THE ADVENT OF GENERIC MEDICINES IN INDIA TO FACILITATE RIGHT TO HEALTHCARE: WHETHER OR NOT IN CONFLICT WITH PATENT LAWS

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CERTIFICATE

This is to certify that the research work entitled **"THE ADVENT OF GENERIC MEDICINES IN INDIA TO FACILITATE RIGHT TO HEALTHCARE: WHETHER OR NOT IN CONFLICT WITH PATENT LAWS"** is the work done by **Aishwarya Dobhal** under my guidance and supervision for the partial fulfillment of the requirement of B.A., LL.B. (Hons.)/B.B.A., LL.B. (Hons) degree at College of Legal Studies, University of Petroleum and Energy Studies, Dehradun.

DECLARATION

I declare that the dissertation entitled **"THE ADVENT OF GENERIC MEDICINES IN INDIA TO FACILITATE RIGHT TO HEALTHCARE: WHETHER OR NOT IN CONFLICT WITH PATENT LAWS"** is the outcome of my own work conducted under the supervision of Dr./Prof. Ms. Charu Srivastava, at College of Legal Studies, University of Petroleum and Energy Studies, Dehradun.

I declare that the dissertation comprises only of my original work and due acknowledgement has been made in the text to all other material used.

Aishwarya Dobhal
Date: 22nd Mar.' 17

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ABBREVIATIONS

- R&D_____RESEARCH AND DEVELOPMENT
- IFPMA_____INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS & ASSOCIATIONS
- TRIPS_____TRADE RELATED ACPECTS OF INTELLECTUAL PROPERTY
- ASEAN_____ASSOCIATION OF SOUTH EAST ASIAN NATIONS
- UNDP_____UNITED NATIONS' DEVELOPMENT PROGRAMME
- WHO_____WORLD HEALTH ORGANISATION
- HIV_____HUMAN IMMUNODEFICIENCY VIRUS
- UDHR_____UNITED NATION DECLARATION ON HUMAN RIGHTS
- EMR_____EXCLUSIVE MARKETING RIGHTS
- IDMA_____INDIAN DRUGS MANUFACTURERS ASSOCIATION
- WTO_____WORLD TRADE ORGANISATION
- WIPO_____WORLD INTELLECTUAL PROPERTY ORGANISATION
- TLO_____TRANSNATIONAL LEGAL ORDER
- IP_____INTELLECTUAL PROPERTY
- FTA_____FREE TRADE AGREEMENTS
- UOI_____UNION OF INDIA
- AIDS_____ACQUIRED IMMUNODEFICIEENCY SYNDROME
- ICESCR_____INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS
- ACHPR_____AFRICAN COMMISSION ON HUMAN AND PEOPLE'S RIGHTS

- USD_____US DOLLARS
- LDC_____LEAST DEVELOPED COUNTRIES
- GATT_____GENERAL AGREEMENT ON TRADE AND TARIFFS
- IPAB_____INTELLECTUAL PROPERTY APPELLATE BOARD
- SC_____SUPREME COURT (INDIA)

LIST OF CASES

- Parmanand Katara v. Union of India, 1989 SCC (4) 286; 1989 AIR 2039
- Maneka Gandhi v. Union Of India, 1978 AIR 597; 1978 SCR (2) 621; 1978 SCC (1) 248
- Indian Medical Association v. V.P. Shantha. 1996 AIR 550; 1995 SCC (6) 651.
- C.E.S.C. Ltd. Etc v Subhash Chandra Bose And Ors.; 1992 AIR 573; 1991 SCR Supl. (2) 267.
- State of Punjab v. Ram Lubhaya Bagga, (1998) 1 SCR 1120
- Paschim banga Khet Samity v. State of West Bengal, Case No. 169, Judgement of 6 May 1996
- Novartis AG v. Union of India, AIR 2013 SC 1311.
- Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 40 (Intellectual Property Appellate Board, Chennai).
- Hoffmann-La Roche Ltd. and Anr. vs. Cipla Ltd.; I.A. No. 642/2008 in CS (OS) 89/2008.
- Cruz del Valle Bermúdez v. Ministerio de Sanidad y Asistencia Social 1999

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AISHWARYA DOBHAL

CHAPTER I

INTRODUCTION

"*The relentless march of intellectual property rights needs to be stopped and questioned. Developments in the new technologies are running far ahead of the ethical, legal, regulatory and policy frameworks needed to govern their use. More understanding is needed–in every country–of the economic and social consequences of the TRIPs Agreement. Many people have started to question the relationship between knowledge ownership and innovation. Alternative approaches to innovation, based on sharing, open access and communal innovation, are flourishing, disproving the claim that innovation necessarily requires patents.*"[1] – UNDP Human Development Report 1999.

The extract above rightly brings our focus on the need to discuss Patents on pharmaceutical products.

The field of Intellectual Property Rights has flourished leaps and bounds in the last few years. This growth has rapidly entered the International Trade scenario as well. There were several other conventions and treaties that laid down provisions for transnational regulation of Intellectual Property, meanwhile also letting member countries to manage their own national Frameworks.

It was felt that patents and other IPRs on inventions and creations played a big role in enhancement and improvement in technology and thereby, a comprehensive instrument had to be brought in force.

The constant research and development going on in the Pharmaceutical sector also led to demands by pharma-companies to extend patent protection to pharmaceutical products:

"*The commercial sector discovers and develops nearly all new drugs and vaccines, but this is expensive and risky; the patent system provides the incentive necessary to*

[1] DR AMIT SEN GUPTA, UNDP Human Development Report 1999; WHO report, based on presentations at the intercountry seminar on Intellectual Property Rights and Access to Medicines, held in Dhaka, Bangladesh, on March 6-8, 2006.

investigate thousands of new compounds and to invest an average of several hundred million dollars in R&D."[2]

However, it was soon realised that the patent regime was hampering with the Right to healthcare of the general public. The pharmaceutical companies were selling drugs at exorbitant prices due to monopoly over their invention. Developing and least developed countries could not fulfil their duty, towards their citizens, of providing medicines at affordable prices.

Therefore, there was a new challenge to be tackled by the world community. The world community had to now balance individual Rights of Patents with the Public's Right to Healthcare. This led to adoption of the Doha Declaration after the coming in force of the TRIPS Agreement

The premise of the dissertation is mainly focussed on India struggle with generic drugs. In the process the dissertation would one by one discuss how the Right to Healthcare developed in India and how it has been also adopted as a Human Right Internationally.

Thereafter, the patent regime of India and its International Counterparts, i.e. TRIPS, TRIPS Plus, Doha Declaration would be discussed in detail. The purpose of the study is to examine and analyse how the patent regime on pharmaceuticals has affected the Right to healthcare. Another important dimension of the study is that how developing countries and developed countries have had different approaches towards the same issue.

Furthermore, Indian cases on Patents in the pharmaceutical industry have been discussed to get a more rounded understanding of how the Indian Judiciary has interpreted the provisions of the Indian Patent Act with respect to its International Contemporary the TRIPS.

Lastly, the aim would be to gather, from all the analysis, whether in India generic medicines have been considered as a violation of patents or not.

[2] International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), ASEAN Workshop on TRIPS, Jakarta, May 2000.

CHAPTER II

RIGHT TO HEALTHCARE: EVOLUTION AND IMPORTANCE

II.1

Introduction

To understand the technicalities involved in the grant and, thereby, the consequent enforcement of the Right to Healthcare, one needs to understand the meaning of 'Health'. For this reason it is best not to refer to the dictionary meaning of the word but to refer to the meaning of the word as given to it by the WHO[3]. As per WHO "health is a state of complete physical, mental and social well-being and not merely the absence of disease."[4]

The Constitution of India in its Preamble[5] itself declares that the State is socialist. This implies that the State must take care of the well-being of the people. But initially access to medical facilities was not enforced as a Right but later on with Court Judgments, pouring in in this regard, it was propounded as 'Right to Health' under the ambit of Article 21. This has been discussed in the next section of this chapter.

At the National Seminar on "Human Right to Health" organized by the Madhya Pradesh State Human Rights Commission in Bhopal on September 14th, 2008, the then Chief Justice of India Justice K.G. Balakrishnan addressed the audience and stated as follows:

"I am here today since I feel that it is my duty to participate in this seminar which touches on an issue of fundamental importance in our society. The responsibility to respect, protect and fulfil the 'right to health' lies not only with the medical profession but also with public functionaries such as administrators and judges."[6]

The words of Justice K.G. Balakrishnan bring into light an important aspect of the civil, natural and human rights that have been granted to the citizens of India or as a

[3]World Health Organisation.
[4]Preamble to the Constitution of the WHO as adopted by the International Health Conference (Official records of the WHO, no 2, P. 100.
[5]Preamble to the Constitution of India, 1950.
[6]SUPREME COURT OF INDIA
http://www.supremecourtofindia.nic.in/speeches/speeches_2008/right_to_health_-_bhopal_14-9-08.pdf (14.09.08).

matter of fact to every person living in any country on the face of Earth. This aspect is the 'Right to Healthcare' which entitles every citizen with access to affordable pharmaceutical products. However, this Right does not only provide access to pharmaceutical products but also increased rate of life expectancy and decreased rate of mortality.[7]

Professor Amartya Sen in a Lecture at the Parliament House correctly stated as follows:

"A government in a democratic country has to respond to On-going priorities in public criticism and political reproach, and to the threats to survival it has to face. The removal of longstanding deprivations of the disadvantaged people of our country may, in effect, be hampered by the biases in political pressure, in particular when the bulk of the social agitation is dominated by new problems that generate immediate and vocal discontent.

If the politically active threats are concentrated only on some specific new issues (no matter how important they may appear), rather than on the terrible general inheritance of India of acute deprivation, deficient schooling, lack of medical attention for the poor, and extraordinary undernourishment (especially of children and also of young women), then the pressure on democratic governance acts relentlessly towards giving priority to only those particular new issues, rather than to the gigantic persistent deprivations that are at the root of so much inequity and injustice in India. The perspective of realization of justice is central not only for the theory of justice, but also for the practice of democracy."[8]

The concepts of individual healthcare and public health are meant to intersect at a point of convergence. And for this very reason it falls upon the state as a responsibility to provide affordable medical curative treatments to the public at large. Thus, every State has to ensure 'Public Health' for its citizens. The propaganda of public health includes aspects like maternity care, child care, and providing labourers

[7] See generally http://www.supremecourtofindia.nic.in/speeches/speeches_2008/right_to_health_-_bhopal_14-9-08.pdf.

[8] JUSTICE SUNIL AMBWANI, JUDGE, Allahabad High Court, Allahabad, U.P., 'COLLECTIVE HUMAN RIGHT TO PUBLIC HEALTH'; In the Auspicious of 'The Rule of Law Society' Advocates' Association on May 9th, 2009.

with facilities of a healthy living environment.[9] However, none of this can be said to be achieved unless access to medicines is ensured for the citizens.

II.2

Legislative Support For Providing Healthcare Facilities

There is no specific legislation or provision that particularly imposes Right to Healthcare but there are several provisions of the *Constitution of India*[10] that touch upon the aspects of Right to Healthcare. Some of the Articles are worthy of being stated:

"1. The State shall strive to promote the welfare of the 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.

2. The State shall, in particular, strive to minimise the inequalities in income, and endeavour 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."[11]

"The State shall, in particular, direct its policy towards securing—

(e) that the 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;

(f) that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity and that childhood and youth are protected against exploitation and against moral and material abandonment"[12]

"The State shall, within the limits of its economic capacity and development, make effective provision for securing the right to work, to education and to public

[9] See: 37 BENJAMIN MASON MEIER AND LARISA M. MORI, 'The highest attainable standard: Advancing a collective human right to public health', Columbia Human Rights LR 101-146, Fall 2005.
[10] INDIA CONSTI., 1950.
[11] INDIA CONST., art. 38.
[12] INDIA CONST., art. 39.

assistance in cases of unemployment, old age, sickness and disablement, and in other cases of undeserved want."[13]

"The State shall make provision for securing just and humane conditions of work and for maternity relief."[14]

"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 endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health"[15]

"The State shall endeavour to protect and improve the environment and to safeguard the forests and wild life of the country."[16]

Even though the above stated Articles are a part of the Constitution, these are only Directive Principles of State Policy and are not justifiable. No person can claim action under these provisions.

