**Master's Thesis**

# A Study of Health-Related Flexibilities in International IP Framework and Patent Law in Pakistan

파키스탄 국제 IP 체계와 특허법의 건강 관련 유연성에 관한 연구

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# Abstract

From a public health perspective, WTO Agreement on Trade-Related Aspect on Intellectual Property has flexibilities those were further enhanced and elaborated under Doha Declaration. Member States can take benefit with incorporation of such measures in national legislation to ensure availability and accessibility to medicines on affordable prices. A study was carried out on opportunities and limitations of the states in this regard wherein a comparison of few developing countries' legislations on patent was also undertaken with focus on law of patent in Pakistan. It has been observed that the widespread ambiguity of policies combined with a lack of national legal and technical expertise is significant problem to meet challenges in access to medicine. An effective cooperation between the various government agencies and institutions with concerted efforts is required nationally and internationally to facilitate the development and access to medicines in developing countries. Consequently, notwithstanding the tentative steps that have been taken in this direction, further clarity and guidance at the international level is required to facilitate the meaningful incorporation of the flexibilities and their use to promote access to medicines.

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# Chapter 1

# Introduction

## 1.1. Background

History of inventions protection can be found before 7th century in a shape of community and regions. Finally, these national and regional approaches turn into international, where 'Paris Convention for the Protection of Industrial Property' is the first agreement which addressed inventions with "patent protection". Although there were merely procedural issues in the convention and scope of subject matter was left on the discretion of Contracting Parties. Provision on national treatment to nationals of other contracting parties was added which paved a path for indiscriminate protection of rights (1)[1].

[1] Bodenhausen, George H. C. *Guide to the Application of the Paris Convention for the Protection of Industrial Property, as Revised at Stockholm in 1967* . s.l. : BIRPI, 1969.

The core aim of the Paris Convention is to become a platform, as soon as possible, for harmonizing legislation on intellectual property in the different countries. So far, the Convention has been one of the most successful treaties in both ways having remarkable number of its Contracting Parties as well as after over 100 years it still exists without any substantial change. Over 150 countries have adopted the Convention, initially it was signed by eleven members including Brazil in 1883 (2)[2].

Under Article-19, the Convention provides opportunity to form special arrangements among the Member States- which formed in the shape of Madrid Agreement for international registration of marks and other agreements. Despite all merits, the industrial states including US showed its dissatisfaction as considering it an insufficient to give protection for intellectual property. Since 1980s, the US tried to transfer the discussions to GATT (General Agreement on Tariffs and Trade) to make stronger protection for patent rights through international instruments. A number of countries showed resistance to this initiative but, after consent of Brazil and India, it was only tabled into GATT agenda in 1989. These states argued that the proper forum for the discussion on intellectual property is World Intellectual Property Organization-WIPO (administrator of the Paris Convention) and not GATT.[3]

The aforesaid US proposal which was negotiated among the states on the forum of GATT was based on three areas including the definition of minimum protection standards (Art. 9 - 40), the introduction of enforcement mechanisms (Art. 41 - 61) regarding administrative and judicial proceedings and lastly creation of international arbitration system (Art. 63 and 64). Instead of only two basic principles in the Convention, that new move stipulated a large number of concepts

[2] **Gontijo, Cícero** *Changing The Patent System from the Paris Convention to the Trips Agreement-The Position of Brazil* Global Issue Papers, 2005, Vol. No.26. p.6
[3] Ibid p.10

and requirements which had to be adopted by all members in their IP legislations. There was a substantial shift in existing legislations which were being followed since centuries. That effort finally became into existence in the shape of WTO agreement on intellectual property.[4]

Formulation of World Trade Organization Agreement on Trade Related Aspects of Intellectual Property (TRIPS) is a significant economic development of twentieth century wherein a vital association between intellectual property rights protection and competitive business growth was established. TRIPS Agreement positioned innovation and creativity into limelight in order to enhance economic activities and wealth creation. The ultimate objective is to address challenges for survival of mankind with support of new creations and inventions (3).[5]

In the Article 27-34, the TRIPS Agreement requires Member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the fulfilling basic criteria of novelty, inventiveness and industrial applicability. Moreover, patents should be available and patent rights will be exercisable without discrimination as to the place of invention and whether products are imported or locally produced (4)[6].

Every member state grants inventions protection according to patent law fulfilling a certain criteria wherein binding benchmarks have roots from the TRIPS agreement. