However, a recent study of user fees in Gujarat, Madhya Pradesh, Orissa, Rajasthan and West Bengal show that they do not contribute more than 2% to the hospital budgets. On the other hand there is a mounting body of evidence which shows that user fees can be highly regressive. Identification of those ‘who can pay’ is an exceedingly difficult task and often large sections of the vulnerable sections may get left out of the count of those who cannot pay. Andhra Pradesh experiment with white cards is an example of this failure and there is genuine fear that the further

298 Quadeer, Imrana (2002); “Debt Payment and Devaluing Elements of Public Health”, Economic and Political Weekly, January 5.
strengthening of user fees will inevitably result in driving out substantial sections of the poor from the public health care system in India. Another notable feature of the new NHP is that it plans to encourage the use of India’s health facilities, particularly in the private sector, to attract patients from other countries. It also suggests that such incomes can be termed “deemed exports” and should be exempt from taxes. The concern has been raised by several observers that such a policy would strengthen a climate subservient to the interests of the rich and powerful in the global health market and create islands of brain and resource drain within the country. Finally, the NHP-2002 proposal regarding privatization of secondary and tertiary level care, ignores the simple fact that 45% of the poorest of the country continue to depend on the public sector hospitals for critical indoor care and such a proposal is bound to push the unit cost of such health care by many times.

There is an apprehension that globalization will lead to an increase in the costs of drugs, thereby leading to rising trends in overall health costs due to stricter compliance to Patents Law.

The Public Health Policy of 2002 just makes a mention in the Paragraph 2.26 making a mention of the plan of the government to provide public health services to combat effect of TRIPs agreement which is not sufficiently made. It states that-

“2.26 The Impact of Globalization on the Health Sector; 2.26.1 There are some apprehensions about the possible adverse impact of economic globalization on the health sector. Pharmaceutical drugs and other health services have always been available in the country at extremely inexpensive prices. India has established a reputation around the globe for the innovative development of original process patents for the manufacture of a wide-range of drugs and vaccines within the ambit of the existing patent laws. With the adoption of Trade Related Intellectual Property Rights (TRIPs), and the subsequent alignment of domestic patent laws consistent with the commitments under TRIPs, there will be a significant shift in the scope of the parameters regulating the manufacture of new drugs/vaccines. Global experience has shown that the introduction of a TRIPs-consistent patent regime for drugs in a developing country results in an across-the-board increase in the cost of drugs and
medical services. NHP-2002 will address itself to the future imperatives of health security in the country, in the post-TRIPs era\textsuperscript{299}.

3. **National Population Policy (NPP) 2000**

In 1951, the draft outlined for the First Five-year Plan, recognized ‘Population Policy’ as ‘essential to planning’ and ‘family planning’ as a step towards improving the health of the mothers and children. Women’s health concerns received less attention than fertility control, and family planning became the focus. The first Family Planning Programme (FPP) was formulated in 1952. The methods propagated then were rhythm and barrier methods, like diaphragms, jellies and foam tablets. In the year 1966, Department of Family Planning was established in the Ministry of Health. A statement of NPP was drafted and, in 1991, a Committee on Population was appointed which strongly recommended NPP.

In the year 1993, a Committee on Population, set up by the National Development Council, proposed the formulation of a National Population Policy. In 1999, the draft NPP was made available, and on February 2000, the cabinet adopted the NPP\textsuperscript{300} The National Population Policy (NPP), adopted in 2000, lays out several objectives and goals to realize the long-term objective of ‘stabilizing population by 2045 at a sustainable level’.

a. The immediate objective is to meet the unmet need for contraception and health infrastructure;

b. The medium term objective is to bring the Total Fertility Rate (TFR) to replacement levels by 2010 through intersectoral action;

c. The long-term objective is to achieve a stable population, consistent with sustainable development by 2045. The policy also states Socio-Demographic Goals to be achieved by 2010, some of which are:

I. reducing IMR, MMR;

II. achieving universal immunization, access to information/counseling;

III. Registration of births and deaths, marriages and pregnancy;

IV. containing spread of infectious diseases; promoting vigorously small family norm;

\textsuperscript{299} Source: http://mohfw.bvbnic.in/

V. Delaying age at marriage. Health activists criticized the policy on many crucial grounds.

First and foremost, the macro issues of income, employment, food basic health and livelihood issues do not find a mention in the NPP. Secondly, the NPP articulates stabilization of population as the precondition for economic development. The quality of health care services including preventive and primary do not find a place in the NPP document. Though NPP 2000 emphasizes on delayed marriage, it is silent about vocational training and occupational opportunities for empowerment, which reflects that its goals are still very much limited to fertility reduction.301


The National Nutrition Policy (1993) advocates a comprehensive inter-sectoral strategy for alleviating all the multi-faceted problems related to nutritional deficiencies, so as to achieve an optimal state of nutrition for all sections of society, but with emphasis on women and children. The strategies adopted include – screening of all pregnant women and lactating mothers for Chronic Energy Deficiency (CED); identifying women with weight below 40 kg and providing adequate ante-natal, intra-partum and neo-natal care under the RCH programme, and ensuring they receive food supplementation through the Integrated Child Development Services (ICDS) Scheme. The ICDS, launched in 1975, provides supplementary feeding to bridge the nutritional gaps that exist in respect of children below 6 years and expectant and nursing mothers. However, the ICDS programme has not been able to reach the nutritional need of children below three years. The policy however, has failed in many ways to meet the nutritional requirements of the population. Though there has been a rise in the country’s food production, an ineffective distribution system has failed to benefit the masses. The policy thrust has been towards micronutrient supplementation rather than addressing the root causes of malnutrition. According to studies, the dismal nutritional scenario is reflected in the persistence of under nutrition in the last few decades, with a marginal reduction (only 20%) in under-nutrition.

Today, India with less than 20% of the world’s children, accounts for over 40% of under nourished children. The National Nutrition Bureau (NNB) has also

been ineffective in screening nutritional disorders like CED among pregnant and lactating women, and identifying their needs. Very often, the nutritional education that is imparted is far removed from the reality of these women’s lives and they fail to relate or articulate their nutritional requirements.

5. National Mental Health Programme (NMHP)

A National Mental Health Programme (NMHP) was launched in 1982, keeping in view the heavy burden of mental illness in the country and the inadequacy of the health system to meet the specific mental health needs. This programme aimed to shift the basis of practice from the traditional (psychiatric) services to community care. The treatment of mental health problems is still heavily relying on the biomedical model and is limited to the dispensing of drugs. Mental health care services are limited to those diagnosed with severe illness, where the patient is treated as a ‘societal burden’. The pattern of institutional care, especially for women, reeks of neglect and paternalism and requires gender sensitive cross-referral systems.\(^{302}\)

The GOI also launched the District Mental Health Programme (DMHP) in 1996-1997 under the recommendation of the Central Council of Health and Family Welfare. The programme, initially launched in 4 states, was extended to 22 districts in 20 states by the year 2000 with a grant assistance of Rs. 22.5 lakhs each\(^ {303}\). The programme has been criticized as giving more importance to curative services rather than preventive measures. There is also a shortage of professional manpower, and the training programmes are not adequate. Moreover, the medical care provided is still custodial in nature and requires a therapeutic approach.\(^ {304}\)

6. Reproductive and Child Health (RCH)

The Mother and Child Health (MCH), nutrition and immunization programmes were brought under the umbrella of the Family Welfare Programme and was finally transformed into the Reproductive Child Health (RCH) programme\(^ {305}\). The national RCH programme was launched in 1997 to provide integrated health and family welfare services for women and children. The programme aimed at improving the quality,

\(^{302}\) Davar, Bhargavi ‘Dilemmas of Women’s Activism in Mental Health’ in Khanna, Shiva and Gopalan (ed) 2002, p 472.
\(^{303}\) http://www.mohfw.nic.in/kk/95
\(^{305}\) Qadeer, Imrana ‘Policy on Women’s Health’ for National Consultation towards Comprehensive Women’s Health Policy and Programmes Feb 18-19. 1999
distribution and accessibility of services and to meet the health care needs of women in the reproductive ages and children more effectively.

The components included:

a) Prevention and management of unwanted pregnancy;
b) Services to promote safe motherhood and child survival;
c) Nutritional services for vulnerable groups;
d) Prevention and treatment of reproductive tract infections (RTIs) and sexually transmitted infections (STIs);
e) Reproductive health services for adolescents;
f) Health, sexuality and gender information, education and counseling;
g) Establishment of effective referral systems;

While the RCH programme entered its second phase, a five-state social assessment of RCH I (1997-2002) revealed306:

a) Health services were not available at suitable timings for women;
b) Unresponsiveness of the health system to problems concerning mobile population;
c) complete neglect of adolescent health needs;
d) low priority accorded to treatment of gynecological morbidities among women, even as the untreated side effects of contraceptives and post delivery complications continued to burden women;
e) Failure to involve men in the programme, thus rendering the RCH programme as ‘women centric’.

Despite the guidelines of the RCH programme and the existing reproductive health care services, there are certain issues that have been completely neglected and ignored by the experts. Women are unable to seek care for problems, which are not related to pregnancy and other gynecological complications. For instance, there are no services for occupational health problems, domestic violence or abuse and mental health problems. In addition to this, the programmes deny a commitment to respond

306 Sama Team ‘Reproductive Health services: The transition from policy discourse to Implementation’ in Leena V, Gangoli, Ravu Duggal and Abhay Shukla (ed) Review of Health Care in India. 2005, p 166
to women’s health needs throughout the life cycle and to go beyond the constricted conceptualization of their reproductive roles as concerned only with child bearing\textsuperscript{307}.


Launched in 18 states that were identified as having poor health indicators – emphasizes on comprehensive primary health care for the rural poor. The main goal of the mission is to provide for effective health care facilities and universal access to rural population. The principle thrust areas as identified in the document are:

a) Strengthening the three levels of rural health care- sub-centre, PHC and the CHC. It also states that all ‘assured services’ including routine and emergency care in Surgery, Medicine, Obstetrics and Gynecology and Paediatrics in addition to all the National Health programmes; and all support services to fulfil these should be available and strengthened at the CHC level.

b) New health financing mechanisms for additional resource allocation and upgradation of facilities.

c) Appointing ASHA (Accredited Social Health Activist) at the village level as the link worker for the rest of the rural public health system.

d) Private public partnerships and regulation of private sector.