The Constitution contains provisions directing Panchayats and Municipalities as well to work on matters related to health.[17]

Directives have also been stated in the Constitution for Panchayats[18]:

"243G. Subject to the provisions of this Constitution, the Legislature of a State may, by law, endow the Disqualifications for membership Panchayats with such powers and authority as may be necessary to enable them to function as institutions of self-government and such law may contain provisions for the devolution of powers and responsibilities upon Panchayats at the appropriate level, subject to such conditions as may be specified therein, with respect to—

(a) the preparation of plans for economic development and social justice;

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[13] INDIA CONST., art. 41.
[14] INDIA CONST., art. 42.
[15] INDIA CONST., art. 47.
[16] INDIA CONST., art. 48A.
[17] See HEMANT KUMAR VARUN, Right to Health, Posted On February 22, 2011, http://www.legalindia.com/right-to-health/.
[18] INDIA CONSTI., art. 243G.

(b) the implementation of schemes for economic development and social justice as may be entrusted to them including those in relation to the matters listed in the **Eleventh Schedule**."

The said Eleventh Schedule lays down several matters that relate to human health but out of them the direct one is Health and sanitation.[19]

Similar directives have been laid down for Municipalities as well[20]:

"243W. Subject to the provisions of this Constitution, the Legislature of a State may, by law, endow—

(a) the Municipalities with such powers and authority as may be necessary to enable them to function as institutions of self-government and such law may contain provisions for the devolution of powers and responsibilities upon Municipalities, subject to such conditions as may be specified therein, Disqualifications for membership with respect to—

(i) the preparation of plans for economic development and social justice;

(ii) the performance of functions and the implementation of schemes as may be entrusted to them including those in relation to the matters listed in the Twelfth Schedule;

(b) the Committees with such powers and authority as may be necessary to enable them to carry out the responsibilities conferred upon them including those in relation to the matters listed in the Twelfth Schedule."

In the twelfth schedule it is directly bestowed upon the municipalities to carry out responsibilities with respect to public health and sanitation.[21]

However, the scenario of health facilities changed its face in India when the Supreme Court started interpreting Article 21 to include "Right to Healthcare" as a significant Right within the meaning of the Article.

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[19] INDIA CONSTI., Item 23 (Health and sanitation, including hospitals, primary health centres and dispensaries) of the Eleventh Schedule.
[20] INDIA CONSTI., art. 243W.
[21] INDIA CONSTI., Item 6 (Public health, sanitation conservancy and solid waste management) of the twelfth schedule.

II.3

Judicial Landmarks

Article 21 has forever been an umbrella section for the judiciary to make interpretations and evolve the ambit of the provision into broader perspectives.[22] Similarly when appropriate situations came up, the Bench did not shy away from interpreting 'Right to Health' as part of enforcement under Article 21.

In the case of *Parmanand Katara v. Union Of India*[23] the Supreme Court of India laid down that:

"(1) Article 21 of the Constitution casts the obligation on the State to preserve life.

(2) There can be no second opinion that preservation of human life is of paramount importance. That is so on account of the fact that once life is lost, status quo ante cannot be restored as resurrection is beyond the capacity of man.

(3) The patient whether he be an innocent person or a criminal liable to punishment under the laws of the society, it is the obligation of those who are in-charge of the health of the community to preserve life so that the innocent may be protected and the guilty may be punished. Social laws do not contemplate death by negligence to tantamount to legal punishment.

(4) Every doctor whether at a Government hospital or otherwise has the professional obligation to extend his services with due expertise for protecting life.

(5) No law or State action can intervene to avoid/delay the discharge of the paramount obligation cast upon members of the medical profession. The obligation being total, absolute and paramount, laws of procedure whether in statute or otherwise which would interfere with the discharge of this obligation cannot be sustained and must, therefore, give way.

[22] See generally Maneka Gandhi v. Union Of India, 1978 AIR 597; 1978 SCR (2) 621; 1978 SCC (1) 248.
[23] 1989 SCC (4) 286; 1989 AIR 2039.

(6) The Court gave directions for giving adequate publicity to the decision in this case by the national media, the Doordarshan and the all India Radio, as well as through the High Courts and the Sessions Judges."[24]

In another landmark judgment[25] the Apex Court has made extremely relevant observations in the 15th Para of the Judgment:

"we are of the view that in order that proper medical facilities are available for dealing with emergency cases it must be that:

1. Adequate facilities are available at the Primary Health Centres where the patient can be given immediate primary treatment so as to stabilize his condition;

2. Hospitals at the district level and Sub-Division level are upgraded so that serious cases can be treated there;

3. Facilities for giving Specialist treatment are increased and are available at the hospitals at District level and Sub-Division level having regard to the growing needs;

4. In order to ensure availability of bed in an emergency at State level hospitals there is a centralise 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;

5. Proper arrangement of ambulance is made for transport of a patient from the Primary Health Centre to the District Hospital or Sub-Division hospital and from the District hospital or Sub-Division hospital to the State hospital.

6. The ambulance is adequately provided with necessary equipment and medical personnel;

7. The Health Centres and the hospitals and the medical personnel attached to these Centres and hospitals are geared to deal with larger number of patients needing emergency treatment on account of higher risk of accidents on certain occasions and in certain seasons."

Another important Remark that the Apex Court has made in the above stated Judgment is as follows:

[24] Sourced from http://judis.nic.in/supremecourt/imgs1.aspx?filename=7839.
[25] Paschim banga Khet Samity v. State of West Bengal, Case No. 169, Judgement of 6 May 1996.

"16. It is no doubt true that financial resources are needed for providing these facilities. But at the same time it cannot be ignored that it is the constitutional obligation of the State to provide adequate medical services to the people. Whatever is necessary for this purpose has to be done."

Another noteworthy decision which reinforced the appreciation of the 'right to health' was that in *Indian Medical Association v. V.P. Shantha*.[26]

In this case all things considered, it was decided that the arrangement of a medical service (regardless of whether diagnosis or treatment) as a by-product of money related consideration added up to a "service" within the ambit of the Consumer Protection Act, 1986. The outcome of the same was that medical experts could be held subject under the statute for lack in service in addition to carelessness. This decision has gone far towards ensuring the interests of patients. Nonetheless, medical services offered free of cost were thought to be past the domain of the said Act.

In the case of *C.E.S.C. Ltd. v. Subhash Chandra Bose and Ors*[27], the Apex Court has thrown light over how workers must be provided with adequate health and medical facilities in order to live their life with liberty under Article 21:

"26. The term health implies more than an absence of sickness. Medical care and health facilities not only protect against sickness but also ensure stable man power 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 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 another landmark case of *State of Punjab v. Ram Lubhaya Bagga*[28] the Supreme Court has made a remarkable observation as follows:

[26] 1996 AIR 550; 1995 SCC (6) 651.
[27] 1992 AIR 573; 1991 SCR Supl. (2) 267.
[28] (1998) 1 SCR 1120.

"When we speak about a right, it co-relates to a duty upon another, individual, employer, government or authority. In other words, the right of one is an obligation of another. Hence the right of a citizen to live under Article 21 casts obligation on the State. This obligation is further reinforced under Article 47, it is for the State to secure health to its citizen as its primary duty."

Recently the Supreme Court has spoken about the rampant spread of HIV/ AIDS. In a case where the court had to determine whether an HIV positive man should divulge his ailment to the woman he was going to marry, the court has held that "the woman's right to good health will precede over the man's right to privacy".[29] It found that the hospital did not err in disclosing his status to his fiancé.[30]

It is pertinent to note that the Indian Judiciary has, since forever, spoken in favour of the Right to Healthcare and has been the propagator of the same. In such a scenario it would be interesting to see how the Judiciary has balanced out two different but intersecting rights together, i.e. right to healthcare and patent rights.

[29] AIR 1999 SC 495.
[30] Legal Position Paper On Right to Heath Care (Part II), http://www.cehat.org/rthc/paper3.htm.

CHAPTER IIA

ACCESS TO MEDICINE & PUBLIC HEALTH: HUMAN RIGHTS' APPROACH ON AN INTERNATIONAL SPHERE

"Access to Drugs is one of the fundamental components in the Human Right to Health"[31]. It is essential to note that the purpose of this study is to understand how patents affect the access to medicines; and, thereby, to analyse the current Healthcare and patent regime. It is to be noted that patents can both restrict as well as improve access to medicines. On one hand, it can improve the technology base when it comes to research and development, and on the other hand it can lead to exorbitantly high prices. Therefore, before we move to the study of Patents and its International framework, we must also study the International Framework on Healthcare. Right to Healthcare has been enshrined even in the Instrument on Human Rights and several other instruments.

IIA.1

International Conventions

A number of International instruments have captured the essence of 'Right to Healthcare', stating it to be a Human Right in its core. And while we sit down to discuss any dimension of Human Rights we cannot afford to miss the tenants of the Universal Declaration of Human Rights. *Article 25 of the Universal Declaration of Human Rights, 1948 (UDHR)* has laid down the Right to Healthcare in the following words:

"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.

[31] PHILLIP CULLET, Patents and Medicines: The Relationship between TRIPS and the Human Right to Health.

2. Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection."[32]

It can be very well noted that the Article even though touches upon the factual definition of standard of health; however, it imposes no obligations on the States to act upon this and to necessarily provide their citizens with accessible medical care.

The *International Covenant on Economic, Social and Cultural Rights* adopted in 1976 has been an important instrument in binding States with obligations for providing adequate healthcare to its citizens. Article 12 of the covenant mandates States to take up measures for public Health:

"1. 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.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;

(b) The improvement of all aspects of environmental and industrial hygiene;

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness."[33]

However, it is pertinent to note that even this Article binds the States only as much as they can afford in accordance with their available resources. This means there is still no absolute obligation. This inference can be made out from Article 2 of *the International Covenant on Economic, Social and Cultural Rights:*

"1. Each State Party to the present Covenant undertakes 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

[32] Source: http://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf.
[33] Source: http://2covenants.ohchr.org/downloads/ICESCR.pdf.

the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.

2. The States Parties to the present Covenant undertake to guarantee that the rights enunciated in the present Covenant will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

3. Developing countries, with due regard to human rights and their national economy, may determine to what extent they would guarantee the economic rights recognized in the present Covenant to non-nationals."

In comparison the *International Covenant on Civil and Political Rights* provides for a more stringent mechanism. It imposes strict and mandatory obligations on States and has complaints mechanism put in place as well.

Several other conventions like the *Convention on Child Rights* and the *Convention against all forms of Discrimination against Women* also refer to medical care facilities.

IIA.2

Indian Adoption of International Obligations

An Indian Judgment has identified the duty of the State to ensure enforcement of Right to Health under International obligations[34]. The relevant portion of the judgment that throws light on India's International Obligations is as follows:

"24. Article 25(2) of Universal Declaration of Human Rights, 1948 assures that everyone has the right to a standard of living adequate for the health and well-being of himself and of his family including medical care, sickness, and disability. Art. 7(b) of the International Convention on Economic, Social and Cultural Rights, 1966 recognises the right of everyone to the enjoyment of just and favourable conditions of work, which ensure, in particular, safe and healthy working conditions. Article 39(e)

[34] C.E.S.C. Ltd. Etc v Subhash Chandra Bose And Ors.; 1992 AIR 573; 1991 SCR Supl. (2) 267.

of the Constitution enjoins the State to direct its policies to secure the health and strength of workers. The right to social justice is a fundamental right."

It is, thus, not only a National duty of the Indian State but also an International obligation to provide right to health care to its citizens. Now the discussion has led us to a broad understanding of the Right to healthcare, which understandably includes universal access, acceptability, availability and quality of medical services to one and all.[35]

Thus, Access to medical care must be widespread and universal, ensured for all on an equitable premise. Health services must be affordable and exhaustive for everybody, and physically available where and when required.

Satisfactory health related framework (e.g. clinics, community health services, trained health experts), goods (e.g. medications, hardware), and services (e.g. essential care, psychological wellness) must be accessible in every single geographical region and to all groups.

IIA.3

Importance of Right to Healthcare for developing countries

Former British Prime Minister, Mr. Benjamin Disraeli was quoted as saying:

"The health of people is the foundation upon which all their happiness and all their powers as a state depend"

In the developing countries, like India, the burden of huge population creates an excessive pressure on the State Governments while catering to the health needs of each and every citizen. The problem is all the more severe because huge population also lead to disparity of income. Moreover, in developing countries the per capita

[35] See "What is the Human Right to Health and Health Care?" ; https://www.nesri.org/programs/what-is-the-human-right-to-health-and-health-care.

income is not high. Consequently, there are wide open inequalities socially and economically.[36]

Hence, it becomes the duty of the State to make healthcare available and easily accessible for all the people of the state. The State has to enforce Right to Health by subsidising pharmaceutical drugs and by implementing measures that would lead to sale of pharmaceuticals at low prices. This way availability, accessibility and affordability become the three key factors in the government's enforcement mechanism with respect to Right to Health.[37]

[36] Report of the Commission on Social Determinants of Health, Geneva: World Health Organisation, 2008.
[37] SUBITHA LAKSHMINARAYANAN, Role of government in public health: Current scenario in India and future scope, 2011 Jan-Apr, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3114612/.

