Chapter-2

Review of Literature
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2.1 INTRODUCTION

Although there are ample of literature available on TRIPs, intellectual property rights and its requirements particularly its economic impact on developing countries, but there is very little has been written about strategic importance intellectual property rights on pharmaceutical industry particularly with special reference to India.

The World Trade Organization (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, in force since January 1995, establishes that all WTO Members must grant patents for all technological fields, including pharmaceutical products and processes. As patent protection can hamper access to medicines, WHO recommends for its Member States to incorporate into their Intellectual Property legislation (IPR) all TRIPS flexibilities, which enable governments to be more efficient in the field of public health.

The subject of intellectual property rights has made its way from the annals of legal and economic journals to the mainstream lexicon. Intellectual Property is one of the fastest growing fields within studies because it impacts various aspects pertaining to the economy of country and also various industry practices.
This chapter represents a selective review of literature on WTO, TRIPs, and how it has impacted development a developing country perspective specially for India. It covers empirical literature on the role of IPP regime in influencing innovative activity, trade, FDI and licensing activity especially in developing countries.

On the international level, there is deep concern that patents and the adoption of the Trade Related Intellectual Property Rights (TRIPS) agreement through the World Trade Organization (WTO) may continue to oppress developing countries by giving industrialized nations another method of extracting profits from the already-burdened countries.

2.2 LITERATURE ON INTERNATIONAL SCENARIO ON THE POSSIBLE IMPACT OF IPR REGIME

There is an article discussing the impact of new patent regime on biological medicine and public health was published in Chicago-kent journal of intellectual property, entitled “The Regulation of Biologic Medicine: Innovators’ Rights And Access To Healthcare”\(^3\), Volume 6, Issue 1, 2006. This article compare the situation US after implementation of new patent law and introduction of new act vis-à-vis the situation likely situation in India.
However, this article does not touch the vital issues in public health concern and also the strategic importance of intellectual property. Rather, this article went on to discuss the regulatory framework in India which would affect the biological medicine in general.

A paper published by Dr. Brook K. Baker in Health GAP, Global access project entitled, “INDIA’S 2005 PATENT ACT: Death by Patent or Universal Access to Second- and Future-Generation ARVs?” This paper discusses the various changes of Indian patent act and its impact on universal access to anti-retroviral.

This study is specifically restricted to anti-retroviral. This paper also discusses some of the flexibilities provided in the TRIPs agreement which can be utilized for the benefit of the nation. This paper predicts data exclusivity provision as threat to the access to medicines.

However, this article remains silent about the strategic impact of IPR regime. Moreover the study also does not provide the overview of the amendments in Indian patent act which is very crucial for studying its complete impact. This article merely addresses the negative impact of the changing product patent regime without giving any suggestions, recommendations which are required to minimize the likely adverse impact.
In another study which was done by an NGO, 3D, based in Geneva, has also studied the TRIPs implication for access to medicine for developing countries perspective, specially discussing the Doha declaration. According to this study the price of drugs would be likely to increasing. The emphasis of this study was to use the flexibility provided in TRIPs regime in such a way that it minimizes its adverse impact.

Moreover, this study also was not focusing the strategy dimension which the TRIPs implementation a brought in the pharmaceutical business model. Moreover the study was in general for all the developing countries taking the account of macro economic scenario and was not India centric.

There are also several reports which are published by several agencies of World Health Organisation discussion the Intellectual Property Rights and it public health concern describing the macro scenario taking into account the implication on developing and least developed countries.

This report was published in April 2006, was the first report of its kind, mandated by the World Health Organization (WHO), and produced by an independent Commission. It analyses the relationships between intellectual property rights, innovation and public
health, mobilizing the available evidence and analysis and the perspectives of different stakeholders.

It makes recommendations aimed to promote innovation (i.e. new diagnostics, vaccines and medicines) relevant to the needs of sick people in developing countries, and the accessibility of health-care products in developing countries. The Director-General of WHO established the Commission in February 2004. The first meeting of the Commission was in April 2004, and the last meeting in January 2006. The Commission's origin lies in resolution WHA56.27 which was adopted at the Fifty-sixth World Health Assembly in May 2003.