The programme document identifies all these as attempts to establish the horizontal linkages of various health programmes and provide comprehensive primary health care rather than promoting the vertical programmes, which has till now failed to provide health for all. However, NRHM 2005 has been criticized by health activists and women’s groups alike as being ‘old wine in a new bottle’. Only a marginal proportion of the increased health budget has gone into the rural health system improvements under NRHM and in reality the budgets for all Family Welfare activities including the RCH II package has been clubbed together as the budget for NRHM. A consequence of such reallocation is the danger of NRHM activities being usurped by RCH programme. The performance indicators of the ASHA and her compensation are related to RCH and there is a high possibility that this disproportionate emphasis on family planning and RCH will undermine the

\textsuperscript{307} Sama Team ‘Reproductive Health services: The transition from policy discourse to Implementation’ in Leena V, Gangoli, Ravu Duggal and Abhay Shukla (ed) Review of Health Care in India. 2005, p 166
effectiveness of other primary health care components.\(^{308}\) Hence, though the NRHM document reflects the renewed commitment of the government to provide comprehensive health care, it has inbuilt problems of becoming selective and abdicating the government’s responsibility for healthcare provisioning.

8. Other Programmes

In the process of planning, a series of vertical programmes evolved towards control and eradication of communicable diseases such as TB, malaria, leprosy, etc. However, despite the vertical programmes, India is experiencing resurgence of various communicable diseases. About 5 lakh people die from TB every year and malaria has remained at a high level of around two million cases annually. The vertical programmes are not based on establishing a wide network of permanent health services to cater to the needs of masses in the country. Most of the programmes seem to offer simple, less effort and resource demanding option, which in no way raise concerns over the larger structural issues of poverty and inequity. The vertical programmes run through a fragmented approach, as they do not locate certain diseases within its specific context, and moreover, they are very expensive and unsustainable in the long run as to the exploitation and against moral and material abandonment.

The pharmaceutical industry of India has matured over the years into a major producer of bulk drugs, rated among the top five in the world. The industry is largely concentrated in the production of “generics” on account of the Process Patent Law introduced in the seventies (repealed under the recent TRIPs Agreement). India has since been able to establish technological capability for manufacture and supplying of generic drugs. This generics capability of India has attracted worldwide attention. A noticeable surge in mergers and acquisitions with either a foreign company seeking a stake in an Indian counterpart or vice versa reflects the attractiveness of what has been called as the “platform of capabilities”\(^{309}\). Indian companies seek to expand and consolidate their platform of capabilities in their endeavor to either develop indigenous branded generics or to acquire established branded generics. Today the Indian pharmaceutical industry has become a prominent provider of healthcare. It meets 95% of the country’s medical needs and constitutes about 1.3% of the world market in value terms and 8% in volume terms represented by 250 large


pharmaceutical manufacturers (5 of these are in the public sector) and about 8000 small scale units. The generics pharmaceuticals sector in India have come of age, their future sustainable growth depends on ensuring competitive markets and the Competition Commission is sensitive to the differing perspectives that are inevitable to an industry so critical to life itself.310

The Indian Pharmaceutical Industry is among top five producers of bulk drugs in the world. Pharmaceuticals market can be roughly classified into Bulk drugs (20% of the market) registering growth rates of 20% and formulations (80% of the market) with an annual growth rate of 15%. There are about 8174 bulk drug manufacturing units and 2389 formulations units spread across the country. Pharmaceutical companies operating in India is a pool representing about 250 large pharmaceuticals manufacturers and suppliers and about 8000 small scale pharmaceutical and drug units including 5 central public sector units. At the time of independence, the bulk drug industry in India was in the infancy stage. Most of the bulk drugs and formulations were imported. Since then, the Indian pharmaceuticals industry has evolved through the opportunities arising within the regulated environment. The Indian Patents Act (1970) and establishment of large public sector companies for the manufacture of bulk drugs enabled the development of the pharmaceuticals industry in India.

The Indian pharmaceutical industry being a pure reverse engineering industry focused on the domestic market, the industry is becoming research driven, export oriented and globally becoming competitive. The industry is dependent on its presence in the therapeutic segment and new categories, viz. cardiovascular, central nervous system and anti diabetic are expanding at double digit growth rates. The generic drug companies in India have broad technological and diversified market capabilities. As more and more patents expire, the generic portion of the pharmaceutical market is expected to continue to have increased sales. Indian companies are attempting to tap the generic drug markets of the developed countries. The technological capability for manufacturing and supplying generic drugs of these companies make them major players in the international generics market. With the WTO commitment in January 1, 2005, to recognize foreign product patents outsourcing in the fields of RandD, contract manufacturing and co-

310 Note by Geeta Gouri. Member Competition Commission of India. DAF/COMP(2009/39 156.
marketing alliances have been identified by industry federations\textsuperscript{311} as an opportunity for Indian companies. India has the best chemistry skills and low cost advantages in research and manufacturing and skilled manpower, which will attract foreign investors, apart from encouraging basic research and drug discovery.

Branded Competition as against Generic Competition has a control on the prices which acts as a check on the pharmaceutical companies as there would be a threat of losing the market. It is interesting to observe the responses of a matured generics player to competition, where large numbers of patents are expected to expire in a few years time. Few cases reported by media and newspapers, given below, provide glimpses of how Indian companies have taken legal measures to refute claims of multinational drug majors for extension of their patents.

A case that attracted a lot of attention in India is that of the Swiss drug company Novartis. Novartis had challenged Section 3(d)\textsuperscript{312} of the Indian Patents Act claiming immunity for their drug Gleevic, a major drug for leukemia on the pleas that the new Gleevic was a major improvement over a older version whose patent was over. This was disputed by Indian companies such as Natco Pharmaceuticals. The plea of Novartis was rejected consequently enabling manufacture by Indian generic companies. Cost estimates of the new generic drug place it at one tenth the price of Gleevic.

In a similar case the Delhi Court rejected the petition of Bayer Healthcare, a German drug major from preventing the Drug Controller General of India giving marketing approval to Indian company Cipla for the generic version of the cancer drug Nexavar. The ruling however had a caveat namely, that if the Indian drug company is found guilty of patent infringement damages will have to be compensated by payment to Bayers.

Cipla in another case won the right to manufacture and market the generic version of the anti-cancer drug Tarceva originally patented by the Swiss pharma


\textsuperscript{312} Section 3(d) of the Indian Patent Act forbids the patenting of derivative forms of known substances unless they are substantially more effective than the known substance. See Jayati Ghosh in her regular column “Economic Currents”, Deccan Chronicle, and also Economic Times, 29 August, 2009.
company Hoffman La Roche both in Delhi Court and the Supreme Court.\textsuperscript{313} Recently, Aurobindo Pharma an Indian drug pharma received USFDA approval for Risperidone Oral Solution a drug used in the treatment of mental and emotional problems. Indian companies are becoming increasingly active in the US market. In the first quarter of 2009 Indian companies had achieved 50 ANDA approvals.\textsuperscript{314} 

The European Commission investigation into the case of “patent pooling” a commonly used tactics for prolonging the life of a patent has attracted a lot of attention in India as EU is probing into the anti-trust violations indulged by Lupin, Matrix Laboratories and Unichem Laboratories for “knowingly delaying” the generic launch of a cardiovascular drug, Perinaopril by teaming with the innovator of the drug, Laboratories Servicer. This makes it clear that in India public health expenditure has been lagging behind in meeting the needs of the people.

5.7.7. Regulation in Pharmaceuticals

The other reason for rise in the prices of the drugs and medicines having a high amount of margins is due to the reason that there is an improper implementation of drug monitoring and price regulations.

The regulatory framework operates at two levels: i) licensing and ii) pricing. Licensing entails the need for manufacturers to get approval from Drug Regulatory Commissions at state-level. The Drugs and Cosmetics Act, 1940, governs the import, manufacture, distribution and sale of drugs, in India. The Drug Controller General of India (DCGI), an authority established under the Drugs and Cosmetics Act, 1940, oversees the conduct of clinical trials and is also responsible for the approval and registration of drugs, and issues manufacturing and marketing licenses for the same.

Essential drugs pricing is fixed by the Central Government. On a regular basis the list of drugs whose prices are controlled and the methodology of fixing prices is issued referred to as the Drug Price Control Order (DPCO). In the last few

\textsuperscript{313} Reported in \textit{Financial Express.}, 5th September,2009 and \textit{Economic Times.},19th August, 2009. The price difference for example, in the case of Cipla v/s Roche, Roche sells Tarceva for Rs.4500 per tablet while Cipla’s generic is sold at Rs.1500 per tablet.

years only a few essential drug prices are regulated and the implementing authority as of now is the National Pharmaceutical Pricing Authority.

The Indian Patents Act (IPA), and the Drug Prices Control Order (DPCO) were both passed in 1970. Under the IPA, substances used in foods and pharmaceuticals could not be granted product patents. Only process patents were allowed for a period of five years from the date of the grant of patent, or seven years from the date of filing for patent, whichever was earlier. The introduction of the IPA provided a major thrust to growth of the Indian generics pharmaceuticals industry; and Indian companies, who through the process of reverse engineering and synthesis, began to produce bulk drugs and formulations at lower costs.

The DPCO is an order issued by the Government, under Section 3 of the Essential Commodities Act, 1955, empowering it to fix and regulate the prices of essential bulk drugs and their formulations. The order incorporates a list of bulk drugs whose prices are to be controlled, the procedure for fixation and revision of prices, the procedure for implementation, the procedure for recovery of dues, the penalties for contravention, and various other guidelines and directions. The order is subject to the guidelines of Drug Policy and supposedly aims to ensure equitable distribution, increased supply, and cheap availability of bulk drugs and played a vital role in directing the pharmaceutical industry’s fortunes.

The first DPCO was issued in 1970, revised in 1979, 1987 and 1995. In its introductory form, DPCO was a direct control on the profitability of a pharmaceutical business, and only an indirect control on the prices of pharmaceuticals. It stipulated that a company’s pre-tax profit from its pharma business should not exceed 15 per cent of its pharma sales (net of excise duty and sales tax). In case profits exceeded this sum, the surplus was deposited with the Government. So, a pharma company had the freedom to decide the prices of its products. Product-wise margins were also flexible, so long as the overall margin did not exceed the stipulated norm. Since individual product prices did not require approval from the Government, bureaucratic hurdles were low. DPCO (1970) effectively put a ceiling on prices of all mass-usage bulk drugs and their formulations. Its primary objective was to protect the interests of consumers, and ensure a restricted but reasonable return to producers. The order was a landmark regulation and has had several implications in shaping the Indian pharmaceuticals industry.
In 1974, the Government of India (GOI) appointed a committee under the chairmanship of Rajya Sabha MP, Mr. Jaisukhlal Hathi, to inquire into the conditions prevailing in the sphere of pharmaceuticals in the country. DPCO 1979 was drafted loosely based on the recommendations of the Hathi Committee. The revised DPCO stipulated ceiling prices for controlled categories of bulk drugs and their formulations. The retail prices of controlled formulations were decided by applying the concept of MAPE (Maximum Allowable Post-manufacturing Expenses).  