CHAPTER III

PATENTS IN THE PHARMACEUTICAL INDUSTRY IN INDIA

III.1

Intellectual Property Rights and Patents

To understand the genesis of patents, one must know the ground of Intellectual Property Rights as a whole. Intellectual Property Rights are legal rights once granted permits the originator(s) or proprietor(s) of the intellectual property to eliminate others from misusing the same commercially for a given period of time. It lets the inventor(s)/proprietor(s) to have the profits from their work when these are subjugated commercially. IPR are granted to an originator or inventor, designer in lieu of the disclosure of his/her expertise.[38]

"Governing Laws in India for IPR as follows:

1. Patent Act 1970

2. Trade Marks Act (1958 original) 1999

3. The Copyright Act 1957

4. The design Act 2000

5. Geographical Indication of Goods (Registration and Protection) Act 1999

6. Plant Variety and Farmers Right Protection Act 2001"[39]

➔ Our point of concern out of all the IPRs lies in the Patents Act, 1970. This leads us to another discussion which is the right that is conferred upon a patent holder. A patent grants its holder an exclusive right to solely manufacture, distribute, market, sell, import his goods.

So basically a patent is an agreement/contract between the inventor of the product and the State, whereby the inventor or applicant gets domination from the State for a fixed pre-decided period in return for revealing full particulars of the invention.[40]

[38] The Patent System of India; http://www.gian.org/north/files/FAQ.pdf.
[39] Ibid.

However, for any person to attain patents for his work he must fulfil the following three parameters:

1. Innovation
2. Novelty
3. Commercial use

As per TRIPS, the said conditions are "new, involve an inventive step and are capable of industrial application".[41]

Before we go into the depth of studying patents and thereby patents for pharmaceutical products, we must know what counts as an invention/innovation.

An invention means: a new item or process including a creative stride and inventive step and fit for modern commercial/industrial application.

An Innovation means: The fruitful use of new ideas as a helpful hardware or process, by any individual, utilizing own intelligence is called as innovation. Each innovation may be a new development but may not be patentable development.

III.1.1

What inventions/innovations are patentable?

With a specific end goal to be suitable for licensing, an innovation must be novel. An innovation is thought to be novel on the off chance that it has not been unveiled to people in general at the time that the patent application was made. For whatever length of time that the date of the patent application goes before any revelation about the innovation to the general public, the development can be legitimately licensed. Assuming notwithstanding, details of the innovation have been unveiled to public at large before applying for a patent, then the creation is no longer thought to be novel in a licensing sense and it won't be conceivable to ensure that it will by granting patents.

This implies that basically anything and everything can be patented. As per the Indian Patents Act of 1970, the legislature has in fact laid down a carefully drafted list of all

[40] Ibid 39.
[41] TRIPS AGREE., art. 27:1.

the things that cannot be patented. The list of what cannot be patented under Chapter II[42] of the Patents Act is as follows:

"3. What are not inventions.—The following are not inventions within the meaning of this

Act,—

(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;

(b) an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

(c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;

(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 substance, unless they differ significantly in properties with regard to efficacy;

(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;

(f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

(g) Omitted by the Patents (Amendment) Act, 2002

(h) a method of agriculture or horticulture;

[42] Source: http://www.wipo.int/edocs/lexdocs/laws/en/in/in065en.pdf.

(i) any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

(j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

(k) a mathematical or business method or a computer programme per se or algorithms;

(l) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;

(m) a mere scheme or rule or method of performing mental act or method of playing game;

(n) a presentation of information;

(o) topography of integrated circuits;

(p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

4. Inventions relating to atomic energy not patentable.—No patent shall be granted in respect of an invention relating to atomic energy falling within sub section (1) of section 20 of the Atomic Energy Act, 1962 (33 of 1962).”[43]

III.2

Changes in patent laws in India

Thus, like all countries in the world, India has its own framework for granting patents. The 1970 Patent Act is not the first law to regulate India's patent grant. Subsequently, the law was also amended. Therefore, it becomes necessary to trace the changes in India's patent policies to understand the evolution of patent legislation in recent years.

[43] PATENTS ACT, 1970, sec. 3 & 4.

The above development is important to understand because it would allow a better understanding of how India's patent policy has developed.

The Patents and Designs Act, 1911 was the first act to come into force, that marked the historical foundation of Patent Laws in India. The Patents Act of 1970, which is currently in force, was enacted in 1972. It revised and united the current laws with respect to Patents in India. Another change was brought about in the Patent Act, 1970 by the Patents (Amendment) Act, 2005 wherein product patent was reached out to all fields of innovation including "drugs, chemical and micro-organisms". The product patents have been introduced as a consequence of India's International obligations under the TRIPS Agreement:

"Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.5 Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."[44]

Even though the Agreement was signed by India way back in 1994, it still took about a decade for it to transform and diffuse it with its National Legislation. This is the reason why the product patent regime was introduced only in 2005 in India.

When the amendment was brought about, the provisions identifying with Exclusive Marketing Rights (EMRs) have been cancelled, and an arrangement for allowing compulsory licensing has been presented. The arrangements identifying with "pre-grant and post-grant opposition" have been similarly presented.

A development identifying with "a Product and/or Process" that is new, including imaginative stride and prepared to do mechanical application can be patented in India. Be that as it may, if the innovation/invention falls into the classification of non-patentable items under section 3 and 4[45], then it cannot be patented. In India, any inventor or proprietor can file an application either by himself or with his co-owner,

[44] TRIPS AGREE., art. 27:1.
[45] PATENT ACT, 1970.

or through his authorised representative.[46] This will be illustrated in detail in the following sections.

III.2.1

Historical Evolution

Changes in the patent laws over time are as follows:

- First legislation in India: Act VI of 1856. The purpose of this statute was to stimulate the development of new and valuable brands and motivate inventors to disclose the secret formulas / procedures of their innovations.
- The Act was therefore cancelled by Act No. IX of 1857, as it had been authorized without the approval of the British Crown.
- New exclusive privileges in legislation were introduced in 1859 as Law XV of 1859. In 1872, the Law of 1859 was combined to give protection in relation to designs. It was renamed "The Law of Protection of Drawings" under Act XIII of 1872. This law remained in force for 30 years without changes, in the year 1883 certain modifications to the Act have been made.
- The 1911 Act on Indian Patents and Designs (Act II of 1911) replaces all previous legislations. This law has introduced the patent organization under the management of the patent controller.
- This Act was additionally changed in 1920 to bring into force an arrangement wherein priority can be secured with countries like UK etc. In 1930, changes were made to fuse frameworks with regard to grant of anonymous licenses, patent of addition, utilisation of innovation by Government, powers of the Controller to amend list of patent and increment of term of the patent from 14 years to 16 years. In 1945, a change was made to accommodate recording of temporary detail and accommodation of full details in a period of 9 months.
- After freedom, it was considered that the Patents and Designs Act of India, 1911, did not serve its purpose. It was considered necessary to adopt a

[46] VIJAY PAL DALMIA, Advocate Partner & Head of Intellectual Property Laws Division, Vaish Associates Advocates, New Delhi India and PAVIT SINGH KATOCH, Advocate Associate, Intellectual Property Laws Division, Vaish Associates Advocates, New Delhi India, Patents Law In India – Everything You Must Know.

widespread patent law due to significant changes in the political and economic conditions of the country. As a result, in 1949, the Government of India set up a committee under the chairmanship of Justice (Dr) Bakshi Tek Chand, retired judge of the Lahore High Court to examine the Indian Patent Law to ensure that the Patent system leads to the national benefit.

- The Committee submitted its provisional report of August 4, 1949 with suggestions and recommendations for the prevention of exploitation or misappropriation of patent rights in India and proposed changes to articles 22, 23 and 23A of the 1911 Act according to the UK Patents Designs Acts of 1919 and 1949. The Committee also noted that the Patent Law should contain clear guidance to ensure that food and medicine and surgical and curative facilities are made accessible to the public at a price that is the cheapest, with reasonable compensation to the holder of the patent.
- On the basis of the Committee's previous recommendation, the 1911 Act was amended in 1950 (Law XXXII of 1950) on inventions and compulsory licensing / revocation. An amendment to issue a compulsory license regarding food and medicines, insecticide, germicide or fungicide and a process for the production of substances or any invention related to surgical or curative devices was made in the year 1952. The compulsory license was issued by the Central Government by giving prior notification. The committee made recommendations, and a bill in Parliament in 1953 (Bill No. 59 of 1953) was introduced. However, the government did not pressure the bill to be discussed and it was, thus, put on hold.

III.2.2

The Ayyangar Committee Report

The Patents Act 1970, alongside the Patents Rules 1972, came into drive on twentieth April 1972, succeeding the Indian Patents and Designs Act 1911. The Patents Act was to a great extent in view of the proposals of the Ayyangar Committee Report headed by Justice N. Rajagopala Ayyangar. One of the proposals was the remittance of just process licenses as to developments identifying with medications, drugs, sustenance and chemicals.

Afterward, India got to be signatory to numerous global treaties with a target of reinforcing its patent law and coming allied with the advanced world. One of the critical strides towards accomplishing this goal was turning into the individual from the Trade Related Intellectual Property Rights (TRIPS) framework.

Thereafter, India likewise got to be signatory of the Paris Convention and the Patent Cooperation Treaty on seventh December 1998 and from that point marked the Budapest Treaty on seventeenth December 2001.[47]

The scenario relating to the Ayyanger committee is discussed in detail further, whereas the International developments will be discussed in further chapters.

In 1957, the Government of India delegated Justice N. Rajagopala Ayyangar Committee to inspect the subject of modification of the Patent Law and exhort government as needs be. The report of the Committee, which contained two sections, was submitted in September, 1959. The initial segment managed general parts of the Patent Law and the second part gave definite note on the few provisos of the lapsed bills of 1953. The initial segment additionally managed the flaws of the patent framework and arrangement with suggestions as per the law. The board of trustees prescribed maintenance of the Patent System, in spite of its inadequacies. This report suggested real changes in the law which shaped the premise of the presentation of the Patents Bill, 1965. The bill was put on hold after being presented in the Lok Sabha on 21st September, 1965. In 1967, again an altered bill was acquainted which was alluded with a Joint Parliamentary Committee and on the last proposal of the Committee, the Patents Act, 1970 was passed. This Act cancelled and succeeded the 1911 Act so far as the licenses law was concerned. Be that as it may, the 1911 Act still remained appropriate for inventions. A large chunk of the provisions of the 1970 Act were enforced on 20th April 1972 after the Patent Rules, 1972 were enforced.

It is to be noted that the Ayyangar Committee Report brought into light the concern areas for grant of patents. Justice N. Rajagopala Ayyangar stated the following two observations in the report:

[47] JAYA BHATNAGAR AND VIDISHA GARG, Anand & Anand Associates, Patent Law in India, 13 December 2007, http://www.mondaq.com/india/x/54494/Patent/Patent+Law+in+India.

"I have already set out the considerations which are said to constitute the quid pro quo for the grant of the patent monopoly, namely; (1) the working of the invention within the country so as to result in the establishment in the country of a new industry or an improvement of an existing industry which would profitably employ the labour and capital of the country and thus increase the national wealth, and (2) disclosure to the public of the invention and the manner of its working so that on the expiry of the life of the patent the public are enabled to work the invention themselves and in competition with each other."

This observation brings us to the implication that the motive of granting patents in India, similar to several other developing countries, is to encourage market innovation which can consequently be used in public interest.

III.2.3

Amendments to the Act of 1970

For around 24 years the Patent Act of 1970 stayed in existence with no change till December 1994. A statute affecting certain adjustments in the Act was issued on 31st December 1994, which stopped to work after six months. Thus, in 1999 another mandate was issued. This law in this was superseded by the Patents (Amendment) Act, 1999, that was enforced with retrospective effect from 1st January, 1995. The new Act laid down provisions for only filing of applications granting product patent licenses in the zones of medications, pharmaceuticals and agro chemicals however such licenses were not permitted. Be that as it may, such applications were to be analysed simply after 31-12-2004. In the meantime, the candidates could be permitted Exclusive Marketing Rights (EMR) to offer/sell or appropriate/distribute/market these items in India, subject to satisfaction of specific conditions.