The resolution requested WHO "to establish the terms of reference for an appropriate time-limited body to collect data and proposals from different actors involved and produce an analysis of intellectual property rights, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries..."

The report particularly states that Intellectual property rights are a general incentive provided by governments to promote innovation in all fields. In respect of public health,
they are embedded in a set of other incentives which influence the pattern of innovation. They need to be looked at as part of a bigger picture.

In particular, because the market demand for diagnostics, vaccines and medicines needed to address health problems mainly affecting developing countries is small and uncertain, the incentive effect of intellectual property rights may be limited or non-existent.

Because intellectual property rights may not be an effective incentive in this area, there is a need for other incentives and financial mechanisms to be put in place and for collaborative efforts between different stakeholders.

Without access to the products of innovation, there can be no public health benefits. Defining the conditions by which products can be accessed is therefore an important aspect of the report.

There has been significant progress in recent years, in particular initiatives taken by different stakeholders to promote innovation in health-care products e.g. increased funding by foundations and the formation of public-private partnerships for product development.
However, this report completely ignores the strategic significance of intellectual property management and it does not discuss the impact of implementation of change in intellectual property regime on pharmaceutical business model.

There exist another study report by commission on intellectual property rights, innovation and public health entitled “The Use of Flexibilities in TRIPS by Developing Countries: Can they promote Access to Medicines?” published on August 2005.

This study was commissioned to: (1) examine the extent to which the flexibilities contained in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) have been incorporated into the legislation of developing countries and the extent of the actual use for public health purposes; (2) review the stated trade policies of major industrialized countries, particularly the United States (US) and the European Union (EU), vis-à-vis developing countries to determine whether these take adequate account of the public health priorities of developing countries; and (3) examine the practical effect and implications of recently concluded bilateral and regional free trade agreements (FTAs) for public health protection in developing countries.
Overall, the study finds that the use of TRIPS flexibilities can promote access to medicines in developing countries. Most developing countries whose laws and practices we reviewed had incorporated one or more of the TRIPS flexibilities and there has been increasing usage of these flexibilities such as compulsory licensing for public health purposes. There remain, however, important gaps both in terms of incorporation and usage of flexibilities, which will need to be addressed if the TRIPS flexibilities are to be used effectively across the developing world.

With respect to the stated trade policies of the US and the EU relating to the protection of intellectual property in third countries, especially developing countries, we find that although some concern for the public health needs of developing countries is reflected, in general, the policies fail to adequately take into account the public health priorities of developing country trading partners. Finally, with respect to FTAs, we find that a number of provisions in recently concluded FTAs between developed countries (essentially the US) and developing countries, pose a real risk of undermining the effective use of TRIPS flexibilities in developing countries for public health purposes.

The analysis and conclusions in the study regarding the use of TRIPS flexibilities by developing countries, the intellectual property-related trade policies of the US and the EU and other developed countries, and the implications of FTAs for public health protection in developing countries, are underpinned by a number of public health principles for the
implementation of intellectual property in the area of pharmaceuticals. It is in this context that we make a range of recommendations for the consideration of the Commission on how intellectual property regimes could be better implemented, used and/or reformed, nationally and internationally, to facilitate the development and access to medicines in developing countries.

This study was also aimed at macro economic scenario particularly based on the effect of intellectual property regime implementation in developing countries and lacks a specific focus to India and does not consider the country specific factor and socio economic factors that affects the implementation specially in India. Moreover, it only focuses to public health concerns and ignore the business strategy aspects.

Another paper which was published in October 2005 by Dwijen Rangnekar, entitled “No Pills for Poor People? Understanding the Disembowelment of India’s Patent Regime”. The paper discusses various aspects of Indian Patent Act starting from 1970 till 2005.