DPCO 1979 put 370 drugs under price control. These drugs were segregated into three categories, having different MAPEs. The most important drugs, including life-saving drugs were put in Category I, which had the least MAPE. Through this DPCO, around 80 per cent of the Indian pharma industry (in value terms) was brought under strict price control. However, 13 Transnational Corporations (TNCs) challenged the order and succeeded in obtaining a stay on the DPCO, 1979, from High Courts and ignored the prices fixed under this. Ultimately the Government of India had to appeal to the Supreme Court, which upheld the validity of its action and directed the Government to assess and recover the amounts.

In 1984, the Government constituted another expert committee to look into the issue of drug pricing known as the Kelkar Committee. The Committee recommended the exclusion of a number of drugs from the purview of price control. Various suggestions were made for determining the criteria for inclusion and exclusion.

DPCO, 1987, was based on the Drug Policy of 1986, and the Kelkar Committee Report. In DPCO, 1987, the number of bulk drugs under price control

---

315 The pricing formula was retail price = (MC + CC + PM + PC) x (1 + MAPE100) + excise duty. MC was the material cost, including cost of bulk drugs/recipients; CC was the conversion cost as per the dosage form; PM was the cost of packing material suitable to dosage form; and PC was the packaging charge calculated in accordance with established costing procedures. Source: OECD Roundtables Generic Pharmaceuticals, 2009 DAF/COMP(2009)39. Available at: http://www.oecd.org/competition

316 In its judgment on April 10, 1987, the Supreme Court made a revealing observation. It discovered that Hoechst India Ltd. had fraudulently priced Earalgan Ketone, a non-essential drug. Hoechst applied for a price level of Rs. 3,500 per kg but was charging Rs. 24,735.38 per kg. The Government, after analyzing the cost, fixed it as 1,810.20 per kg. Before the DPCO, Hoechst was charging a price of Rs. 24,735.38 per kg. But instead of reducing it to Rs. 1,810.20 per kg., or even Rs. 3,500 per kg., as requested of them, they continued to sell the drug for Rs. 24,735.38 per kg., under the protection of the High Court’s stay order. The angered Supreme Court observed thus: “We see that the price, of Rs. 24,735 per kg; at which the manufacturer was previously selling the drug, and at which he continues to market the drug to this day because of the quashing of the order fixing the price, by the high court; is so unconscionably high, even compared with the price claimed by itself, that it appears to justify the charge that some manufacturers do indulge in „profiteering”. Source: OECD Roundtables Generic Pharmaceuticals, 2009 DAF/COMP(2009)39. Available at: http://www.oecd.org/competition.
was significantly reduced from 370 to 142. In addition, the categories of control were reduced to two, and higher MAPE was provided for each category of controlled drugs (75 per cent and 100 per cent respectively). However, around 75 per cent of the pharmaceutical industry was still under price control.

In September 1994, the New Drug Policy was announced. The New Drug Policy liberalized the criteria for selecting bulk drugs, or formulations, for price control. In addition, industrial licensing was abolished for all bulk drugs. All hindrances to capacity expansions were removed, and it was expected that, as a result, supply would rise, resulting in higher competitive pressures. Foreign investment up to 51 per cent was also permitted in the case of all bulk drugs, their intermediates and formulations. FDI above 51 per cent could also be considered on a case-to-case basis. Nevertheless, five bulk drugs; Vitamin B1, Vitamin B2, Folic Acid, Tetracycline and Oxy-tetracycline were reserved for the public sector till 1998.

The latest Drug Price Control Order was passed in 1995. The basic structure of this DPCO is the same as that of the earlier orders, except that a uniform MAPE of 100 per cent was granted to all controlled formulations. Nevertheless, the span of price control, under DPCO 1995, was liberalized considerably from 142 drugs to just 76. It was under the New Drug Policy, National Pharmaceutical Pricing Authority (NPPA) was appointed to implement and enforce the provisions of the Drugs (Prices Control) Order 1995 in accordance with the powers delegated to it. Thus, the objective of the Government was to decontrol in order to induce increased competition and to make essential drugs affordable to the weaker sections of society. But it would be too early to make any comment on how the price regulations would work in the practical life as DPCO does not make a clear mention as to how the patented drug price can be controlled effectively in the patent scenario. For example as per the observation, In 1995, the amendment of the Drug Price Control Order of 1987 (which had kept 163 drugs under price control) deregulated the drugs market leaving only 76 drugs under price control mechanism. An analysis of its impact by the Delhi Science Forum (DSF) showed that out of a set of 28 essential drugs (8 under price control and 20 outside it) - whose price movement was studied - “prices of 6 of the 8 controlled drugs decreased; on the

317 DAF/COMP(2009)39 159
other hand, the prices of the 20 drugs outside DPCO mechanism showed an increase in excess of 10% and in some cases in excess of 20%.

“The DSF also analyzed the increase in prices of 50 top-selling drugs between February 1996 and October 1998. It showed that the average increase in case of brands under price control was 0.1%, whereas that in the case of brands outside price control was 15%. It was also found that the price-rise was not a one-time increase owing to an escalation in raw material costs but was indicative of a trend of a continual increase in the prices of decontrolled drugs.”

The National Pharmaceuticals Pricing Policy 2012 presently seeks to limit itself to the central objective of promulgating the principles for pricing of Essential Drugs as laid down in the “National List of Essential Medicines – 2011 which was declared by the Ministry of Health and Family Welfare, Government of India.

The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2012 are:

(1) Essentiality of Drugs
(2) Control of Formulations prices only
(3) Market Based Pricing

The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be on the basis of essentiality of drugs. This is different from the economic criteria/market share principle adopted in the Drug Policy of 1994. The reasons for the adoption of the principle of “Essentiality” as a key criteria are:

(i) The “Essentiality” criteria for drugs under the NPPP-2012 is to be met by considering the List of medicines specified in the National List of Essential Medicines as revised from time to time and most recently declared by the Ministry of Health and Family Welfare, Government of India.
(ii) The NLEM has been prepared by an Expert Core Committee constituted by the Director General of Health Services (DGHS) out of the WHO model list of essential medicines, Essential Drugs Lists of various States, medicines used in various National Health Programmes and Emergency Care Drugs.

---

319 Ibid.
320 vide communication No.12-01/essential medicines/08-DC/DFQC, dated 8th June, 2011. Available at www.mohfwg.in
(iii) The NLEM contains such medicines that satisfy the priority health needs of the country’s population.

(iv) The NLEM medicines are required to be made available within the context of a functioning health system at all times in adequate quantities in the appropriate dosage forms to serve large public masses.

(v) The Hon’ble Supreme Court in its Order dated 10.03.2003 in SLP No. 3668/2003 (Union of India V K.S. Gopinath and others) has also emphasized the need to “..... Consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control.....”

(vi) The current principle of economic/market share criteria needs to be changed now, given the fact that out of the 348 medicines listed in the NLEM-2011, only 34 drugs are included amongst the 74 drugs listed in the First Schedule of “The Drugs (Prices Control) Order, 1995 (DPCO 1995).

The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012\textsuperscript{321} would be on the basis of regulating the prices of formulations only. This is different from the earlier principle of regulating the prices of specified Bulk Drugs and their formulations adopted in the Drug Policy 1994. The reasons for adoption of this principle of price control of “Formulations Only” are:

(i) That the Bulk Drug - API (Active Pharmaceutical Ingredient) - may not fully reflect the ‘Essentiality’ of the actual drug formulation – now the subject of focus - due to the possible applicability of the API in manufacture of various formulations which may or may not be considered “Essential” for the larger healthcare needs of the masses.

(ii) The emphasis on price control starting at the bulk drug stage itself has in recent times, resulted in amongst other reasons shifting of manufacture of drugs away from the notified bulk drugs under price control. In fact only 47 bulk drugs out of the 74 notified in the First Schedule of the DPCO, 1995 are now under production. This has had a cascading effect on the formulations manufactured

from the concerned bulk drugs which in turn has affected the availability of such formulations. The consumer-patient has been adversely affected in the process.

(iii) The task of pricing both the bulk drug and the formulation makes it complicated and time consuming without commensurate direct benefits to the consumer who is actually affected only by the price of the final end product, i.e., the formulation - made from the bulk drug rather than its bulk constituents.

(iv) The price control in the form of formulations only ensures more specific pricing control of the required medicine which is in the interest of the consumer from the point of view of the actual prescription by the Doctor. This aspect is more important for a country like India where there is large asymmetry in the information between the doctor and the patient.

(v) Since the bulk drug manufacturer is constrained to sell at a fixed price, the manufacturer is always likely to give preference to an existing buyer rather than to a potential new entrant. This constrains the emergence of new companies and formulations in the price-controlled segment and is inherently anti-competitive and also does not benefit the consumer-patient for the same reason.

The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012\(^{322}\) would be on the basis of regulating the prices of formulations through Market Based Pricing (MBP). This is different from the earlier principle of regulating the prices through Cost Based Pricing (CBP) under the Drug Policy 1994. The reasons for adoption of this principle are:

i. Under Cost Based Pricing, the prices of drugs have to be calculated in detail every year which requires a complex variety of data. For this, the manufacturers are required to provide their pricing data in an extremely detailed manner which is intrusive and so highly resisted by the individual manufacturers resulting in possible manipulation and time delay of provision of the base costing data. This also makes it difficult to properly check the data provided by individual manufacturers in a timely and adequate manner. Additionally the data can vary in terms of production cost depending on technologies used for production.

ii. Under Marked Based Pricing, the pricing would be based on widely available information in the public domain as against individual manufacturer level production costing data which would result in more transparent and fair pricing.

iii. Under Cost Based Pricing as the controlled prices of formulations of a particular API are determined on a “lowest common denominator” basis, they tend to be clustered within a narrow band. This allows virtually no space for a new entrant to come in at an uncovered price point. As a result, production activity and competition in the product segment tend to stagnate. This is neither good to the consumer-patient nor for industry growth.

iv. The Indian economy is today largely market-driven and, particularly in the area of pricing of manufactured products, prices are determined by market conditions and market forces. Administered prices exist in a few areas, such as pricing of petroleum products and procurement prices of food-grains but these are closely connected with a regime of subsidies paid by the Government. To determine the price on the basis of costing, particularly where the inputs prices themselves are not subject to any form of price control and are determined in the open market by market forces, would indeed be anomalous and would, in the medium and long term, lead to severe distortions, particularly in the product-mix and investment patterns in the industry and there could be a serious possibility of production moving out of controlled drugs into non-controlled drugs. As indicated in para 3.2(ii) above, this has, amongst others, been a factor in the shifting of manufacture away from bulk drugs notified under the DPCO, 1995. This would have serious implications for the availability of NLEM medicines in the future and for the growth and structure of the pharmaceutical industry as a whole. Further the resultant implications of this on the growth and innovation may also impact the industry’s ability to invest in enhancing in capabilities to capture the export potential likely to open up on account of the almost US$ 300 billion worth of drugs (including biological drugs) falling off patent in the US and other western countries up to 2015. In the new policy, where Ceiling Prices will be fixed, there would be ample space for manufacturers to position themselves in an appropriate price band below the Ceiling Price thereby also retain competition in the market.
v. Since the prices fixed of all drugs (bulk and formulations) under the existing DPCO are envisaged to be frozen for one year in the policy with increases allowed up to WPI, the impact of the policy will be an additional impact.

**5.7.8 Principles for Drugs Price Control and Determination in NPPP-2012**

(i) Price regulation would be on the basis of ‘Essentiality’ of the drug as laid down in the “National List of Essential Medicines - 2011” declared by the Ministry of Health and Family Welfare, and modified from time to time, in public interest under Drug Price Control Order.

(ii) Price regulation would be applied only to formulations, i.e. the medicine actually used by the consumers, and not to any upstream products such as bulk drugs and intermediates.

(iii) The Span of Price Control shall be as per the dosages and strengths as listed in NLEM-2011.

(iv) The methodology of fixing a ceiling price of NLEM medicines, by adopting the Simple Average Price of all the brands having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine, will be as per the formula below:

\[
\text{(Sum of prices of all the brands of the medicine having market share more than and equal to 1% of the total market turnover of that medicine) / (Total number of manufacturers producing such brands of the medicine)}
\]

(v) The formulations will be priced only by fixing a Ceiling Price (CP). Manufacturers would be free to fix any price for their products equal to or below the CP. The CP’s would be fixed on the dosage basis, such as per tablet/capsule/standard injection volume as listed in NLEM-2011.

(vi) The Ceiling Price will be fixed on the basis of readily monitorable Market Based Data (MBD). To begin with, the basis for this readily monitorable market data would be the data available with the pharmaceuticals market data specializing company – IMS Health (IMS). Wherever required this data would be checked by appropriate survey/evaluation by the National Pharmaceutical Pricing Authority (NPPA). As the IMS data gives price figures for stockist level prices hence in order to arrive at ceiling Price (which will be the maximum retail price), the IMS

---

price will be further increased by 16% as margin to the retailer so as to arrive at a reasonable ceiling price chargeable from the consumers.

(vii) For drugs not in the IMS data, NPPA would collect data by commissioning the same.

(viii) For the medicines where there is no reduction of price due to absence of competition, the overall percentage reduction in the price of same molecule with other dosage and strength will be applied; otherwise the overall percentage reduction in the price of medicines in the same therapeutic category will be applied.

(ix) The CP for a drug listed in the NLEM would be the Simple Average of Prices as calculated on the basis of IMS data six months prior to the date of announcement of the new National Pharmaceutical Pricing Policy i.e. the “Appointed Date” for bringing the new Policy into effect. For a drug whose data is not available in IMS, the NPPA will commission the data within a reasonable time for determining the Simple Average Prices also on the basis of prices prevailing six months prior to the Appointed Date. Thus the Simple Average Prices data date for the drugs available in IMS data and collected by NPPA would be same. Once the Simple Average Price is fixed, NPPA would monitor its implementation on a continuous basis through a proper methodology and system.

(x) The prices of these NLEM-2011 medicines will be allowed an annual increase as per the Wholesale Price Index as notified by the Department of Industrial Policy and Promotion. It is proposed to fix the 1st April of every year as the reference date for this. Accordingly, on 1st April of every year, companies will be automatically authorized to revise their prices up to the limit of the increase in the Wholesale Price Index for the previous year. In case of decline in Wholesale Price Index, a corresponding reduction in the ceiling price will be obligatory. The NPPA itself will also separately notify the revised ceiling prices as applicable as on the 1st of April each year, and in case any company has fixed the prices not consistent with the revised ceiling prices, the NPPA will take appropriate action to have these revised.

(xi) The Simple Average Price of all the brands of the medicine having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine - the Reference Prices for calculation of Simple Average Price - may also change on an annual basis due to changes in the MAT value. However, there would be no annual revision of Ceiling
Prices on the basis of MAT. Revision of Ceiling Prices on the basis of MAT value would be carried out only once in five years or as and when NLEM is updated/revised. However, the Government will revise the ceiling price of a medicine under NLEM, if there is a significant change in the market structure of the particular medicine even in between 5 years.

(xii) Non-price Control Drugs: Under the existing price control regime, the prices of Non-Scheduled drugs are monitored, and in case the prices of such drugs increase by more than 10% in a year, subject to certain criteria, government fixes the prices of such medicines from time to time. In the proposed policy, all essential drugs are under price control. It would follow that non-essential drugs should not be under a controlled regime and their prices should be fixed by market forces.

However, in order to keep a check on overall drug prices, it is proposed that prices of such drugs be monitored on regular basis, and where such price increase at a rate of above 10% per annum is observed, the Government would be empowered to have the price of these drugs reduced to below this limit, for next 12 months.

(xiii) Imported Drugs: The Ceiling Prices determined for drugs falling under the span of control as in 4(iv) above shall also be applicable to such drugs that are imported. There will be no separate determination of Ceiling Prices for imported drugs falling under the span of control.

5.7.9 Findings

The right to life and health is a fundamental right guaranteed to every person living in India and is not negotiable. But in new patent regime, product patent protection for medicines and agrochemicals creates monopoly and eliminates competition in the pharmaceutical market. Drug companies often abuse the patent monopoly and fix exorbitant prices for the patented medicines in spite of having the guidelines which the companies fail to adopt as they fix the prices arbitrarily. The introduction of product patent thus reduces accessibility and affordability of drugs. The populations specially the down trodden and the poor do not have access to the medicines that could save lives is because the price of health is high, as many medicines are owned by pharmaceutical corporations that either
sell their products at high prices, or request that the developing countries purchase licenses to produce or import those medicines.

In spite of having various regulations and guidelines to fix the prices along with control over the prices of medicines it has not effectively brought down the prices of many generic and essential medicines which are being consumed by the public at large. Many of the patented medicines are out of price control regulations and out of National list of essential medicines. There is no instance where we can see that the patented medicines are being supplied at a government hospital especially cancer medicines either free of cost or at a discounted price. The government has expressed its inability to supply even the generic medicines free of cost in case of dog bite; example Rabipur injection is given at a cost of Rs 100/- in most of the government hospitals in Karnataka. We find a number of examples where government supplies various medicines at a price though minimal but costly to poor patients. So we can clearly make a conclusion that poor patients do not have any voice or say when it comes to the matter of the health sector. Though the government has a duty to protect its subject, but in spite having right to life available to the general public under Article 21 of the Indian constitution when it comes to health issues the right to health is inefficiently implemented. As right to health is not enforceable effectively even when courts have passed an order directing the state to make policies to provide effective health treatment by making a provisos in health sectors in its budget, but in reality enforceability becomes mute as the state duty to protect its people in health issues and policies comes under directive principles of the state policy.

The study on the same issue by the International Intellectual Property Institute (2000) similarly concluded that the problem of access is not caused by pharmaceutical patents. The study concluded that the major factor inhibiting access was inadequate government and private sector finances, essential to the proper functioning of the general healthcare system. The objective is to carefully assess these contrasting arguments, in order to foster a clearer understanding of the complex interaction between both phenomena, and identify specific steps that need to be taken at both national and international levels based on such insight.

The result of this system is an obvious discrepancy between the prices of the medicines and the possibility of those who need them to acquire these required
medicaments. Thus access to essential drugs is a key ingredient for good public health. “The essential drugs” as defined by WHO are drugs that that individuals can afford.” An unnoticed feature of this definition is the conflict between need and affordability of a drug. Whether or not a drug is considered essential must not depend on its price.

5.8 THERE IS A NEED TO AMEND THE EXISTING NATIONAL AND INTERNATIONAL LAWS AND POLICIES TO EXTEND THE FUNDAMENTAL RIGHT TO HEALTH ON PAR WITH THE FUNDAMENTAL RIGHT TO EDUCATION

On the analysis of the above five hypothesis it can be made clear that that is a requirement to amend the constitutional law recognizing right to life which includes right to health is a mere lip service which although recognized and implemented both at the international level in the form of human rights and at the national level the same is backed and supported by the courts in India as well. An illustration of which can be supported by looking at various court decisions in support of ‘Right to health’ a positive move made by the courts recognizing this right coming to the rescue to the people who are in need of it. However the Right to Health is still a dream come true in a country like India as the government has not taken sufficient steps in meeting the needs of the people in respect of Right to health.

Human rights “derive from the inherent dignity of the human person”,324 and establish an absolute minimum standard for the protection of a dignified life for every human being, with a particular emphasis on the most marginalized and vulnerable among them. These rights shall be exercised without discrimination of any kind. While the single patent examiner might have difficulties in providing for decisions that aim at ensuring the human rights of everyone, including the most vulnerable, the drafting of intellectual property rights treaties must include provisions that ensure that the rights of individuals and the interests of the community are appropriately balanced with the rights of the patent rights holders. The TRIPs Agreement allows for adopting legislation, which, including exceptions provisions, for instance legislation that exempts “innocent bystanders” from liability for patent infringements, allows compulsory licenses without any strict procedural requirements in cases of public, non-commercial use, and allows for revocation and forfeiture provisions that provide a sufficiently wide basis for

---

324 Third preambular paragraph to the ICESCR and the ICCPR.
making appropriate decisions. The right holder’s expectations and the predictability of the patent system can be taken into account without sacrificing the wider community interests. Moreover, the rights of minorities and peoples are protected under human rights treaties. Minorities “shall not be denied the right, in community with the other members of their group, to enjoy their own culture”\(^{325}\).

The Provisions relating to intellectual property rights protection makes it more difficult for a minority community to enjoy their culture is problematic from a human rights perspective. People, including indigenous peoples, have rights over their natural wealth and resources. Moreover, both the ICESCR and the ICCPR state: “in no case may a people be deprived of its own means of subsistence”\(^{326}\). Also, this provision, which sets out a collective right and not an individual right, must be taken into account when drafting patent legislation, and when granting individual patents. An appropriate system for the protection of the traditional knowledge of local communities and indigenous peoples could be adopted, based on this provision and article 15.1(c) of the ICESCR.\(^{327}\)

If these “steps” or “appropriate means” are being impeded by the provisions of the TRIPs Agreement, there is a need to assess whether the state has made use of all of the exception provisions of the TRIPs Agreement, and whether there are more provisions that can be applied in order to balance the obligations of the ICESCR better with the obligations of the TRIPs Agreement.

\(^{325}\) The full text of article 27 of the ICCPR reads:

In those States in which ethnic, religious or linguistic minorities exist, persons belonging to such minorities shall not be denied the right, in community with the other members of their group, to enjoy their own culture, to profess and practice their own religion, or to use their own language.