The second change to the 1970 Act was made via the Patents (Amendment) Act, 2002 (Act 38 0f 2002). This Act was brought into force on 20th May 2003 with the presentation of the new Patent Rules, 2003 by succeeding the prior Patents Rules, 1972.

The third alteration to the Patents Act 1970 was presented through the Patents (Amendment) Ordinance, 2004 w.e.f. 1st January, 2005. This Ordinance was later succeeded by the Patents (Amendment) Act 2005 (Act 15 Of 2005) on 4th April, 2005 which came into force from 1-1-2005.[48][49]

III.3

Patents in Pharmaceutical Industry

In 1950 the patent strategy of India was to guarantee that medicines should be produced at home (within local markets). In 1950, multinationals from around the world made up for all of the medications supply of India. Multinationals from foreign lands controlled over 90% of the pharmaceutical business in India and subsequently decided sourcing and availability of medications. Drugs were earlier produced outside the territory of India and then imported at higher cost. The cost of medicines in India was among the most astonishing amongst all the countries. The costs of medications were high to the point that in 1961, the US senate advisory group, whose head was Senator Estes Kefauver, noticed that India positioned amid the countries where the prices of drugs were exorbitantly high.

Around a similar time the Indian Government made a five year plan to lower India's advancement way. Numbers show that salary from businesses/productions was as low as an insignificant 6.6% of the cumulative national wage. An insignificant 8% of the total work drive was working in factories. Plague infections characterized 5.1% of the combined mortality. The primary five-year plan recorded that India was the biggest repository of scourge maladies.

Destitution was at its top in India. Around half of India's masses were living under destitution and were not able to bear the cost of medicines. Therefore, future was hazy and death rate because of ailments was extraordinary. The government at the centre imported required drugs, under the Drugs Act of 1940, since India had bulk drugs being produced locally. Not able to control the intake on medications the legislature

[48] History of Indian Patent System, http://www.ipindia.nic.in/history-of-indian-patent-system.htm.
[49] Also refer History of Indian Patent System, http://www.patentregistration.co.in/history-indian-patent-system.php.

of India found a way to cure the circumstance. In the first place, the legislature consented to an arrangement with UNICEF to set up a plant for processing and assembling of penicillin and various other anti-microbials. This laid the foundation of Hindustan Antibiotic Limited in 1957 to produce drugs at a less costly rate for the general public.

Next, the legislature formulated a Committee in 1957 under the leadership of Justice Rajagopala Ayyangar to prescribe modification to the patent law to compliment modern needs. The aim of the said committee was to get assurance that India builds up a locally feasible pharmaceutical market. A report was thereby presented by the advisory committee in 1959.

The report laid down that the patent enactment necessitated a reasonable mandate. In suggesting changes, the committee was bound by the guiding principles and Constitutional provisions. "*Article 21 of the Constitution*" guarantees right of life, that incorporates the privilege to great wellbeing. The prelude of the Constitution lays down that approaches should be such so as to adjust social and financial aspects of the Right. Henceforth general wellbeing concerns should be evaluated with economic interests in correcting the patent enactment. The Ayyanger report mentioned that if a particular drug manufacturing company is given the utmost monopoly it would lead to great loss for the general public, as such company would fix prices as per their whims and fancies.

The report reasoned that a regime with absolutely free monopoly would jeopardise the principles of the Constitution[50]. The report basically brought together the patent frameworks of various developed nations like U.K, Germany and the U.S and pointed that Germany's patent framework empowered the progress of drugs industry. Subsequently the report prescribed a mandatory framework for "compulsory licensing" and grant of "process patents" to pharmaceuticals. The statute in light of the Ayyanger report and the rules were enforced in 1972.

Since for the general public healthcare facilities were a noteworthy concern, the Drug Price Control Order was additionally passed in 1970. The said order laid down that the control over the cost of medicines would remain with the government, in this way

[50] INDIA CONST., 1950.

complimenting the "compulsory licensing" provision in the Indian Patent Act, 1970. After the "Drug Price Control Order" was passed, the administration of India set most medications under value control.

Indian hasn't gotten away with the monetary brunt of the 1970 patent arrangement. Once, the main players, Multinational organizations got to be distinctly hesitant to deal in India. By 1997, multinationals represented under 3% of mass produced and 20% of privately produced drugs. Most multinational companies followed the base preconditions, important to keep their name going in the Indian market, (for instance, manufacturing ingredients from imported masses), while expecting more grounded patent rights. The legislature reacted by insistently decreasing value control on medicines. Most medicines were under value control in 1970; this was decreased to 347 medicines by 1984, and by 1987 to 163 medicines. In 1994 just 73 drugs stayed under control. The drug policy was set up in 1978.

In 1986 India deliberated on whether or not it should sign the Paris Convention. The "Indian Drug Manufacturers Association (IDMA)" was at the front line of all the deliberations regarding the dilemma, emphasizing the dangers of joining the Convention before India in the end yielded to extreme universal pressure. Meanwhile the IDMA was said to have been exhorted by retired judges and had a considerable measure of support from the judicial field as well.[51]

India was effectively required in restricting the TRIPs segment of the GATT agreement, particularly the proposition grant of "product patents" on pharmaceutical developments. Indira Gandhi briefly summed up the Indian sentimentality at the "World Health Assembly" in 1982:

"The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death."

Even though reluctantly, however since India has joined the aforesaid treaty which is focused on "granting pharmaceutical patents", an examination i.e. cost-benefit analysis of this move is fundamental for India.[52]

[51] G.S. SRIVIDHYA, Introduction to IPR and Patent, Module-1.
[52] 3 DAMANJEET GHAI, Patent Protection And Indian Pharmaceutical Industry, Issue 2, July – August 2010; Article 008.

Section 3(d) is the most important section for any study regarding Patents in the pharmaceutical industry in India as it restricts Pharmaceutical companies from "ever-greening" their patents. The said provision is reproduced as under:

"Section 3- 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 known efficacy of that substance or the mere discovery of any new property or new use for a known substance or that 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, practical size, isomers, and mixtures of isomers, complexes, combinations and other derivatives of a known substance shall be considered the same substance, unless they differ significantly in properties with regard to efficacy."[53]

Another Section that is important for our study of patents is Section-48 that lays down the Rights of Patent Holders:

"Rights of patentees.—Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee—

(a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;

(b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India."[54]

Another provision important for the purpose of this study is Section-107A that exempts certain acts from the purview of infringement of patent. This provision is

[53] PATENT ACT, 1970, Sec. 3(d).
[54] PATENT ACT, 1970 Sec. 48.

often used by pharmaceutical companies and the Government itself to by-pass the Patent Rights of the patentee companies:

"107A. Certain acts not to be considered as infringement.—For the purposes of this Act,— (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product; (b) importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights."[55]

III.3.1

The Changes brought about in the Patent regime for Pharmaceutical Industry

The Third Amendment has erased Section 5 of the Act, which banished patent being conceded in regard of substances:

• intended for utilize or equipped for being utilized as sustenance, prescription, or drugs; or,

• prepared or created by concoction forms (counting amalgams, optical glass, semi-conveyors and between metallic mixes).

In this manner, product patents for pharmaceutical substances are permitted in India. Section 3 of the Patent Act, 1970, be that as it may, cuts out specific exemptions. Under Section 3 (j) "plants and creatures in entire or any part thereof (other than small scale living beings) including seeds, assortments and species and basically organic procedures for the generation of plants or creatures" – can't be licensed. This is in accordance with Article 27.3 of TRIPS. Accordingly small scale life forms, which fulfil the patentability criteria, might be protected in India. Section 3(d) as changed by the Third Amendment clears up that unimportant revelation of another type of a

[55] PATENT ACT, 1970, Sec.-107A.

known substance, which does not bring about the upgrade of the known adequacy of that substance is not a development and in this way not patentable. For the reasons for this statement, "salts, esters, ethers, polymorphs, metabolites, unadulterated frame, molecule measure, isomers, blends of isomers, edifices, mixes and different subordinates of known substances"[56] are to be thought to be similar substances, unless they contrast fundamentally in properties as to viability. Subsequently, "Swiss Cases" are not permitted in India.[57]

This aforementioned proviso had drummed up a significant buzz when it was instituted, essentially by Big Pharma as this Section was authorized to forestall "ever-greening"[58] of licenses. Also, since there was very little lucidity on how known substances are to be resolved, what adequacy is and how to demonstrate upgrade of viability, a considerable measure of cases encompassing this Section were being started at different legal and semi legal forums as the patent office had rejected numerous pharmaceutical patent applications under Section 3 (d). The most original case in such manner was the Swiss pharmaceutics monster, Novartis AG ("Novartis") dismissal of its Indian patent application for the beta crystalline type of Imatinib Mesylate documented in July 1998 on the grounds of Section 3 (d) when the application was analysed post 2005. This case at long last made it to the Indian Supreme Court ("SC") which conveyed a historic point judgment on April 1, 2013, dismissing Novartis Patent application.[59]

[56] Supra Note 45.
[57] A 'Swiss Claim' is a claim wherein the use of a substance or composition that has already been used for a medical purpose is intended or specified to be used for a new medical purpose.
[58] See European Generic Medicines Association, Evergreening and Pharma Research Costs, http://www.egagenerics.com/gen.reserch.
[59] NISHITH DESAI ASSOCIATES , Intellectual Property Law in India- Legal, Regulatory & Tax, July 2015.

CHAPTER IV

NATIONAL FRAMEWORKS AND INTERNATIONAL REGIMES GOVERNING PATENTS: WHETHER IN CONTRAST WITH RIGHT TO HEALTHCARE

The various regimes that are in place, be it National or International for that matter, which govern Intellectual Property Rights and consequently lay down provisions for grant of patents, are more often than not aimed at public welfare. It is pertinent for the subject matter of this research to understand whether or not these pieces of legislation also cater to the needs of public policy or healthcare in a nation.

IV.1

International Regimes

The most famous and exclusive International instrument on Intellectual Property Rights is the TRIPS agreement. The said agreement was signed to lay down guidelines for transnational registration of patents. The TRIPS agreement was followed by TRIPS plus and thereafter another International instrument which is integral to this study is the Doha Declaration on TRIPS Agreement and public health.

IV.1.1

TRIPS Agreement

The TRIPS Agreement recognizes the need to not hinder International trade under the garb of protecting Intellectual property:

"Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property

rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;"[60]

The agreement has been adopted not only to recognize Intellectual Property Rights but to facilitate International Trade. The said implication can be drawn from the following perambulatory clause itself:

"Desiring to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (referred to in this Agreement as "WIPO") as well as other relevant International Organizations;"[61]

The TRIPS agreement has also pointed out the need for protecting public health and this has been enshrined as one of its principles:

"Members may, in formulating or amending their 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."[62]

The Agreement also allows exemptions. A particular State can, if need be, exclude any invention from the purview of patentability. However, this condition is applicable in order to protect their public and environment. Protecting public health is one of the reasons where the State can exclude inventions from patentability:

"Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre* public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."[63]

IV.1.2

[60] TRIPS AGREE., Perambulatory clause.
[61] Ibid.
[62] TRIPS AGREE., Art. 8, cl. 1.
[63] TRIPS AGREE., Art. 27, cl. 2.

TRIPS Plus

Negotiators of TRIPS perceived that the local Intellectual Property laws and authorization measures would be confusing and tedious. To facilitate the move, the settlement gave a time of up to ten years amid which developing, furthermore least "Developed Nations", were not required to broaden full patent rights to pharmaceutical items.[64]

It likewise included arrangements –, for example, "compulsory licences", exceptions, and "parallel importation rules"– that permitted all WTO individuals a smidgen of adaptability to adjust pharmaceutical patents against other social and financial objectives.

These move and adaptability arrangements tempered TRIPS' hard edges. Be that as it may, those edges were immediately honed again by "bilateral and regional trade pacts" that the United States and the European Community consulted with developing nations.