The paper begins with a discussion of India’s Patent Act, 1970 (henceforth, IPA) where key provisions are discussed and presented in terms of the consequent transformation of the pharmaceutical sector. This is followed by an analysis of recent changes in and
around the Doha Declaration that have changed the context of TRIPs- implementation. It is within these two frames that the third amendment is presented and analysed. A conclusion closes the paper by drawing attention to changing perceptions and governmental ambivalence with respect to intellectual property and noting how this might have constrained the opportunities to launch a radical challenge to the proposed amendments of IPA.

This paper only touches the public health concern from the government’s perspective and does not take into account the perception of medicos which are prime influencers in prescribing medicine. Moreover this paper remains silent about the strategic significance of intellectual property and the likely paradigm shift in pharmaceutical business.

An article published in intellectual property quarterly update which is jointly published by South center of an intergovernmental organization of developing countries and centre of international environmental law discusses the Doha declaration in a great details\textsuperscript{10}. At the WTO, the Doha Declaration defined the relationship between IP protection and public health.
This article went on to state that the Declaration affirmed that the TRIPS Agreement can and should be interpreted and implemented in a manner that supports WTO Members right to protect health, particularly ensuring access to medicines for all.

Further, this paper states that the key issue at Doha, which the Ministers, however, failed to resolve was how countries which desired to exercise the right to protect public health through the use of compulsory licensing but had insufficient or no manufacturing capacity in the pharmaceutical sector could be assisted. Consequently, under paragraph 6 of the Declaration, the Ministers, recognizing that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing instructed the Council for TRIPS to find an expeditious solution to the problem. Based on this mandate, and due to mounting pressure towards the Fifth WTO Ministerial Conference in Cancun in September 2003, the WTO General Council adopted a decision to implement paragraph 6 (the Decision) on 30 August 2003.

This was a general article and it lacked focus on specific issues which are largely affected by the country specific factors. Moreover, it does not touches any of the issues are undertaken in the present study.

In another study entitled “Struggling to Balance Free Trade with Access to Medicines in the post-TRIPS Era throughout the Arab World” authored by Othoman Mellouk,
Association de Lutte Contre le Sida (ALCS), Marrakech, the emphasis on effect of post-TRIPS era in Arab world.

This article states that Access to medicines in the Arab world will in the future depend on how these countries can deal with the challenges of world trade, and in particular the issue of how to protect intellectual property (IP) without compromising public health needs, especially in terms of access to medicines at affordable prices.

Many countries in the region are members of the WTO and are obliged to apply the TRIPS Agreement as from January 1st 2005, with all its constraints concerning IP rights. More stringent measures are being imposed on these countries as a direct result of the increase of bilateral and regional agreements, especially by the European Union and the United States.

This article further states that it is widely accepted today that strengthening IP protection has an impact on the price of patented medicines, and subsequently on the availability of affordable drugs, especially in developing countries. Arab countries, some with fragile health systems and populations with limited purchasing power, will soon be confronted with the real problem of access to medicines and the attendant consequences for public health.
It is becoming increasingly urgent to begin reflecting upon this problem in the region so that adequate policies can be put in place in order to protect public health, as stipulated in the Doha Declaration in 2001.

The purpose of this paper was to consider some of the options available to these countries so that they can fully benefit from the flexibilities afforded to them by the TRIPS Agreement and thereby secure fairer access to medicines. These flexibilities have not always been taken into consideration by countries when implementing the TRIPS Agreement in national patent laws, as seen in the examples of Egypt and Morocco.

This paper also focused on the Free Trade Agreements (FTA) with the United States as the greatest danger to the right to health in the region, as these agreements are the most restrictive of their kind in terms of IP rights. It details in particular the Morocco-US FTA, concluded in 2004, which includes several 'TRIPS+' provisions, and which now serves as a model for future negotiations with other countries.

The main focus of this paper was Arab countries and how these countries would be affected in post-TRIPS era. Therefore, this article does not destroy the novelty and uniqueness of the present study.
In another paper which was published by Meir Perez Pugatch, University of Haifa in October, 2004 entitled “Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access”\textsuperscript{12}. This paper particularly discusses a specific TRIPs provision given in Article 39.3 which relates to data exclusivity.