\(^{326}\) The full text of joint article 1.2 of ICESCR and ICCPR reads: All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefit, and international law. In no case may a people be deprived of its own means of subsistence. International Covenant on Economic, Social and Cultural Rights, adopted by the General Assembly on December 16, 1966 and entered into force January 3, 1976. On the right to health, see General Comment 14 of the UN Committee on Economic, Social and Cultural Rights, which analyses the normative content of Art.12 ICESCR: http://www.unhchr.ch/tbs/doc.nsf/symbol

\(^{327}\) The full text of article 15.1(c) of the ICESCR reads: The States Parties to the present Covenant recognize the right of everyone . . . [to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author. The relationship between this paragraph and the other paragraphs of article 15.1 (the right “to take part in cultural life” and the right “to enjoy the benefits of scientific progress and its applications”) is “. . . mutually reinforcing and reciprocally limitative” (United Nations, 2006, paragraph 4). The fact that the paragraph is closely linked to and “. . . dependent on the enjoyment of other human rights . . .” other provisions of the ICESCR and the ICCPR (United Nations, 2006) is obvious, as all human rights are interdependent and interrelated (United Nations, 1993, paragraph 5). Philippe Cullet, ‘Human Rightsand Intellectual Property Protection in the TRIPs Era’ 29(2) Human Rights Quarterly (2007)403–430; p. 425–9
The interests protected by the two treaties must be considered to differ if there is no means to protect the subjects from the strict implementation of IPR protection. There is general agreement that the interests protected by human rights treaties represent a “vital matter”.\footnote{International Law Commission, 1967, p. 217, paragraph 13.}

The interests protected by intellectual property treaties are established by means of instrumental treaties in order to serve higher societal objectives. As stated by the British Commission on Intellectual Property Rights: “We therefore consider that an IP right is best viewed as one of the means by which nations and societies can help to promote the fulfillment of human economic and social rights”.\footnote{Commission on Intellectual Property Rights, 2002, p6}

IPRs are not compatible with the natural-law understanding of property rights adduced to support them. By asserting an IPR in an innovation, the innovator claims not merely rights to the products made from their own materials but also new property rights over the same materials owned by others, who then lose their freedom to convert their materials into the same products.

Such a deprivation of freedom conflicts with the natural-law understanding of property rights in material items, which protects owners against unilateral expropriation by others. If the rights one has to use one’s own material property cannot be diminished by others without the owner’s consent, then there can be no IPRs; that is, no innovator can unilaterally impose restrictions on what others are allowed to do with their own property.

Certain provisions address the interests of the society at large by protecting the individual rights by means of the human rights treaties the provisions on limitations in the ICESCR, says that if the enjoyment of human rights is to be justifiably limited, this can only be done only in accordance to law, according to the nature of the human rights and “…solely for the purpose of promoting the general welfare in a democratic society”.\footnote{The full text of article 4 of the ICESCR reads: The State Parties to the present Covenant recognize that in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law, only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare of the democratic society.}

The main ethical demand on human beings, according to Aquinas, is that “good is to be done and pursued, and evil is to be avoided”.

\footnotetext[328]{International Law Commission, 1967, p. 217, paragraph 13.}
\footnotetext[329]{Commission on Intellectual Property Rights, 2002, p6}
\footnotetext[330]{The full text of article 4 of the ICESCR reads: The State Parties to the present Covenant recognize that in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law, only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare of the democratic society.}
According to Aquinas, the right to life takes precedence over the right to property. For him:

“Whatever certain people have in superabundance is due, by natural law, to the purpose of succoring the poor... Since, however, there are many who are in need, while it is impossible for all to be succored by means of the same thing, each one is entrusted with the stewardship of his own things, so that out of them he may come to the aid of those who are in need. Nevertheless, if the need be so manifest and urgent, that it is evident that the present need must be remedied by whatever means be at hand (for instance when a person is in some imminent danger, and there is no other possible remedy), then it is lawful for a man to succor his own need by means of another’s property, by Access to Life-Saving Medicine taking it either openly or secretly: nor is this properly speaking theft or robbery”.

In the natural law tradition following Aquinas, the right to property or intellectual property is therefore only valid as long as it does not interfere significantly with the right to life. Although Aquinas promotes the concept of property and hopes that the affluent’ benevolence will help the poor, he supports the acquisition of another’s property without their consent in situations of imminent danger to life.

This principle has been upheld by John Locke (1632–1704), one of the most eminent Western theorists on property rights. According to Locke, Charity gives every man a title to so much out of another’s plenty, as will keep him from extreme want, where he has no means to subsist otherwise.

This provision, that the enjoyment of human rights can only be justifiably limited if all three criteria of Article 4 are met, implies that it is perceived to be a positive relationship between human rights enjoyment and the general welfare of the society. Hence, human rights provisions can be part of the public interest considerations, and give legitimacy to these. As was also found with regard to the exclusion and exception provision of the TRIPs Agreement, however, there are strict requirements for the application of these provisions.

The states right to make use of an exception under the TRIPs Agreement can represent an obligation for the state under ICESCR, in order to be able to
comply with obligations imposed by both treaties. The same author observes: “. . . the WTO jurisprudence has not yet clarified the impact of human rights (e.g. to human health and food) on the interpretation of, intellectual property rights guaranteed in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights…” (He continues: “GATT and WTO jurisprudence has so far hardly ever challenged the sovereign right of GATT and WTO Member states to protect the human rights of their citizens through internal and international social rules... if procedural due process requirements have been met”).

Helfer and Austin suggest that the human right to health offers a valuable framework for addressing this gap by: “reframing existing legal discourses that privilege legal rules protecting intellectual property over those protecting individual rights and social values”; “providing a mechanism to hold governments accountable for providing at least minimal levels of health care”; and “emphasizing the need to restructure incentives for medical research and innovation toward the treatment of neglected diseases and the health needs of the world’s poor.”

In one of the cases it was observed in a lawsuit, which was filed in May 2001 at the Thai Central Intellectual Property and International Trade Court by the AIDS Access Foundation (a Thai foundation that provides social support to people with HIV/AIDS) and two patients with HIV against Bristol-Myers Squibb (A global biopharmaceutical company), was believed for the first time a court decision has used the Doha Declaration to protect public health and the rights of patents. It concluded that “injured parties... are

---

337 The Accelerating Access Initiative (AAI), begun in 2000, is a partnership between UNAIDS, the World Health Organization (WHO), the UNChildren's Fund (UNICEF), the UN Population Fund (UNFPA), the World Bank and nine research-based pharmaceutical companies(Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Gilead Sciences, Merck and Co Inc, Pfizer, Roche and Tibotec) that work with governments and other stakeholders to broaden access to medicines for HIV/AIDS via preferential prices and supply of genericdrugs: “Health Partnerships for the Developing World--2008, The R&D Pharmaceutical Industry’s Contribution to the Health-Related UN Millennium Development Goals” http://www.ifpma.org/index.php?id=672
not limited to manufacturers or sellers of medicines protected by patent. Those in need of the medicine are also interested parties to the granting of the patent”. 338

5.8.1 Relation Between TRIPs and Public Health

The general complaint made from developing countries regarding IP is that it has shifted too far in favor of producers. In the case of drugs this means that IPRs have shifted too far towards the protection of the pharmaceutical patents owners.

Patent rights and public health involve also different rationales and values that are not necessarily reconcilable, such as trade and human rights. Although a supportive international framework for the right to health exists through the different United Nations declarations339, and the Millennium Development Goals340, the balance is still in favor of patent rights, favored by a binding enforcement mechanism.

From a legal perspective, the sources of human rights relating to TRIPs are customary international law. The Universal Declaration of Human Rights, and other human rights instruments including the Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic Social and Cultural Rights (ICESCR). The Report prepared by the Office of the High Commissioner of Human Rights entitled “The Impact of The Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights” insightfully survey’s the relevant human rights instruments and their potential application to TRIPs issues341.”


339 See for instance, United Nations, Report of the High Commissioner of the Human Rights Commission on Economic, Social and Cultural Rights, The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, UN Doc, E/CN.4/Sub.2/2001/13, at 14. The argument is made in this study that access to medicine is a Human Right and TRIPs should be interpreted in a way to facilitate access to medicine. See also, Alan O. Sykes, TRIPs, Pharmaceuticals, Developing Countries, and the Doha “Solution”, 3, Chicago Journal of International Law, 47, Spring 2002 at p. 5.


According to the critics, IPRs are not inherent natural rights and should not be treated as such. This debate revolves around the general issue of the monopoly and private rights granted through patents, as opposed to the public interest and social benefits deriving from science and technology. Due to this conflict, patent laws that are strong for protecting private interest are thus weak for protecting the public interest, at least initially.

There is a lack of explicit human rights references in the TRIPs Agreement. This, however, does not imply that human rights are possible to ignore in the context of formulating and enforcing legislation seeking to comply with the TRIPs Agreement.

Three contexts where the WTO could encounter human rights: first, human rights are introduced in order to support trade-restricting arguments; second, if and when general trade restrictions in the form of sanctions can justifiably be imposed due to a state’s gross and systematic human rights violations; third, to what extent human rights protection is weakened due to the obligation to comply with obligations imposed by the WTO.

Regarding the impact of implementation of the agreements under the WTO on human rights realization, the general observation is that a state in order to comply with its other obligations must make maximum use of the exceptions that the TRIPs Agreement allows for.

Different authors have different views on what role human rights can play in the context of the TRIPs Agreement. One recognized intellectual property rights author says: “the human rights side of the TRIPs dialogue may in the longer term have significant effect”. Another author who has a generally positive view on the role human rights can play says that “…human rights per se offer little guidance in defining complex regulatory issues” and that “…human rights, once identified, need to be translated into economic regulations”.

---

342 W Pretorius, in Drahos and Mayne (eds), Global Intellectual Property Rights, 183.
343 Ibid. Pretorius claims that some interest groups are promoting IPRs as natural rights – “rights that have a moral force that somehow elevates them above political challenge”.
344 V Shiva, Protect or Plunder? Understanding Intellectual Property Rights (2001) at 6 (V Shiva, Protect or Plunder?).
345 Clapham, Andrew, Human Rights Obligations of Non-State Actors (Oxford University Press), 2006. see also Harrison, 2007.
The human right to health, protected under various international, regional and domestic constitutional instruments, has served as the starting point for the human rights community’s interactions with access to medicine and the intellectual property regime. A number of human rights institutions and actors have played a critical role in the development of these norms. These include treaty bodies such as the Committee on Economic, Social and Cultural Rights;\(^\text{348}\) inter-governmental bodies such as the U.N. Human Rights Council (formerly the Commission on Human Rights);\(^\text{349}\) and special procedures and individual office holders such as the U.N. High Commissioner for Human Rights\(^\text{350}\), and the U.N. Special Rapporteurs on the rights to Health and Food.\(^\text{351}\) The right to health is fairly well established under international law, in several UN human rights instruments and treaties, as


well as in the 3 regional human rights systems. Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) which best articulates the right to health establishes: “The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” Article 12.2 enumerates non-exhaustive examples of state parties’ obligations: (1) the provision for the reduction of the stillbirth rate and of infant mortality and for the healthy development of the child; (2) the improvement of all aspects of environmental and industrial hygiene; (3) the prevention, treatment and control of epidemic, endemic, occupational and other diseases; and (4) the creation of conditions which would assure to all medical service and medical attention in the event of sickness.”