These arrangements are known as "TRIPS Plus" agreements since they contain IP assurances that are more stringent than those of TRIPS, force Developing states completely to actualize TRIPS before its period for transition terminates, or require those nations to join or hold fast to other multilateral IP understandings.[65] By arranging treaties with developing countries reciprocally or in little gatherings, the United States and European Community utilized their more noteworthy arranging influence to fasten up IP rights and to "push . . . harmonization forward at a pace that is greater than is apparently possible within the framework of the WTO"[66]. They likewise effectively "integrated the patent offices of many developing countries . . . into a system of global governance" that is firmly displayed on the patent frameworks of industrialized countries. As the prior examination uncovers, the "agreement of TRIPS and TRIPS Plus agreements" brought on a checked development of the Intellectual Property (IP) Transnational legal Order (TLO).[67]

[64] TRIPS AGREE., Arts. 65, 70; Gervais 2003 : 349, 365–366.
[65] GRAIN 2001.
[66] OECD 2001 : 112.
[67] LAURENCE R. HELFER, Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines.

"The United States has been negotiating free trade area agreements with an increasing number of countries that include extensive "TRIPS-Plus" commitments on intellectual property rights. In particular, these agreements limit the grounds upon which it is permissible to grant compulsory licences. The recent U.S.-Singapore FTA, for example, allows it only in cases of national emergency/extreme urgency, for public non-commercial use or to remedy anticompetitive practices. These new FTAs also incorporate requirements for extending the term of patents in the event of unreasonable delay by the patent office in granting them. And they mandate that countries provide a five-year period of protection for the data submitted in the course of regulatory approval of a medicine, even if the approval was granted in another country."[68]

"The cumulative effect of these provisions is to create significant new impediments to entry of generic medicines on the market, and to diminish the ability of the poor to have access. As the United States is able to obtain concessions outside the WTO from governments that otherwise have resisted making them within the WTO, this weakens the developing countries as a group and undermines the multilateral trading system as a whole."[69]

IV.1.3

Doha Declaration on the TRIPS Agreement and Public Health

The Doha Declaration was adopted in the year 2001 on November 14, 2001 in Doha by the Ministerial Conference of WTO. The said Declaration was passed when concerns started to be raised by developing countries. The said concerns were pointed out because the Patent Regime under the TRIPS Agreement had burdened the developing and the least developed countries and restricted the access to medicines in these countries. Therefore, these countries united to advance their common concern. The fact was that the industrialized/developed countries agree to unanimously adopt the declaration.

[68] IISD Trade and Development Brief No. 9; International Institute for Sustainable Development.
[69] Ibid.

The Doha Declaration, collectively embraced by WTO members, incorporates three perambulatory clauses[70], certain principles/standards to interpret the TRIPS Agreement with regard to "public health and policy"[71], "provisions confirming existing TRIPS flexibilities and reaffirming WTO member sovereignty"[72], a "mandate for negotiations regarding compulsory licensing for countries with limited or no manufacturing capacity"[73] and a further "extension of compliance deadlines for least developed WTO members"[74].

WTO individuals have an "Right" to secure general wellbeing. This privilege must be taken into account when analysing claims by IPRs holders. An adjusting is visualized, yet that adjust must support advancing "Access to medicines for all".

IV.2

National Framework

The Indian Framework on Patents has a number of provisions through which the control has been in the hands of the State. The State does not risk giving complete Monopoly to pharmaceutical companies. This has been done for the reason that a large chunk of the Indian Population is living below the poverty line. In a situation like this, it becomes imperative for the State to take actions. Being a WTO India is bound by its obligations under the TRIPS Agreement; hence, it had to introduce patents in the Pharmaceutical industry and also product patents. Certain provisions that have been imported from International instruments and trade practices help the State to regulate the supply of medicines and pharmaceuticals to the general public. If a patented invention has to be used by the government, it can do so under its National

[70] DOHA DECLARATION on the TRIPS Agreement and Public Health, Para 1-3.
[71] DOHA DECLARATION on the TRIPS Agreement and Public Health, Para 4: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.
In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."
[72] DOHA DECLARATION on the TRIPS Agreement and Public Health, Para 5.
[73] DOHA DECLARATION on the TRIPS Agreement and Public Health, Para 6.
[74] DOHA DECLARATION on the TRIPS Agreement and Public Health, Para 7.

framework as well as per the International instrument[75]. The other provisions have been discussed in the following sub-chapters.

IV.2.1

Compulsory Licensing

A standout amongst the most imperative parts of Indian Patents Act, 1970, is "Compulsory Licensing" of the patent subject to the satisfaction of specific conditions. Whenever after the lapse of three years from the date of the fixing of a patent, any individual intrigued may make an application to the Controller of Patents for concede of necessary permit of the patent, subject to the satisfaction of certain prerequisite conditions, i.e.

- the sensible necessities of people in general as for the licensed creation have not been fulfilled;
- or that the protected innovation is not accessible to the general population at a sensible cost;
- or that the protected innovation is not worked in the domain of India.

It is further critical to note that an application for "Compulsory License" might be made by any individual despite that he is now the holder of a permit under the patent.

With the end goal of "Compulsory License", no individual can be restricted from raising allegations that the sensible prerequisites of people in general as for the "patented invention" are not fulfilled or that the licensed development is not accessible to the general population at a sensible cost by any reason, regardless of whether in such a permit (licence) or by reason of his having acknowledged such a permit (licence).

The Controller, if content that the sensible prerequisites of people in general as for the "patented invention" have not been fulfilled or that the "patented invention" is not accessible to the general population at a sensible cost, may arrange the patentee to give a permit upon such terms as he may think fit. Notwithstanding, before the giving

[75] TRIPS AGREE.

a "Compulsory License", the Controller of Patents might consider the following elements:

- The nature of innovation;
- The time slipped by, since the fixing of the patent;
- The measures officially taken by the patentee or the licensee to make full utilization of the creation;
- The capacity of the candidate to work the innovation to general society's advantage;
- The limit of the candidate to embrace the hazard in giving capital and working the invention, if the application for "compulsory license" is allowed;
- As to the reality whether the candidate has tried endeavours to acquire a permit from the patentee on sensible terms and conditions;
- National crisis or different conditions of outrageous direness;
- Establishment of a ground of "anti-competitive" practices that the patentee has taken up.

It is not mandatory to grant a "compulsory license" as it is not a guaranteed right, since it is liable to the satisfaction of above conditions and watchfulness of the "Controller of Patents". If the "controller of patents" passes any arbitrary or illegal order while granting a "Compulsory License" then a legal recourse can be taken against him.[76]

In order to fully understand the utility of "Compulsory Licensing" in India, one must also go through the provision as produced below:

"84. Compulsory licences.—(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:—

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied,or

[76] Supra Note 42.

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India.

(2) An application under this section may be made by any person notwithstanding that he is already the holder of a licence under the patent and no person shall be estopped from alleging that the reasonable requirements of the public with respect to the patented invention are not satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price by reason of any admission made by him, whether in such a licence or otherwise or by reason of his having accepted such a licence.

(3) Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.

(4) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may grant a licence upon such terms as he may deem fit.

(5) Where the Controller directs the patentee to grant a licence he may, as incidental thereto, exercise the powers set out in section 88.

(6) In considering the application field under this section, the Controller shall take into account,—

(i) 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 licensee to make full use of the invention;

(ii) the ability of the applicant to work the invention to the public advantage;

(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

(iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit:

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anticompetitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application. Explanation.—For the purposes of clause (iv), "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months.

(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied—

(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,—

(i)an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or

(ii)the demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii)a market for export of the patented article manufactured in India is not being supplied or developed; or

(iv)the establishment or development of commercial activities in India is prejudiced;

or

(b) if, by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or

(c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing; or

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable; or

(e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by—

(i) the patentee or persons claiming under him or

(ii) persons directly or indirectly purchasing from him; or

(iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement."[77]

IV.2.2

Ever Greening

"Evergreening" of patents means continuance of a patent's domination over and above the restricted period of 20 years by recurring patent grants, based on making miniscule amendments to the originally invented product. However, the evergreening is restricted with the help of a provision in the 2005 Act[78]:

"The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy"[79] is held to be out of the purview of patentability. The provision is followed by the following explanation:

"Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".[80]

[77] PATENT ACT, 1970, Sec.- 84.
[78] PATENT (AMENDMENT) ACT, 2005.
[79] PATENT ACT, 1970, Sec.- 3(d).
[80] Ibid.

The said provision has been an effective tool in restraining large pharmaceutical companies from keeping their patent in a perpetual manner.

In the meantime, be that as it may, Indian law has characterized the creative stride (one of the three criteria for patentability) as an element of a development that "includes specialized advances when contrasted with the current information or having financial essentialness or both". It has been contended that an “inventive step” should apply to specialized advances as it characterizes the creative substance in an innovation. Therefore, the joining of “economic significance” would appear to weaken the criteria for what is an “invention”. It is however to be perceived how this condition will be practically applicable.

In a recent decision of Novartis v. UOI, the Apex Court has passed a judgment that refrained a pharmaceutical giant from ever-greening their patent. The said judgment has been discussed in detail in the chapters below.

IV.2.3

Exceptions

The Patent Act lays down exceptions in its provisions under section-107A. The said provision has been adopted on the lines of the exceptions adopted in the TRIPS Agreement. The provision primarily contains two kinds of exceptions: 1. Parallel importation; and 2. Bolar Provision. These two provisions have been discussed in the following sub-chapters.

IV.2.3.a

Parallel imports

The provision that allows parallel importation is as follows:

"Importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product,"[81]

The provision basically means that any country can import generic drugs from another country from a dealer who is so authorised by the patent holder to produce the patented drug. This importation is done without the permission of the Patent Holder. The earlier Act included that, for such importation, permission had to be taken from the patent holder. However, after the amendment of 2005, there was no bar with respect to permissions. This exception has been adopted in light of the AIDS Crisis in various poor countries like Venezuela and Africa and after the Doha Declaration was adopted.[82]

IV.2.3.b

Bolar Provisions

The Bolar Exemption is laid down in the following provision:

"Any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product."[83]

The provision was added for the purpose of providing access to drugs to one and all. The provision was inserted on the lines of a similar provision of the TRIPS Agreement[84].

The provision basically means that any company or individual can import a generic drug without the permission of the patent holder, solely for the purpose of research

[81] PATENT ACT, 1970, Sec. 107A (b).
[82] CHRISTOPHER HEATH, Parallel Imports and International Trade, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, Munich; http://www.wipo.int/edocs/mdocs/sme/en/atrip_gva_99/atrip_gva_99_6.pdf.
[83] PATENT ACT, 1970, Sec. 107A (a).
[84] TRIPS AGREE., art. 30: "Parties may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.".

and development, so that an application for a license can be made right before the expiry of the original patent.

In the case of *Natco v. Bayer*, the High Court has clarified the correct meaning of the provision and has observed as follows:

"India is one of the largest producers of generic versions of drugs around the world. Given the economic realities of our country, providing cheaper medicines is a necessity. The parliament in its wisdom has, thus couched the exclusion to a patent, as provided under Section 107A, in wide terms. The sweep of the plain language of Section 107A, thus, cannot be restricted in the manner as canvassed on behalf of Bayer.

…Plainly, Section 107A of the Act takes within its fold any sale of a patented invention which is required for development and submission of information under any law in a country other than India that regulates the manufacture or sale of any product. Indisputably, under the Chinese Law, submission of studies and data related to bio-equivalence and bio-availability of API in a generic version, is required as discussed earlier and the sale of 1 kg. of Sorafenib to Chinese company can be reasonably stated to be related to the studies that are required to be conducted by Chinese company for obtained the regulatory approvals.

…the language of Section 107A of the Act is determinative of the question whether export as sought for by Natco is permissible within the exemption of Section 107A of the Act. The use of the expression 'reasonably related to' as used in Section 107A of the Act would plainly mean a reasonably nexus. Thus, the only question that needs to be answered is whether there is any reasonable nexus between the sale of Sorafenib by Natco to Chinese company and submission of information under the law in force in China. In my view, the answer to this question is clearly in the affirmative.

…It is also important to note that the language of Section 107A of the Act is materially different from the law as applicable in U.S. Whilst, the US Law restricts the safe harbour to a sale within United States and solely for purposes related to information under a Federal Law, Section 107A of the Act is circumscribed by no such conditions. Thus, a sale even outside India would fall within the sweep of

Section 107A, provided it is reasonably related to development and submission of information as required under a law in force in India or outside India".

Therefore, the provision has taken an important place in the Indian Patent Laws.

IV.3

Interplay of provisions

It is interesting to note that the provisions that lay down the rights of patent holders seem to give a whole range of monopoly on the market to the patent holders. It is, however, far from being true because from what we can easily gage from the afore-two sections is that from all corners of the market dimension patent rights are restricted to suit the requirements of different countries. Indian provisions on patents anyway do not support complete monopoly for patent holders.