The paper provides a brief overview of the nature of data exclusivity; elaborates on the economic significance of data exclusivity; considers the implications of data exclusivity relating to the clash of interests between research-based and generic-based pharmaceutical companies; discusses the December 2003 resolution of the European Parliament on data exclusivity; adds some further insights on data exclusivity as a North-South issue, particularly with regard to the recent free trade agreements (FTAs) and regional trade agreements (RTAs) between developing countries and the US.

However, this paper does not elaborate other provisions which are equally important in post-TRIPs era. It also remains silent about the public health concern. Moreover, this paper was not India specific, rather it discusses the data exclusivity in global context.

In another study paper by Karin TIMMERMANS; World Health Organization, Indonesia
This article critically discussed the health concerns in post-2005 era and the measure which affect the government decisions in implementation of TRIPs provisions in post-2005 era.

This article recommends appropriate intellectual property laws, which enable them to make full use of the flexibilities in TRIPS. They may also have to rely on other, equally unfamiliar but potentially countervailing legal and regulatory mechanisms, such as competition law. But it is at least as crucial that countries learn how to make use of these sophisticated legal tools.

This paper also lacks focus on strategic issues as well as the socio economic factors which affect the ever changing environment as well. Moreover this paper remains silent about the strategic significance of intellectual property and the likely paradigm shift in pharmaceutical business.

Another paper entitled “Access to Medicines in Under-served Markets: What are the implications of changes in intellectual property rights, trade and drug registration
This paper discusses the policy issues and context very meticulously particularly from developing countries government point of view. It emphasis on utilizing the flexibilities provided in the TRIPs.

The paper states that Long-term policy and financing signals are needed to secure a sustainable and affordable supply of key drugs. For example, some development partners are considering longer-term commitments for The Global Fund to Fight AIDS, TB and Malaria, which is a major financer of commodities. WHO’s 3 by 5 ARV treatment targets, and The Clinton Foundation’s efforts to secure API supply, are further examples of such signals to the market.

The paper further went on to state that The WHO (or WIPO) should develop a model TRIPS-compliant law that makes maximum use of TRIPS flexibilities to achieve public health goals. Systems for monitoring the public health impact of TRIPS, as well as the impact of regional and bilateral trade agreements, also need strengthening.
There exists another paper entitled “Public-Private Management of Intellectual Property for Public Health Outcomes in the Developing World: The Lessons of Access Conditions in Research and Development Agreements”\textsuperscript{15}.

This study paper was authored by Antony Taubman and published by Initiative on Public-Private Partnerships for Health, Global Forum for Health Research Published by the initiative on Public-Private Partnerships for Health, Global Forum for Health Research, June 2004 (ISBN 2-940286-19-1)\textsuperscript{15}. This paper particularly describes the important of public private partnership for proper intellectual property management.

This study considers specific practical options for managing intellectual property (IP) to promote the creation, development and effective dissemination of medical research outcomes for neglected diseases or diseases of poverty. In contrast to the diseases prevalent in industrialized countries, established drug development processes have given scant attention to a number of widespread infectious diseases that are suffered by the poor and predominantly afflict the developing world.

The research and development effort falls well short of the level of need proportionate with the scale of this disease burden. This ‘fatal imbalance’ can be attributed to many causes, and has led to calls for international policy initiatives to refocus research and drug development.
Further this paper suggests that there are three main challenges to the creation and delivery of new pharmaceuticals for neglected diseases:

- the identification of promising leads and the creation of new compounds as candidate drugs and vaccines, an essentially scientific activity requiring the application of basic research capacity to neglected diseases;

- the transformation of promising compounds into new medicines, a complex process which typically requires extensive clinical testing, regulatory approval, and access to associated technologies, manufacturing capacity and delivery platforms;

- health infrastructure, distribution chain and cost issues which can determine how many patients gain access to new medicines and how effectively they are delivered and administered within the context of overall health care.