A number of jurisdictions, both civil and common law, either explicitly provide for the right to health in their constitutions or have interpreted an inter-related right (like the right to life) as including the right to health. In domestic jurisdictions the right to health is protected only in 63 of 184 countries of which data is available. The right to health has been further elaborated in General Comment 14, specifically: (1) social determinants: poverty, inequality, water, sanitation, food, discrimination (gender, race, sexual orientation etc); (2) freedom (from non-consensual treatment, torture and cruel treatment) and entitlements (Access to medicines); (3) essential elements: availability, accessibility, acceptability, quality; (4) obligations of the state to respect, protect, and fulfill rights; and (5) the core minimum obligations.

The recognized human rights are already identified, even if there might be disagreements on the scope of certain of the recognized human rights. Moreover, human rights do give guidance, also in the context of interpreting and managing intellectual property rights. In this context, however, it must be observed that Helfer warns against an “intellectual property balancing paradigm” that he sees developing in the European Court of Human Rights, arguing rather for a “rule of law paradigm” strictly addressing “...arbitrary government conduct.”

---

If one addresses the dispute-settlement system of the WTO, there is general agreement that because the covered agreements must be clarified in light of public international law, human rights are to be taken into account in the dispute settlement system. To “take into account” is stronger than “take into consideration”, but obviously weaker than “apply”\(^\text{355}\). A proper clarification by the dispute-settlement system—which is not considered an interpretation\(^\text{356}\)—must also take into account other relevant treaties also, but an interpreter can only “apply as law” treaties under its jurisdiction\(^\text{357}\). Therefore, the human rights are of specific importance in the dispute-settlement system, and can be taken into account in any clarification of the “covered agreements”.

The opposition comes from different states regarding different treaties. WTO member states considered to be developing countries are eager to see human rights provisions in the fields of intellectual property and services only, and held that human rights applied on trade in goods allows for protectionism, and keeping their good off relevant markets. The reasoning among industrialized states is totally opposite, and they are reluctant to introduce human rights in policy areas of trade other than trade in goods. With a decision-making based on consensus, any state can reject a reference to a human rights provision or principle.

One document referring to substantive ICESCR provisions only included this reference in the preambular paragraph. The paragraph reads:

. . . the obligation to protect and promote the fundamental human rights to life and the enjoyment of the highest attainable standard of physical and mental health, including the prevention, treatment and control of epidemic, endemic, occupational and other diseases and the creation of conditions which would assure to all medical service and medical attention in the event of sickness, as affirmed in the International Covenant on Economic, Social and Cultural Rights.\(^\text{358}\)


\(^{356}\) In the WTO, the Ministerial Conference and the General Council shall have the “exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements” (agreement establishing the WTO, article IX.2), while the mandate of the WTO dispute-settlement system is to “clarify the existing provisions of those agreements” (Dispute Settlement Understanding, article 3.2).

\(^{357}\) For this position, see Marceau, 2002, pp. 786, 795 and 804; contra, see Pauwelyn, 2003a, p. 263, pp. 465–72; Pauwelyn, 2005, pp. 212–8.

\(^{358}\) WTO, 2001d, preambular, paragraph 3.
The human rights reference was not included in later versions of the declaration on the TRIPs Agreement and Public Health\textsuperscript{359}. Also in documents where a broad range of implicit human rights concerns are raised, human rights provisions are not explicitly applied.

An explanation for the infrequent references to human rights provisions in the context of the WTO is to be found in a document from the UN High Commissioner for Human Rights: “...human rights might be associated too closely with trade restrictions. This could work against the wider objective of human rights approaches to trade and development, which place the realization of human rights among the objectives of trade rules”\textsuperscript{360} Other UN documents have applied a more conciliatory approach when assessing the relationship between human rights and the international trade regime.

An explanation derived from an earlier, more general document, where the High Commissioner identifies the following elements in a “human rights approach to trade”: respecting the principle of non-discrimination; promoting popular participation; using human rights impact assessments and consultations with individuals and communities to guide trade rule and policy making; promoting progressive liberalization of trade to promote the progressive realization of human rights; promoting accountability; ensuring corporate social responsibility; and encouraging international cooperation and assistance\textsuperscript{361} Even in the United Nations Declaration on the Right to Development recognizes in its Preamble that ‘development is a comprehensive economic, social, cultural and political process, which aims at the constant improvement of the well-being of the entire population and all individuals on the basis of their active, free and meaningful participation in development and in the fair distribution of benefits resulting there from’ (emphasis added).\textsuperscript{362} In relation to developing countries and economies in transition, the United Nations Millennium Declaration further calls for ‘policies and measures, at the global level, which correspond to the needs of developing countries and

\textsuperscript{359} WTO, 2001a
\textsuperscript{360} United Nations High Commissioner for Human Rights, 2005, p. 15
\textsuperscript{361} (United Nations High Commissioner for Human Rights, 2003, pp. 4–5).
economies in transition and are formulated and implemented with their effective participation’ (para. I.5).³⁶³

All these terms are important for serving the same public interests that the realization of the recognized human rights seeks to achieve. These broad principles are, however, not always easy to apply by the dispute-settlement system, which is mandated to clarify the covered agreements in accordance with customary rules of interpretation of public international law.

Almost as soon as the ink dried, the August 30 Decision rules and requirements were criticized for creating a regime so cumbersome and costly it would be difficult to use. For instance, Ellen’t Hoen of MSF stated, “[The August 30 Decision] involves an awful lot of red tape …. The statement doesn’t say it’s not possible to import generics – it says it’s possible. But the list of conditions attached is almost as long as the trade group’s entire agreement on intellectual property rights.”³⁶⁴

This sentiment was echoed throughout India’s pharmaceutical industry, government, and academic community. In interviews with industry groups, pharmaceutical experts, trade experts and trade economists, government officials, and the WHO regional office, there was a general sense of dissatisfaction with the August 30 Decision. Most prominently, the obligations under the decision were criticized as so “cumbersome” for the producer as to be “practically inoperative.” In addition, Dr. Weerasuriya of the WHO points out that “the process of getting a compulsory license according to that procedure has not yet been tried. It will be on this first attempt that it will become clear whether it is a minefield as in a war or a simple obstacle race as in a school sports meet.”³⁶⁵

There are many complex challenges preventing broad political support for the human rights mechanism. Passing more human rights legislation will not overcome these challenges as they represent fundamental differences in values, or blatant disregard by those in charge.

In traditional international law only states are subjects of the law. The duty to promote and protect health as a human right is therefore assumed to lie with the state, although the liberal expectation is that this duty can only be fulfilled progressively. However, given the conditions of globalization, the changing contexts of the social determinants of health are becoming increasingly supranational, in turn challenging the notion of national duty-holders. Recent additions to human rights legislation have sought to bind non state actors as duty-holders, especially transnational corporations.

5.8.2 TRIPs Agreement, Human Rights and Consumers Rights:

Since the establishment of the WTO and the entering into effect of the Agreement on TRIPs, government official, international bureaucrats, intergovernmental and non-governmental organizations, courts, and scholars have focused more attention on the interplay of human rights and intellectual property rights. The U.N. Sub-Commission on the Promotion and Protection of Human Rights recently noted the considerable tension and conflict between these two sets of rights. To avoid these conflicts, the Sub-Commission recommended “the primacy of human rights obligations over economic policies and agreements”.

In the report assessing the impact of TRIPs on human rights, the High Commissioner of Human Rights also reminded governments that “human rights are the first responsibility of Governments,” citing the Vienna Declaration and Program of World Conference on Human Rights. The international document, which can perhaps be said to constitute the human rights regime, is the Universal Declaration of Human Rights (1948). The Declaration does not expressly refer to intellectual property rights, but Article 27.2 states that “Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic

---

367 One important step in clarifying these responsibilities was taken in the form of Norms adopted in 2003 by the UN Sub-Commission on the Promotion and Protection of HR which include reference to economic, social and cultural rights. Another example, is the “Ethical Globalizations Initiative” which explores with pharmaceutical companies what the right to health and corporate responsibility implies, particularly in relation to patents, pricing and RandD (Robinson, 2004; Hunt 2005). Robinson, M. (2004). Neglected diseases and neglected communities: a human rights perspective. Available at http://www.realizingrights.org/?option=contentandtask +viewid=61, last accessed on 8th December, 2011.
production of which he is the author.” At the same time Article 27.1\(^{369}\) states that everyone has “the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits”. Article 27 thus carries with it a tension familiar to intellectual property law—the tension between rules that protect the creators of information and those that ensure the use and diffusion of information. The recognition of the interests of authors in the Declaration is complemented by the proclamation in Article 17.1 of a general right of property.

This Article states that “everyone has the right to own property” and 17.2 states that “no one shall be arbitrarily deprived of his property”. The implication of Article 17.2 is that states do have a right to regulate the property rights of individuals, but that they must do so according to the rule of law. The status of the right of property in international law raises some complex issues. It does seem uncontroversial to suggest that the right forms part of the norms of international law. States through practices and treaties routinely recognize the property rights of their citizens as well as those of other states and their nationals. Without that recognition, travel, diplomacy, investment and international commerce would be impossible. Schermers concludes that most property rights cannot be included in the category of fundamental human right. His argument assumes that human rights and property rights can be broken up into categories.

Fundamental human rights, he suggests, are “human rights of such importance that their international protection includes the right, perhaps even the obligation, of international enforcement”. In Schermers’ view, most property rights do not fit into this category\(^{370}\). Certainly it is hard to see how intellectual property rights do. He suggests that the only possible exceptions to this are those needs-based personal property rights, without which the exercise of other rights like the right to life would be meaningless. Attempting to put the property right into the category of fundamental human rights also encounters a conceptual problem. Both private international and public international law recognize the right of sovereign states to regulate property rights, to adjust them to economic and social


circumstances. Yet this is precisely not the way in which we think about fundamental human rights norms that prohibit genocide, torture and slavery, norms that at least some scholars argue are part of customary international law. States cannot adjust these norms to suit their convenience. In the case of property, however, not only is it convenient for states to adjust property norms, but it seems vital to the development of their economies that they have the power to do so. It is for this kind of reason that the European Commission on Human Rights concluded that the grant under Dutch law of a compulsory license in a patented drug was not interference in the patent holders thinking about the right of property in the context of human rights reveals nicely the “paradox of property”. At one level it is inconceivable that the development of human personality and the protection of individual interests within a group can take place in the absence of property rules that guarantee the stability of individual possession. Yet within the context of the social group no other rules require the continuous adjustments that the rules of property do. Modern governments continuously change the rules relating to the use of land, personal chattels, tax, welfare programmes and so on. In modern societies property rights are in a constant state of adjustment. They are the means by which governments solve externality problems. It is for this reason that, when a general right of property is recognized in a human rights instrument, it is made subject to some sweeping public interest qualification. The Rights provided under Article 1 of Protocol 1 of the European Convention on Human Rights states that the “compulsory license was lawful and pursued a legitimate aim of encouraging technological and economic development”.