It is, therefore, required to reproduce the Indian provision for Rights of Patentees:

"Rights of patentees.—Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee— (a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India; (b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India."[85]

Similarly, the TRIPS agreement lays down the following Rights for Patent holders:

"1. 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;

[85] PATENT ACT, 1970, Sec.-48.

(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.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts."[86]

There are certain exceptions in the Indian legislation, under which an act would not be considered a violation of patent. Similarly, the TRIPS agreement lays down exceptions:

"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[87]

In fact apart from the aforesaid exception, certain other uses are also permitted but only under the following circumstances:

"Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.

[86] TRIPS AGREE., art.-28.
[87] TRIPS AGREE, art. 30.

In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive

practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent."[88]

It can, thus, be noticed that the rights granted to patentees are wide ranging. However, the exceptions imposed on the Patent protection are also broad in purview. Even though TRIPS Agreements and TRIPS Plus agreements impose huge obligations on States to protect the Rights of Patentees, but the Right to Healthcare of citizens has been given utmost importance. This has come into light from this chapter and would become utmost clear in the subsequent chapters.

[88] TRIPS AGREE., art. 31.

CHAPTER V

IMPACT OF PATENTS ON DEVELOPING COUNTRIES: THE DEVELOPING V. DEVELOPED DEBATE

It is easy to understand that developed countries allow patents for pharmaceutical products, and enforce patent rights stringently, mainly because developed countries have a huge Government largesse which is consequently used by them to subsidize the pharmaceutical products for their citizens, even when the pharmaceutical companies are selling them at exorbitant prices.

The basics of this cycle can partly be reasoned by economic terms and processes. Since the pharmaceutical companies are based in the native countries themselves, they incur costs for the 4 basic inputs/factors of production (land, labour, capital and entrepreneur) and by way of these expenses borne by the pharmaceutical companies the developed countries earn revenue. This is partly the reason that developed countries do not oppose monopoly of pharmaceutical companies.

Initially only the developed countries had provisions for grant of patents, even though pharmaceutical patents were still not recognized. Britain and the United States first perceived licenses for new prescriptions in the late 1700s. The laws of both nations recognize "product and process patents" for new medications. A "product Patent" concedes the proprietor "special economic rights" over the concoction compound itself; a "process patent" covers just the methods by which that compound is made and permits others to create a similar medication utilizing a process which is different. Numerous different nations, be that as it may, explicitly barred pharmaceuticals from one or both sorts of patents. For instance, generally developing countries and many industrialized nations did not perceive item licenses for new medications until well into the second 50% of the twentieth century. This exclusion was not incidental yet rather reflected a cognizant decision to advance the creation, importation, and dispersion of less expensive "generic medicines". In reflection of this reality, the Paris Convention did not require signatory countries to perceive either "product or process patents" for pharmaceutical drugs.[89]

[89] Correa 2007 : 271; Hestermeyer 2007 : 28, 37.

It was only after, in 1980s, the pharmaceutical companies started protesting for stronger protection under the worldwide IPR Regime that the Protection was extended to Pharmaceutical products. However, these International instruments still had provisions to help developing countries to frame policies as per their National needs.

The TRIPS agreement not only aims to create a Uniform International framework but to also harmonize with the National Regimes of Nations:

"Recognizing, to this end, the need for new rules and disciplines concerning:

……..(c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;"[90]

The National policies of Nations have also been recognized:

"Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;"[91]

It goes without saying that even the TRIPS agreement recognizes the needs of Developing Nations. The following perambulatory clause addresses the needs of the least developed nations:

"Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;"[92]

Clause 1 of Article 1 of Part 1 of the Agreement lays down the following:

"Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. **Members shall be free to determine the appropriate**

[90] TRIPS AGREE., Perambulatory cl.
[91] Ibid.
[92] Supra Note 53.

method of implementing the provisions of this Agreement within their own legal system and practice."[93]

The purpose of stating the aforementioned clause is to understand that the agreement draws a provision wherein member nations of WTO are allowed and set free to enforce the agreement in their territory as per their own territorial requirements.

V.1

Case Study of Developing Countries: Access to Medicines

In an early and influential case, about 150 HIV-contaminated people drove a dissension against the Venezuelan Ministry of Health and Social Action affirming that the inability to give anti-retroviral drugs disregarded various rights ensured by the Constitution of Venezuela and by worldwide law. In a point of interest choice, the Supreme Court of Venezuela ruled for the offended parties[94]. The court dismissed the protection of insufficient assets and requested the "Health Ministry" to look for the resources/monetary capital expected to give "antiretroviral" prescriptions to all HIV-tainted people in the nation. The request was both far reaching and very specific, directing the Venezuelan Health Ministry to:

"• take measures necessary to ensure an uninterrupted supply of "antiretroviral" drugs;

• cover all tests necessary for the use of "antiretroviral" drugs;

• provide medications necessary for treating opportunistic infections;

• develop a policy of comprehensive medical assistance for people living with HIV/AIDS eligible for social assistance; and

• undertake research on HIV/AIDS to develop programs and infrastructure to prevent HIV transmission and care for those infected."[95]

[93] TRIPS AGREE, pt. 1, art. 1, cl. 1.
[94] Cruz del Valle Bermúdez v. Ministerio de Sanidad y Asistencia Social 1999.
[95] Ibid.

After a decade of "Bermúdez choice"[96], residential mediation of access to medicine claims expanded forcefully, pushed forward by supporters who depended on the translations of the privilege to wellbeing explained by the ICESCR Committee and other UN human rights bodies. National judges reacted positively to these cases, with high courts in Argentina, Colombia, Costa Rica, Ecuador, El Salvador, Kenya, Peru, and South Africa perceiving that HIV/AIDS patients have a privilege to get "antiretroviral" medications[97]. A recent report distinguished seventy-one cases from twelve nations conjuring a privilege of access to medications, with a win rate of 83%.[98]

Prosecution before territorial human rights bodies has strengthened this pattern. In 2001, the Inter-American Commission on Human Rights pronounced acceptable a grumbling testing El Salvador's inability to give "antiretroviral" medications to HIV/AIDS patients. The administration immediately settled the case after a Salvadorian court led in the offended parties' support, a prominent decision of the Court that "contributed to treatment activism throughout the region, complementing high-profile cases before a number of domestic courts"[99]. In 2008, the "*African Commission on Human and Peoples' Rights"* (ACHPR) received a "Resolution on Access to Health and Needed Medicines" in Africa that tracks the "tripartite system of the ICESCR Committee".

However even as a developing number of courts of various developing countries were implementing a privilege of access of medicines, the United States and the European Community were venturing up endeavours to fix IP rules for pharmaceutical licenses in territorial, pluri-lateral, and two-sided exchange agreements.

"Many of these treaties undercut the Declaration on TRIPS and Public Health by adopting provisions to restrict the very same flexibility mechanisms that the declaration had previously reaffirmed"[100], including the accompanying:

[96] Supra Note 76.
[97] Byrne 2009 ; Yamin & Gloppen 2011 ; O'Neil Institute 2013.
[98] Hogerzeil et al. 2006.
[99] UNAIDS 2006 : 71.
[100] 't Hoen 2009 : 70–71, 74–75.

"• Patent linkage: Prohibits public health authorities from granting approval to market lower-cost generic drugs during the patent term without the consent of the patent holder;

• Data exclusivity: Prohibits the use of pharmaceutical test data for regulatory purposes, delaying the approval of generic medicines;

• Patent extension: Lengthens the term of pharmaceutical patent protections beyond the twenty years required by TRIPS to offset regulatory delays in approving new drugs;

• Second use patents: Requires the recognition of pharmaceutical patents for new uses of existing chemical substances;

• Compulsory license restrictions: Limits the grounds for authorizing local drug companies to manufacture and distribute generic medicines, provided that they pay reasonable royalties to patent owners;

• Prohibitions of parallel importation: Prevents the importation of generic medicines manufactured in other countries."[101]

"In addition to negotiating treaties that enhanced the protection of pharmaceutical patents, the United States and the European Community also launched plurilateral treaty initiatives to augment the criminal and civil enforcement of IP rights. Among the most notorious of these initiatives is ACTA, whose signatories include Australia , Canada , Japan , Mexico , Morocco, New Zealand , Singapore, South Korea , and Switzerland. According to EC officials, ACTA seeks nothing less than "to create a new global gold standard on IPR enforcement"."[102]

"The treaty has engendered strong opposition from civil society groups not only because its enforcement rules exceed those in TRIPS but also because its draft texts were kept secret until the agreement was all but finalized in late 2010."[103]

[101] Supra Note 46.
[102] European Commission 2007.
[103] Geist 2010.

"ACTA applies to all types of IP, but A2M advocates are especially concerned that the treaty will hamper trade in pharmaceuticals by enabling patent owners to seize generic drugs in transit between countries that are not parties to the treaty."[104]

V.2

The struggle of developing countries in balancing patents with Right to Healthcare: Indian Viewpoint

The patent approach sought after by India empowered it to wind up distinctly as an enormous global player in the "generic drug" manufacturing industry. The patent strategy of 1970 drastically changed India's condition. In 30 years, the Indian pharmaceutical industry is esteemed at USD 70 billion contrasted with a minor USD 2.1 million preceding 1970. Right now 24000 pharmaceutical organizations are authorized in India. Of the 465 "bulk drugs" utilized in all parts of India, around 425 are manufactured inside the nation. Indian industry has developed as a world pioneer in the creation of various "bulk drugs". Indian industry has risen as a pioneer for the generation of mass medications like "sulphamethoxazole" and "ethambutol". Indian generation represents almost half of the world creation. A few organizations like "Ranbaxy", "Dr Reddy's" and "Cipla" have the potential to end up distinctly billion dollar organizations inside the next couple of years.[105]

Other than creating indigenous pharmaceuticals, India has developed as a noteworthy player in the worldwide "generic drugs market". The U.S amid the Anthrax panic considered bringing in "generic drugs" from India. India developed as a solid exporter of the genric AIDS medicates in South African AIDS emergencies.

Some different illustrations, the cost of ciprofloxacin were Rs. 27 (60 pennies) per tablet eight year prior in India. The cost of ciprofloxacin at present is Rs. 1.50 (4 pennies). Indian drugmakers trade the "generic" form of ciprofloxacin to Russia, Brazil, Southeast Asia and Middle East at prices that are highly competitive.[106]

[104] Grosse Ruse-Khan 2011 ; Yu 2012.
[105] See generally Adams plucks Patent & Trademark Attorneys, http://www.adampluck.com.au.
[106] History of Indian Patent System; http://www.patentoffice.nic.in/ipr/patent/history.htm.

Despite such fierce advancement of the indigenous pharmaceutical industry, just a negligible 30% of Indian populace has secured access to current drugs. Until the whole populace has admittance to medications, India needs to follow the pre-TRIPS patent arrangement.

TRIPS patent arrangement requires developing nations to grant patent licences only to the product. Novel procedures won't be patentable in developing nations since these nations do not utilize "process by product claims". Significantly, innovations patentable in developing countries by utilization of "process by product claim" will fall outside TRIPS agreeable patent enactment of developing countries. A few "generic" medications patentable in developed country utilizing "process by product claim" will be unprotected in developing countries.

TRIPS, the protected innovation segment of the Uruguay round of the GATT Treaty, have offered ascend to a caustic civil argument between the "developed nations" and "less developed nations (LDCs)". Business interests in the developed world guaranteed vast misfortunes from the impersonation, furthermore, utilization of their technology in LDCs. They likewise affirmed that IPRs would profit the developing nations like India by "encouraging foreign investment, by enabling transfer of technology and greater domestic research and development (R&D)". On the opposite side, LDC[107] governments were stressed about the higher costs that robust IPRs would involve and about the mischief that their presentation might bring about to new-born cutting edge businesses.[108]

Indian drug makers trusted "exclusive marketing rights"(EMR) would prompt to the decimation of the local industry and that it was more prohibitive than even the product patent administration. They contended that multinational companies from foreign grounds would get the privilege for "exclusive marketing" in India before experiencing an examination in India. Be that as it may, the greatest hindrance to the usage of the EMR enactment was the dread that the cost of medications would increment significantly. It was likewise expected that the Indian drug organizations would be driven bankrupt.

[107] As of Dec. 2007, the following countries in the WHO South-East Asia Region are LDCs: Bangladesh, Bhutan, Maldives, Myanmar, Nepal and Timor-Leste.
[108] G.S. SRIVIDHYA, Introduction to IPR and Patent, Module-2.