Analysis of the problem of neglected diseases has highlighted impediments or shortcomings at each of these stages, but particularly emphasis has been laid on the need to improve the drug development pipeline, since there is evidence of promising new compounds remaining undeveloped due to the lack of incentives to take such compounds through the development process.
This paper also stresses on policy settings which are also seen as an obstacle to translating medical knowledge into actual tangible benefits, where the basic science is well known and current technology offers solutions in principle. There are diverse possible structures for filling this drug development gap, which draw on a range of inputs and are adapted to the practical needs in each case.

However, this paper remains silent about the major impact of product patent regime on access to medicine and how the business strategy of pharmaceutical industry is being affected by the change in patent regime and implementation of the minimum standards laid out by TRIPs requirement.

In another study which was carried out by James Love, Director, Consumer Project on Technology on Intellectual Property rights. He has published a paper as an outcome of the study carried out by him entitled “From TRIPS to RIPS: A better Trade Framework to support Innovation in Medical Technologies”16 which was presented in Workshop on Economic issues related to access to HIV/AIDS care in developing countries Université de la Méditerranée, Marseille, France, on May 27th, 2003.

The study was unique in itself since he has derived a new equation to manage the trade framework by applying various logics after which a global strategy for implementation was derived and explained in the article. This article states that The WTO TRIPS agreement now sets a global standard for the protection of intellectual property. In the
absence of any new agreement, it places significant burdens on consumers to pay for R&D. The development of a new framework for funding R&D could be offered as a substitute for TRIPS. It would not have to replace TRIPS entirely, or for every country.

In discussions of this framework, some have expressed concerns that there is considerable opposition to measures that might be construed as a global tax, particularly from the US government.

However, this study also does not discuss the strategic management and use of intellectual property as a strategic tool to face the challenges posed by the new patent regime. Moreover, it also remains silent about the medicos perception of impact of new IP regime on access to medicine. It also lacks the specific India focus, rather it discusses the global strategy and investment flows particularly in research and development and policy consideration at macro level.

2.3 SUMMARY

In summary, the available literature depicts the international development because of TRIPs compliance and the minimum standards laid down by the TRIPs agreements. However, none of the literature describes of studies the strategic impact of the IP regime on pharmaceutical business. Particularly literature remains silent about the significance of intellectual property management as one of the most important strategic element of the pharmaceutical business after the implementation of the new patent regime. None of the literature have actually studied the impact specifically for Indian scenario. Second most important affected area in the new patent regime would be the drug prices. None of the
literature has evaluated the perception of medical fraternity on how they perceive the likely changes in the patent regime and how it can impact the access to medicine. The researcher feels that, it is also imperative to understand the impact on drug prices from doctors’ perception since they are the actual influencer and directly affected by the change in drug price.

It is therefore, the study undertaken is indeed novel and non-obvious and was never undertaken or discussed by any of the previous literature since this study addresses combination of two unique dimensions, one use of intellectual property as strategic tool which can change the complete direction of the business model which not only helps in surviving in the changing industry environment but also gives a competitive edge to the Indian pharmaceutical industry to compete at global level.

Another dimension of the study is to measure the perception of medicos about the likely impact of changing patent regime on drug prices and access to medicine along with strategic importance of intellectual property as the medical fraternity drives the business of pharmaceutical industry as influencer.

Further the study would also cater the unmet need of understanding the strategic impact of new IPR regime on pharmaceutical business particularly in the strategy formulation. The study would also evolve a suggestive new business model wherein there would be a built in strategic dimensions to face the changing IPR regime and challenges posed by the same.
The study is based on a set of hypotheses which is being tested to arrive at suggestions and recommendations which are provided in the end of the study.

The third chapter is devoted to explain the WTO's evolution and the agreements. It also narrates the most important TRIPs agreements which have impacted the most to pharmaceutical industry and raised public health concerns worldwide, particularly for developing countries.