Ideally, the human rights community and the intellectual property community should try to harmonize the conflicting issues. The two communities have a great deal to learn from each other. Viewing intellectual property through the eyes of human rights advocates will encourage consideration of the ways in which the property mechanism might be reshaped to include interests and needs that it currently does not. Intellectual property experts can bring to the aspiration of human rights discourse regulatory specificity. At some point the diffuse principles

that ground human rights claims to new forms of intellectual property will have to be made concrete in the world through models of regulation. These models will have to operate in a world of great cultural diversity. Moreover, the politics of culture is deeply factional, globally, regionally and locally. It is in this world that the practical issues of ownership, use, access, exploitation and duration of new intellectual property forms will have to be decided. It is here that intellectual property experts can make a contribution 373.

The right to health is a fundamental part of our human rights and of our understanding of a life in dignity. The right to the enjoyment of the highest attainable standard of physical and mental health, Internationally, it was first articulated in the 1946 Constitution of the WHO, whose preamble defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. The preamble further states that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.”

The 1948 Universal Declaration of Human Rights also mentioned health as part of the right to an adequate standard of living (Art. 25). The right to health was again recognized as a human right in the 1966 International Covenant on Economic, Social and Cultural Rights. Since then, other international human rights treaties have recognized and conferred the right to health or to elements of it, such as the right to medical care. The right to health is relevant to all States: every State has ratified at least one international human rights treaty recognizing the right to health.

Coming to the issue on consumers rights the same U.S which has forced to adopt strict compliance to the IPR regime advocates the rights of consumers and has identified the rights. The UN General Assembly adopted the guidelines on protecting the human rights on 9th April, 1985, and is also called as “Chapter of Human Rights” which includes Right to Safety, Right to Information, Rights to Choose, Right to be Heard and Right to Consumer Education. The rights clearly shows that a person should not be discriminated or exploited unfairly and charge an exorbitant prices from the consumers on the product they offer moreover the consumers should be provided an

opportunity to choose the alternatives this can be done only if there are availability of alternatives where as the grant of patent on products ensures that the consumers have no choice to choose. In case of the product patent regime when it provides the patent holder an exclusive right to manufacture and sell the product at a price fixed at his discretion again it is nothing but a violation of human rights. So efforts should be made to address the issue in a serious manner.

5.8.3 Human Rights to Health

Right to health is definitely human right to be protected effectively in this regard, Former United Nations Secretary General, Kofi Annan says that “It is my aspiration that health will finally be seen not as a blessing to be wished for, but as a human right to be fought for.”

A fundamental distinction in human rights law is between the so-called civil and political rights (“first generation” rights), on the one hand, and socio-economic rights (“second generation” rights), on the other. The former are “negative” rights that curb state power by imposing a duty on it not to act in certain ways; the latter are “positive rights” that impose obligations on the state to secure for its citizens a basic set of social goods - education, health care, food, water, shelter, and access to land and housing.\(^{374}\)

The right to the highest attainable standard of health (the right to health) was first reflected in WHO’s Constitution and has been firmly endorsed in a wide range of international and regional human rights instruments.\(^ {375}\) The most authoritative interpretation of the right to health is outlined in Article 12 of the ICESCR, which has been ratified by about 150 Countries.\(^ {376}\)


\(^{375}\) Most HR and health issues are thoroughly covered at the website of the United Nations Commission on HR available at www.unchr.ch. Health-related information, including explicit references to HR, is available at the website of the WHO (www.who.org). The Francois-Xavier Bagnoud Center available at http://www.hsph.harvard.edu/fxbcenter/international_hhr.htm and Global Lawyers and Physicians for HR have collaborated in the preparation of a ‘Perspectives in Health and Human Rights’ Gruskin (eds) (2005) which is accompanied by a special website containing links to documents, organisations and other references on health and human rights (http://www.glphr.org/resources/appendix.). The University of Minnesota Human Rights Collection also provides a valuable list of documents on bioethics (see http://www1.umn.edu/humanrts/links/bioethics.html)

The pursuit of economic growth often has disastrous consequences for human health, particularly in the areas of food safety and access to lifesaving medicines. These aspects of the human right to health form the basis for our two core rights to health in an RTA. The ICESCR ensures the right to “the enjoyment of the highest attainable standard of physical and mental health,” as well as the right to enjoy the fruits of scientific development. As explained in the Universal Declaration, every person “has the right to a standard of living adequate for the health and well-being of himself and of his family.”

The manner in which creative works, cultural heritage, and scientific knowledge are turned into property has significant human-rights implications. Beginning with the provisions of the American Declaration on the Rights and Duties of Man, key international human-rights instruments have acknowledged that intellectual products have an intrinsic value as an expression of human creativity and dignity. Several enumerate the right of authors, creators, and inventors to some form of recognition and benefit from their intellectual products.

Today, the right to health is firmly embedded in international, regional and national human rights declarations. This right was first introduced in the 1946 World Health Organization’s Constitution and was later followed in Article 25 of the Universal Declaration on Human Rights.

The WHO Constitution stated that “the enjoyment of the highest attainable standard of health” is “a fundamental right of every human being without distinction of race, religion, political belief, economic or social condition.” Two regional agreements

---

378 ICESCR, , at arts. 12 and 15(1).
379 Universal Declaration, , at art. 25 (1).
381 [25(1)] “Everyone has the right to a standard of living adequate for the health and well-being 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” (United Nations Department of Public Information 2005).
383 WHO 1946, 2
with similarly embedded rights include the European Social Charter (Art. 11) and the African Charter on Human and Peoples’ Rights (Art. 16). These declarations legitimize the basic right to access medical care and affordable drugs.

Similarly, IP rights are defined under the UDHR as a human right, in so far as they provide the basis or preconditions for essential participation, cultural freedoms, and innovation. This right to IP is seen to induce future creation by protecting both the moral and material right to intangible property. This right was further condoned by the European Community in their statement purporting “that intellectual property and public health can and should be mutually supportive because without effective medicines, public health policies would be hampered”.

Article 27 of the Universal Declaration of Human Rights (UDHR), states that ‘everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author’. This right is linked to another provision of Article 27: ‘Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.’ Building on Article 27 of the UDHR, the International Covenant on Economic, Social and Cultural Rights (hitherto ICESCR or the Covenant) has similar provisions. Article 15 (1) (c) requires States parties, the countries which have ratified this instrument, to recognize the right of everyone ‘to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.’ Also like the UDHR, other components of Article 15 link this obligation to the rights ‘to take part in cultural life’ and ‘to enjoy the benefits of scientific progress and its applications.


Article 27 of the UDHR notes that: “1. everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits. 2. Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author” (United Nations Department of Public Information 2005)

European Commission 2001, par. 2


‘To achieve these goals, the Covenant mandates that States parties undertake a series of steps. These include ‘those necessary for the conservation, development, and diffusion of science and culture’. States parties are also directed to ‘undertake to respect the freedom indispensable for scientific research and creative activity.’ The centrality of intellectual property to almost every sphere of economic life means that international treaties, national legal codes, and judicial decisions about intellectual property can have significant ramifications for the protection and promotion of human rights. This is particularly the case for the economic, social, and cultural rights enumerated in the Covenant. Thus, as various economic actors rush to stake claims over creative works and forms of knowledge, human rights are being trampled. Noting that actual or potential conflicts exist between the implementation of the TRIPs Agreement and the realization of economic, social and cultural rights, the United Nations Sub-Commission on the Promotion and Protection of Human Rights adopted a resolution addressing this topic at its August 2000 session. The resolution affirms that the right to protection of the moral and material interests resulting from any scientific, literary or artistic production of which one is the author is a human right, subject to limitations in the public interest. It declares that: since the implementation of the TRIPs Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination, there are apparent conflicts between the intellectual property rights regime embodied in the TRIPs Agreement, on the one hand, and international human-rights law, on the other. It reminds all governments of the primacy of human-rights obligations over economic policies and agreements. Furthermore, it makes a number of recommendations, among them that the WTO and particularly its Council on TRIPs take existing state obligations under international human rights instruments fully into account during its ongoing review of the TRIPs Agreement. The resolution also requests governments to protect the social function of intellectual property in accordance with international human-rights obligations when shaping national and local legislation.

---

Since its inception the UN has focused on classic civil and political rights, such as the right to a fair trial. However, in 2000, the UN began to address cases of historical neglect when the UN Committee on Economic, Social and Cultural Rights, which monitors the Covenant, adopted a General Comment (14) on the right to health that further clarified the nature, scope and content of the right to health.

The General Comment 14 of ICESCR sets out four criteria by which to evaluate the right to health: availability, accessibility (affordability), acceptability (medical ethics) and quality. This Comment acknowledged that health promotion goes beyond the health sector and that coordinated, multi-sector action is necessary to foster greater equity in health, income and social policies.

The Ottawa Charter\textsuperscript{391} provides a common understanding of health promotion internationally which reflect the human rights ideology. It was developed at the first International Conference on Health Promotion meeting in 1986 as a charter for action to achieve health for all by the year 2000 and beyond. The Ottawa Charter built on the progress made through the Declaration of Primary Health Care at Alma Ata, the World Health Organization’s Targets for Health for All document, and debate at the World Health Assembly on moral action for health.

Health has a mandate to focus on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, as reflected in Article 25 (1) of the Universal Declaration of Human Rights, Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), Article 24 of the Convention on the Rights of the Child (CRC) and Article 12 of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), as well as on the right to non-discrimination as reflected in Article 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination (ICERD).