The patent strategy of 1970 has taken into account the necessities of the Indian poor. Medicine costs in India are one of the least expensive in the world today and are moderate to the populace.[109] On a normal, drugs produced in India are more than 100% less expensive than a similar medication in U.S. The legislature of India has accomplished the Constitutional order of social monetary benefits by setting such a system of pricing where the selling price is low and yet there is margin of profit for the drug makers.[110]

TRIPS endeavors to strike a harmony between the long haul social target of giving motivating forces to future innovations and creation, and the transient goal of permitting individuals to utilize existing developments and manifestations.

In the zone of licenses, TRIPS references the key articles of the Paris Convention and obliges individuals to go along with them. It requires both "national treatment"[111] and "most favoured nation treatment"[112]. It gives that no country may separate in its patent framework in view of field of innovation, an arrangement critical to the pharmaceutical and biotechnology businesses whose medications were not patentable in various states that are members of the WTO.

For pharmaceutical licenses, the adaptability has been cleared up and improved by the 2001 "Doha Declaration on the TRIPS Agreement and Public Health". The improvement was put into hone in 2003 with a verdict empowering nations that can't make drugs themselves, to import pharmaceuticals made under obligatory permit. In 2005, individuals consented to settle on this choice and make a changeless correction to the TRIPS Agreement.

A patent might be allowed for "a product, or a procedure". In the instance of a product patent, the patent is at last item. In the instance of a procedure the patent does not lie at last item, however, just during the time spent in generation. The demonstration simply grants process licenses for developments identifying with sustenance, medications, solutions and concoction forms. The suggestion is that the giving licenses should be restricted to the procedure or the strategy for making for

[109] A. SHAMSI, Indian Pharmaceutical Industry, Issues and strategies in the Post-GATT/WTO Era, http://www.pharmalliance.net/seminardetails.html
(April 10, 2003).
[110] A. KUMAR, Legal Service India.com.
[111] TRIPS AGREE., art. 3.
[112] TRIPS AGREE, art. 4.

innovations falling inside the arrangement said above. By changing the procedure, a similar item can be a subject of another procedure patent.[113]

WTO individuals need to give patent security for any innovation, regardless of whether an item, (for example, a prescription) or a procedure, (for example, a technique for delivering the synthetic elements for a prescription), while permitting certain exemptions. The TRIPS Agreement is striking for not simply expressing the rights, which Members must ensure, additionally characterizing in awesome detail the national common and criminal methods by which they are to be implemented.[114]

V.3

Use of exceptions by developing countries

The topic that is patentable under the TRIPS is extensively characterized. The agreement lays down that "licenses should be accessible for any "Inventions", regardless of whether it is 'product or process', in all fields of technology including pharmaceutics." Member nations should now offer patent insurance to both product and process developments, as long as they are new and non-self-evident. This change for the most part will require less-developed nations to embrace more extensive meanings of what is patentable, predictable with the laws of developed nations.

India for example did not give product licenses to pharmaceutical medications. It accommodated process licenses. The laws in India offered ascend to a flourishing "generic drug" industry wherein basically every remote medication was figured out without the fear of violating any patent. The pharmaceutical industry was incredibly influenced by this and turning around this pattern among developing nations was the need for the US as discussions around TRIPS agreement had just started taking ground. However, developing nations rebelled against enforcement of this norm without having the imperative infrastructure to actualize it. They looked for some trade off whereby the Article 27:1 states: "Subject to the arrangements of sections 2 and 3, licenses should be accessible for any developments, regardless of whether items or procedures, in all fields of innovation, given that they are new, include an innovative stride and are equipped for modern application. Subject to passage 4 of

[113] European Generic Medicines Association, Data Exclusivity http://www.egagenerics.com/gen.reserch.
[114] Supra Note 46.

Article 65, passage 8 of Article 70 and section 3 of this Article, licenses might be accessible and patent rights agreeable without segregation with regards to the place of innovation, the field of innovation and whether items are transported in or privately delivered"[115].

The protection level that the US requested would in the long run be given however it would be conceded in a staged way.

The trade-off came about for developing and least developed nations separately. Developing nations like India[116] had until January 1, 2005 to completely execute the entire range of TRIPS arrangements and least developed nations had until January 1, 2015. Developing nations got an extension time of 5 years to execute the agreement what's more, a further time of five years to concede product licenses to those zones of innovation in which product patents were not allowed. They needed to however accommodate EMR to pharmaceutical organizations. This is basically a right appropriate for promoting a drug in a member country for five years or until a product patent is conceded or rejected, whichever period is shorter. Because of this it is feasible for organizations that manufacture such invention to record patent applications in developing nations preceding their executing the TRIPS arrangements in full. Under TRIPS, despite the fact that a patent may not be allowed until the end of the effortlessness time frame, the development must be managed patent insurance for the rest of the patent term, as measured from the recording date.

Under the TRIPS Agreement, governments can make constrained exemptions to patent rights, if certain conditions are met. For instance, the exemptions must not "absurdly" strife with the "typical" abuse of the patent.

Member countries may likewise individually reject from patentability:

"(a) Diagnostic, helpful and surgical techniques for the treatment of people or creatures;

(b) Plants and creatures other than microorganisms, and basically natural procedures for the creation of plants or creatures other than non-biological and microbiological forms. In any case, Members might accommodate the assurance of plant assortments

[115] TRIPS AGREE., art. 27.
[116] S. JAYASWAL, Extension in Term of Pharmaceutical Patents, Findlaw Australia.

either by licenses or by a compelling sui generis framework or by any blend thereof. The arrangements of this subparagraph should be assessed four years after the date of enforcement of the WTO Agreement."[117]

Numerous nations utilize this arrangement to propel science and innovation. They permit scientists to utilize a protected development for research, keeping in mind the end goal to comprehend the innovation all the more completely. What's more, a few nations permit producers of "generic drugs" to utilize the patented development to acquire advertising/endorsement approval; for instance from authorities responsible for public health, without the patent proprietor's consent and before the patent duration terminate. The "generic drug" makers can then market their adaptations as soon as the patent lapses. This arrangement is now and again called the "regulatory exception" or "Bolar" arrangement.

This provision has been debated and upheld as appropriate according to the provisions of the TRIPS Agreement in a WTO debate meeting. In its report embraced on 7 April 2000, a WTO debate settlement board said Canadian law adjusts to the TRIPS Agreement in permitting producers. (The case was titled "Canada-Patent Protection for Pharmaceutical Products").[118]

"Compulsory Licensing" is the point at which a legislature permits another person to create the licensed item or process without the assent of the patent proprietor. In current open talk, this is normally connected with pharmaceuticals, be that as it may, it could likewise apply to licenses in any field.[119]

The agreement permits "Compulsory Licensing" as a feature of the agreement's general endeavour to strike a harmony between elevating access to existing medications and advancing examination furthermore, advancement into new drugs. Yet, the term "Compulsory Licensing" does not show up in the TRIPS Agreement. Rather, the expression "other use without approval of the correct holder" shows up in the title of Article 31. "Compulsory Licensing" is just piece of this, since "other use" incorporates use by governments for their own purposes.

[117] Supra Note 46.
[118] In Indian Statute laid down in Sec. 107A of the Patent Act, 1970.
[119] Ibid; Sec. 84.

In the principle Doha Ministerial Declaration of 14 November 2001, WTO members focused that it is imperative to execute and decipher the TRIPS Agreement in a way that backs general wellbeing by elevating both access to existing drugs and the formation of new drugs. Therefore, when it was felt that public health is of utmost importance, they adopted an individual declaration on TRIPS and public health. They concurred that the TRIPS Agreement does not and should not keep member countries from taking measures to secure public wellbeing of its citizens. They underscored nations' capacity to utilize the flexibilities/adaptabilities/exemptions that are incorporated with the TRIPS Agreement, counting "Compulsory Licensing" and "parallel importation" in. What's more, they consented to broaden exclusions on pharmaceutical patents for least developed nations until 2016.

Article 31(f) of the TRIPS Agreement says items made under "compulsory licensing" must be "predominantly for the supply of the domestic market". This applies to nations that can produce drugs-it confines the sum they can trade when the medication is made under "compulsory licensing". Also, it affects nations not able to make medications and consequently needing to import generics. They would think that its hard to discover nations that can supply them with medications made under "compulsory licensing".

The lawful issue for exporting nations was settled on 30 August 2003 when WTO member countries concurred on lawful changes to make it less tough for nations to import cheaper generics made under "Compulsory Licensing" on the off chance that they are not able to produce the drugs themselves. At the point when member countries conceded to this decision, the Chairperson of the General Council likewise read out an announcement setting out shared understandings of members on how the choice would be "interpreted and implemented". This was intended to guarantee governments that the choice won't be mishandled.

There were three waivers in the aforesaid decision:

- Exporting Nations' commitments under Article 31(f) are postponed: any member nation can trade generic pharmaceutical items made under "compulsory licences" to address the issues of nations that have to import to fulfil their pharmaceutical needs.

- Importing Nations' commitments on compensation to the patent holder under "Compulsory Licensing" are waived to maintain a strategic distance from twofold payments. Compensation is just compulsory on the export side.
- Exporting imperatives are waived for "developing and least developed nations", with the goal that they can export if they have a RTA (Regional Trade Agreement) with another country, when during the time of the decision half of the countries were distinguished as least developed Nations. That way, developing nations can make utilization of economies of scale.

Precisely arranged conditions apply to pharmaceutical items imported under the framework. These conditions point to guarantee that recipient nations can import the generics without undermining patent frameworks, especially in rich nations. They incorporate measures to keep the meds from being redirected to the wrong markets. Also, they require governments utilizing the framework to keep all different members educated each time they utilize the framework, in spite of the fact that WTO endorsement is not required. In the meantime expressions, for example, "reasonable measures within their means" and "proportionate to their administrative capacities" are included to keep the conditions from getting troublesome also, unreasonable for the importing nations.[120]

So basically developing countries have found a middle ground for their enforcement mechanism of IPRs (patents in the present case) in the field of Pharmaceuticals. The said ground lies between the International Human Rights and the International IPR Regime. This ground has been cemented by the developing countries by their own National Policies, domestic laws, and economic repercussions.

[120] B. SUBRAMANIAN, K; Access to medicines and Public Policy Safeguards under TRIPS; Multi stakeholder dialogue on Trade, Intellectual Property and Biological Resources in Asia, Bangladesh, April 19-20, 2002.

CHAPTER VI

JUDICIAL APPROACH TOWARDS SIMPLIFYING THE INTERTWINED RIGHTS

VI.1

Novartis AG v. UOI[121]: The Landmark case on Evergreening

An Indian patent application had been documented by Novartis AG ("Novartis") for the beta crystalline type of Imatinib Mesylate in July 1998. Since at that time the Indian Patent Regime was going through changes, the application was kept on hold.

5 pre grant oppositions opposed the application of Novartis. In 2006, the application was dismissed on the premise that the application " lacked novelty, was obvious and was not an invention in perspective of Section 3(d) of the Act."[122] The Controller held that the Product was another rendition of a more established particle that Novartis initially licensed in 1993 and the addition in "efficacy" is not sufficiently generous to get a patent. An appeal was filed under the steady gaze of the Madras High Court, amid the pendency of which, the case was then "transferred" to the Intellectual Property Appellate Board ("IPAB"). The IPAB maintained the choice of the Controller as for the finding that the patentability of the "drug" was banished under Section 3(d). Against the decision of the Controller, the company "Novartis" filed a Special Leave Petition (SLP) before the Supreme Court of India. The SC made an exemption and conceded the Special Leave Petition evading the purview/jurisdiction of the Madras High Court, because of the significance of the case and the quantity of original issues that were involved in it. The SC observed that this case was an exemption and any endeavour to straightforwardly challenge an IPAB order before the SC avoiding the High Court, was unequivocally demoralized.

The creation as asserted in the patent application was the beta-crystalline type of Imatinib Mesylate. This was a subsidiary of the free base frame called Imatinib

[121] AIR 2013 SC 1311.
[122] PATENT ACT, 1970, sec. 3(d).

unveiled vide illustration 21 of a patent application documented by Novartis in US on April 2, 1993 **("Zimmermann patent").**

Novartis' contention was that the referred to substance was Imatinib as unveiled in Zimmerman patent from which beta-crystalline type of Imatinib Mesylate was inferred and that the substance instantly going before beta crystalline type of Imatinib Mesylate was Imatinib and not Imatinib Mesylate as the Zimmerman patent did not reveal Imatinib Mesylate. The SC dismissed this contention in the wake of looking at the confirmation on record and inferred that the known substance was Imatinib Mesylate from which beta-crystalline type of Imatinib Mesylate was determined.