The UN Special Rapporteur is mandated to apply a gender perspective and to pay special attention to the needs of children in the realization of the right to health. The role also serves as a useful political tool to apply pressure to developed countries to remove TRIPs-plus from FTAs. For example, in 2005 a collective of international NGOs wrote to the Special Rapporteur citing the impact on the right to health, as interpreted by Article 12 of the ICESCR, for an urgent appeal to stop

\textsuperscript{391} For a description of the Ottawa Charter see WHO/HPR/HEP/95.1 at www..WHO.int
European-FTA member states (Switzerland, Norway, Iceland and Liechtenstein) from imposing TRIPs-plus rules in an FTA with Thailand.392

In the early 2000’s, the UN human rights system began addressing trade laws and practices in relation to human rights law. The Commission on Human Rights in 2001 adopted a resolution on access to medication in the context of pandemics such as HIV/AIDS393 which reaffirms that, in this context, access is a fundamental element for the progressive realization of the right to health. States are called upon to promote the right to health indicators: availability, accessibility and affordability for all, without discrimination for treatments, and to adopt legislation, or measures, to safeguard access to pharmaceutical and medical technologies, from any limitations by third parties.

The effect of TRIPs-plus provisions would raise drug prices, limiting treatment for the high (800,000) HIV/AIDS population394. This would also mean there was no going back as HIV-positive people inevitably develop resistance to first-generation drugs, the public health services will be morally and legally obliged to find new ways to ensure access to second- and third-generation treatments to keep these people alive and healthy.

It was observed that in reaching decisions under Art XX, the Appellate Body has shown willingness to consider extra-textual materials such as multilateral agreements and conventions when weighting and balancing competing priorities. The right to health, enshrined in the International Covenant on Economic, Social and Cultural Rights (‘ICESCR’), appears to directly conflict with the right to intellectual property protection with regard to the need to access essential pharmaceuticals395. However, the GATT Art XX case law shows that, to date, the ‘right’ to liberalized trade trumps the right to environmental protection.

392 Personal correspondence with field research interviewee, “Letter to UN Special Rapporteur on the right to health regarding the forthcoming EFTA-Thailand negotiations”, 20/6/05.
393 United Nations Commission on HR resolution 2001/33: access to medication in the context of pandemics such as HIV/AIDS (E/CN.4.RES.2001.33), available www.unchr.ch
The fact that human rights treaties and the provisions contained therein have a “constitutional” nature, which implies that these treaties prevail over ordinary contract-based treaties, is not challenged. The challenge is to identify a correct and proper use of human rights provisions in treaty formulation, in the adoption of legislation nationally and in the proper taking into account done by the dispute-settlement system. Human rights represent relevant rules of international law, which are to be taken into account in treaty interpretation, in accordance with the Vienna Convention on the Law of Treaties, Article 31.3(c). A criterion for the taking into account of such a “rule” outside of the WTO is that the non-WTO provision “. . . may be evidence of specific international relevance”\(^{396}\).

The doctrine of state sovereignty precludes extra-territorial obligations concerning the right to health, as a state’s obligation in this area applies only to individuals within its own territory or otherwise within its jurisdiction. Just as there is no single document that is universally recognized as the international environmental law ‘constitution’,\(^{397}\) the absence of a centralized international health law institution with adjudication and enforcement mechanisms renders many of these multilateral instruments merely hortatory, with variable enforceability at state level.

In addition, prior GATT-WTO jurisprudence has indicated that positive rights cannot easily be recognized and acted upon through the dispute settlement process. Indeed, economic, social and cultural rights are less justifiable than, for example, civil and political rights because they require policy decisions on relative government funding appropriations for different sectors\(^{398}\). While it is a fundamental legal principle that private property rights can be curbed if doing so serves a greater public purpose, differences occur in determining what constitutes a ‘greater public purpose’\(^{399}\). “In relation to access to essential pharmaceuticals, a

\(^{396}\) Gabrielle Marceau, *WTO Dispute Settlement and Human Rights*, 13 EUR. J. INT’LL. 753, 754 (2002) (“It is suggested that a good faith interpretation of the relevant WTO and human rights provisions should lead to a reading of WTO law coherent with human rights law.”), p782


\(^{398}\) Article 2(1) of the ICESCR obligates each state party to take the necessary steps ‘to the maximum of its available resources.’ Interpretations of the universal right to health point to the right to access medical treatment for serious illnesses; meaning that, in theory, a developing country government who appropriates funds for intellectual property protection and enforces intellectual property rights violates the right to health for its citizens.

crude balancing test weighing up the relative value of the lives of HIV-AIDS sufferers in sub-Saharan Africa versus the economic interests of the corporation that invented the pharmaceutical seems repugnant to notions of justice, outside of the neo-liberal paradigm.  

In accordance with international human rights law, it should therefore be seen as a core human rights entitlement to receive minimally adequate health care. Under these rights, governments have a range of duties with regard to medicines, which include, inter alia, ensuring the affordability of essential medicines and preventing restrictions on access. In this light, government use of TRIPs flexibilities to provide access to lifesaving medicines should be seen as necessary to fulfill their duties under rights to health and life. In cases where the adoption of patent provisions in TRIPs-plus Free-Trade Agreements will result in the loss of life due to limited access to lifesaving drugs, this action should be seen as a violation of these duties.

Support for the idea that the enforcement of trade-related intellectual property rights may violate human rights is found in the work of Thomas Pogge. He argues that those who uphold social rules, such as trade and economic policies, can violate human rights when these rules “Foreseeable and avoidably deprive human beings of secure access to the objects of their human rights.  

Pogge argues that the present international patent system fulfills these conditions. While Pogge’s argument that current trade rules violate the human right to health rests on ethical and not legal grounds, it is suggested that the legal basis of this claim is increasingly well established. Certainly this statement must contend with common arguments disputing the legal force of a “right to health.” Perceptions that such a right would create limitless entitlements and place indeterminate duties on governments are somewhat reinforced by the international law formulation of this right as an entitlement to “the highest attainable standard of health,” with state duties limited to progressive realization to the maximum of available resources.

Minimum core duties under the right to health are roughly consistent with essential primary health care, and include providing essential drugs as defined by

---

the WHO. This implies that the duty to provide medicines requires states to prevent corporations from obstructing access, including through prohibitive pricing. Indeed, ICESCR indicates that these duties extend to ensuring that international agreements do not adversely impact the right to health either domestically or in other countries, and that a failure to do so violates the right. The overarching obligation imposed by the Covenant is “to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.” It is important to note that the obligation is not absolute states have to move “progressively” towards the full realization of the right, and they have to do so within their available resources.

This implies that states must use TRIPs flexibilities to fulfill their duties under the right to health, and that they must negotiate less restrictive intellectual property rights in bilateral free-trade agreements. Yet while governments are the primary duty holders under international human rights law, they are not the only actors obligated to ensure the realization of this right. All members of society, including the private business sector, have responsibilities regarding the realization of the right to health. In addition, states hold international obligations with regard to the right to health, which the committee suggests include duties not to obstruct this right in other countries, to prevent corporations from violating it elsewhere, and to ensure that international agreements do not adversely impact the right to health.

However, we must consider the competing societal interests that may be found at the intersection of trade and health. On one hand, a healthy population is necessary to create a productive and prosperous economy and thus is fundamental to trade and sustainable development. On the other hand, the human right to health must be balanced against the human rights to property and self-determination as


ICESCR, Art. 2(1).

Compare Art. 2(1) of the International Covenant on Civil and Political Rights, GA res. 2200A (XXI), 21 UN GAOR Supp. (No. 16) at 52, UN Doc. A/6316 (1966); 999 U.N.T.S. 171; 6 IL.M. 368 (1967); “Each State Party ... undertakes to respect and ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant.”

Committee on Economic, Social and Cultural Rights (CESCR), General Comment 14, para. 42, August 11, 2000; available atwww.ohchr.org/english/bodies/cescr/comments.htm.
represented in intellectual property rights (IPR) protections. For this reason, it is important that RTAs (Regional Trade Agreements) not only take care to ensure that trade policies avoid adverse impacts on public health—and even that they take reasonable steps to promote health—but also that IPRs be preserved.\footnote{Stephen Joseph Powell and Trisha Low, Beyond Labor Rights: Which Core Human Rights Must Regional Trade Agreements Protect? Available at www.icai.org.} It is imperative that governments learn the consequences of globalization on issues such as food safety and access to medicines, in order to determine policies to best deal with them.\footnote{The Effects of Globalization on Working Conditions in Developing Countries: An Analysis Framework and Country Study Results, Employment Policy Primer No. 9 (2008), available at http://siteresources.worldbank.org/INTLM/214578-1103128720951/21692675/EPPNoteNo9_Eng.pdf [hereinafter Globalization on Working Conditions].} These issues affect not only individuals, but states and the global economy. We find that two core rights to human health, the right to essential medicines and the right to food safety have such close linkage to trade that RTAs must explicitly account for them.

The *sine qua non* of a healthy population is its access to essential medications, which will prevent or control epidemics and plagues. Article 4 of the Doha Declaration on TRIPs and Public Health,\footnote{WTO, Declaration on the TRIPs Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001), at para. 4 [hereinafter Doha Declaration].} later memorialized as an amendment to the Agreement,\footnote{Amendment of the TRIPs Agreement, Decision of Dec. 8, 2005, WT/L/641.} recognizes a state’s right to protect public health and to promote access to medications for all of its citizens despite the IPRs protected by the TRIPs Agreement. The WHO defines essential medicines as medications that “satisfy the priority health care needs of the population.”\footnote{WHO Policy Perspectives on Medicines: The Selection of Essential Medicines 1 (2002), available at http://archives.who.int/tbs.sel/s2296e.pdf (last visited Apr. 11, 2012) [hereinafter WHO Essential Medicines].} This broad recognition of the link between trade and essential medicines confirms its place in RTAs (Regional Trade Agreements) as a core right to human health.

It seems clear that meaningful observance of human rights to health in this area requires the prioritization of direct protection of those rights. This can be accomplished through treatment with existing medicines over protection of business incentives to innovate new medicines and treatments, which has only an attenuated benefit to human health rights. Recognizing the need for access to essential medicines as a fundamental aspect of the right to health would ensure medicines with regard to the prevalence of a disease. The concept of essential medicines
means those pharmaceuticals that satisfy the priority health care needs of the population, those that address diseases reaching epidemic proportions or that present a threat to public health.

5.8.4 Findings

Since the TRIPs Agreement has not addressed properly all the issues with regard to the use of the flexibilities in a proper manner as there are cumbersome procedures that the countries should have to follow the failure of which would lead to litigation between the patent holders and the government of member countries due to infringement of patent rights on the allegation of wrongly using the exceptions and not complying strictly to the rule included in the TRIPs Agreement. This all leads to multiplicity of litigations due to which utilization of flexibilities would not work as expected. As the developed countries allegations on the developing countries is that these countries are taking the fruits of the innovations made by them at free of cost as exceptions are used without proper interpretations and strict implementations of the TRIPs Agreement and that it is not due to TRIPs but it is the member countries inability to provide health care facilities especially supply of medicines is the main cause that many people do not get proper medication. Hence If at all the governments are really concerned to meet the people’s expectations with regard to health supplements a separate legislation recognizing “Right to Health” is required in the light of the TRIPs Agreement.

412 See generally WHO Essential Medicines Summary.