Since the expression "efficacy" is not characterized in the Act, the SC alluded to the Oxford Dictionary and watched that Efficacy signifies "the ability to produce a desired or intended result". In like manner the SC watched that the trial of "efficacy" depends "upon the function, utility or the purpose of the product under consideration". In this manner, the SC held that in the event of prescriptions, whose capacity is to cure infection, the trial of adequacy must be "therapeutic efficacy".

In connection to "enhanced efficacy", the SC held that the parameters for demonstrating improved helpful adequacy particularly in the event of meds ought to get a tight and a strict "interpretation". In any case, the SC called attention to that in light of the fact that "efficacy" must be given a strict elucidation under Section 3 (d), and that does not at all imply that it bars every single incremental innovation of synthetic and pharmaceutical substances. Basically Section 3 (d) gives a bar that the incremental innovations of concoction and pharmaceutical substances need to go through while keeping in mind the end goal of getting patents.

The SC had presumed that the known substance was Imatinib Mesylate and not free base Imatinib. In any case, all the proof put together by Novartis contrasted the adequacy of the Product and that of Imatinib, however there was no confirmation given by Novartis which contrasted the "efficacy" of the Product and that of Imatinib Mesylate.

In any case, SC went ahead to look at the affidavit statements put together by Novartis as indicated by which the accompanying properties showed by the Product exhibited its improved "efficacy" over Imatinib:

i. more advantageous stream properties
ii. better thermodynamic solidness
iii. hygroscopicity is lower; and
iv. 30 % expansion in bio-accessibility[123]

The SC held that the initial three properties of the Product identified with enhancing "processability and storage", along these lines they didn't in any capacity show upgrade of "therapeutic efficacy" over Imatinib Mesylate as required to finish the trial of Section 3(d). The SC reached this conclusion despite the fact that the contentions put together by Novartis analysed the Product over Imatinib in terms of eficacy.

The SC after this was left with 30% expansion in "bio-availability", as to this the SC held that expansion in "bio-availability" could prompt to improvement of efficacy, however, it must be particularly guaranteed and proved by research information. For this situation the SC did not discover any information to this impact other than the contentions of the lawyer and material "to demonstrate that the beta-crystalline type of Imatinib Mesylate will deliver an upgraded or improved efficacy (therapeutic) on molecular premise than that could be accomplished with Imatinib free base in vivo animal".

In perspective of the above discussion the SC held and inferred that Novartis' assertion for the Product was unsuccessful with respect to the trial of patentability under Section 3 (d) of the Act.

VI.2

Natco v. Bayer[124]: The first ever compulsory License in India

"Natco's application for a compulsory license for Nexavar[125] was filed before the Controller General of Patents in 2011, under S. 84(1)[126] of the Indian Patents Act,

[123] Supra Note 52.
[124] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 40 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.htm.
[125] "Chemically known as 'Sorafenib Tosylate', the drug is used for the treatment of advanced stage liver and kidney cancer. By stopping the growth of new blood vessels and impacting other cellular growth mechanisms, the drug can extend the life of a patient, the duration being between 6 months and 5 years.".
[126] The INDIAN PATENTS ACT, 1970, §84(1) reads as follows:

1970."[127] A licence was granted to Natco by the controller general, in a judgment delivered on March 9, 2012, against which Bayer appealed to the Intellectual Property Appellate Board (IPAB). Meanwhile, Bayer also tried to achieve a stay on the Controller's Judgment but the IPAB denied granting a stay order.[128]

The "Justice N. Rajagopala Ayyangar Committee Report", "TRIPS Agreement" and the "Code of Federal Regulations of the United States" were all referred to by both the bodies, i.e. the Controller General and the IPAB to pass their orders.

There were a number of grounds on which the application of Bayer was rejected by the bodies. The aspects important for the purpose of this study will be further discussed.

Both the bodies disagreed with Bayer's contention that "Natco had not made reasonable efforts to negotiate the terms of a potential license, categorically stating that once Natco's request was rejected as per §84(6)(iv), there was no obligation to make further attempts to do so. Although this finding of the IPAB seems to have been reasonable with respect to the particular facts of this case, its application elsewhere could be problematic. The order itself recognises that even though the Controller had found the language of the letter sent by Natco to be harsh, the IPAB did not believe there was any need for niceties."[129]

"In dealing with the question of whether the reasonable requirements of the public were being met by Bayer, including whether the drug was publicly available at a reasonably affordable price, the IPAB once again chose to adopt the public interest lens. Dismissing Bayer's contentions, it opined that the sole consideration in granting

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"84. Compulsory licences.—(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:
(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
(b) that the patented invention is not available to the public at a reasonably affordable price, or
(c) that the patented invention is not worked in the territory of India".

[127] 6 MANSI SOOD, Natco Pharma Ltd. V. Bayer Corporation And The Compulsory Licensing Regime In India, NUJS L.Rev. 99 (2013).

[128] Reuters, Bayer's Plea for Stay on Nexavar Generic in India Dismissed, September 17, 2012, available at http://in.reuters.com/article/2012/09/17/india-bayer-natco-idINL3E- 8KH5F320120917.

[129] See Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 16 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.htm.

compulsory licenses was whether the patented product was available to the public at a price that was reasonably affordable for them."[130][131]

The IPAB observed that "the patent holder's position was irrelevant in the consideration of compulsory licenses, and the affordability of the patented product for the public was the sole factor in the determination of a compulsory license application."[132] Hence, the IPAB basically rejected Bayer's appeal and upheld Natco's compulsory License that was granted to it by the Controller General.

VI.3

Roche v. Cipla[133]: The battle over licence infringement

"F.Hoffmann-La Roche AG ("Roche"), the patentee of the small cell lung cancer drug Erlotinib (sold under brand name Tarceva) in January, 2008 filed a suit for injunction at the High Court of Delhi54 against Cipla Ltd., for allegedly infringing its patent in the drug Erlotinib by engaging in manufacturing and selling of generic version of Erlotinib in India, under the brand name "Erlocip"."[134]

The Court held that "as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a lifesaving drug, the balance has to be tilted in favor of the latter."[135]

"This judgment is landmark because it lays down principles for patent infringement analysis. The court borrowed heavily from the English Law on this issue, since the Indian jurisprudence on this issue is almost nil.

The court held that in cases where there exists a patented claim for a product and the impugned product which may substantially contain the patented product but also

[130] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 40 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.htm.
[131] Supra Note 127.
[132] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, ¶ 39-40 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.htm.
[133] Hoffmann-La Roche Ltd. and Anr. vs. Cipla Ltd.; I.A. No. 642/2008 in CS (OS) 89/2008 decided on 19.03.2008 [2008(37) PTC71 (Del)].
[134] Ibid.
[135] I.A. No. 642/2008 in CS (OS) 89/2008 decided on 19.03.2008 [2008(37) PTC71 (Del)].

contain some other variants or some other parts in addition to the patented article or product, the test of purposive construction has to be used to determine whether the impugned product infringes the patent or not. The court has held that this is the test to be followed even in cases of pharmaceutical patented products or process."[136]

"The principle of purposive construction for the infringement analysis has to be undertaken in three steps:

Step 1

Whether a person skilled in the art based on reading of the specification would understand that the patentee intended strict compliance with the claims of the patent to be essential to the invention. If, yes then any variant of the patent will not amount to an infringement of the patent.

Step 2

In case where the variant of the patented invention is a major variant and has material bearing upon the working of the invention. If, yes then there is no infringement of the patent.

Step 3

In case where the patentee did not intend to exclude minor variant of the invention and the said minor variant does not have any material impact on the way the invention is worked. If, Yes then there is an infringement of the patent."[137]

➔There have been very few patent litigations in India that have been decided by the Indian Courts, however, the decisions discussed in this chapter are enough to understand how the analysis of patent provisions is done in India.

[136] NISHITH DESAI ASSOCIATES, Intellectual Property Law in India- Legal, Regulatory & Tax, July 2015.
[137] Ibid.

CHAPTER VII

CONCLUSION AND SUGGESTIONS

By tracking the advancement of Intellectual Property and Human Rights provisions administering access to drugs, this dissertation has three observations that have prima facie been discussed and noticed. Initially, the dissertation questions the standard way of thinking that the access to medicines issue range is portrayed by high sanctioning of Patent (mandatory and exact principles representing pharmaceutical licenses) and low sanctioning of the human "Right to Health" (weak norms and low enforcement). The dissertation additionally shows that the sanctioning of the "Right to Health" all in all and access to medicine specifically has expanded strongly over the past decade, principally in response to a past time of fast extension of pharmaceutical patent rules. The outcome is a Trans-national legal Order (TRIPS) described by continuous high-profile conflicts over contending legitimate standards in a wide and differing cluster of fields.

The dissertation investigates and examines the components and techniques utilized by various nations and coalitions of non-state players to create contending legitimate standards identifying with the convergence of the "Human Rights" on one hand and Intellectual Property (Patents in the case) on the other. These include:

1. Growing the quantity of multilateral, territorial, pluri-lateral, and two-sided scenes in which bargains and delicate law standards are received;
2. Entrepreneurially moving arrangements among these settings; and
3. Directing how distinctive nations actualize global standards in their local legitimate processes.

These components and procedures highlight a few bits of knowledge of the Transnational Legal Order, i.e. the TRIPS Agreement.

It is demonstrated that investigations of regularizing settlement and institutional arrangement are deficient unless they contemplate on collaborations at the transnational, national, also, nearby levels[138]. Second, they recommend that

[138] HALLIDAY AND SHAFFER, Chapter 1.

researchers must give careful consideration to "defining the limits of TLOs and changes in their limits after some time"[139].

The dissertation shows that if after one Transnational Agreement, another Transnational Agreement is introduced and that keeps happening again and again then it can induce quick unsettlement and a misalignment of standards and organizations that had been steady and uncontested for an augmented timeframe.

This dissertation proposes a conclusion that when Trans-national legal Agreements, like the TRIPS, are examined it would lead to the result that:

When controversial International tenets are enforced, they are more often than not challenged instead of being abided by. Such tenets of International Law only narrow the arrangement space accessible to governments when those tenets are transformed into national also, sub-national lawful frameworks and can be challenged by National Groups and individuals.

This is the reason that when TRIPS was enforced and signed by various countries, there was major reluctance from the side of Developing Countries. However, all the WTO members still signed it.

"Developing Nations" came out with flying colours during the in the Doha deliberation for certain reasons. Among the most essential is that they could coordinate amongst themselves and reach a middle ground where there was an agreement. Not only did they reach an agreement, they unanimously put forward their stand before the developed nations.

This sort of participation is shockingly hard to keep up as governments look to amplify their own particular favourable circumstances and benefits; and in doing as such surrender what might be aggregate best advantages. A noteworthy test for developing nations is that how they can carry on their cooperation on a long term basis. They must coordinate to yield collective advantage.

The impact of pharmaceutical patents on the Indian Public and economy can be expressed in the following points:

[139] Supra Note 106.

1. The Indian economy has been persistently rising due to positive impact of manufacture of generic drugs;
2. Since investment is increasing in the sector, naturally income levels are rising;
3. Increasing infiltration of “insurance” on all fronts, particularly subsequent to permitting private players to enter;
4. For the 60% of "poor people" in India, for whom there is no availability of pharmaceuticals, rise in price is immaterial. Consequently just a little piece of the market will be influenced by the new administration,
5. India is represented by a government which depends more on populist legislative issues for its survival; therefore, the government is generally not affected by the pressure put upon it by International forces.

   Thus, it can be foreseen that India can get more benefits out of this Patent Regime.

Even though going by the needs of the country enforcing Right to Healthcare facilities is of utmost importance. However, if the scenario continues that the government intervenes in each and every pharmaceutical patent holder’s rights, the day won’t be far when pharmaceutical companies would be reluctant to invest in India. The companies are profit based and if they yield no profit out of the capital that they invest in research and development, they’ll start moving out of India. This, consequently, would lead to lack of technology in the field of pharmaceuticals.

Thus, it can be said that in India advent of generic medicines is not considered a violation of patents but is a legitimate exception that can be exercised to fulfil the State’s obligations towards its citizens. But India must tread with caution. In order to attract investments in the pharmaceutical sector it must also offer incentives to companies because the patent protection regime is not stringent enough for them to work as profit entities.

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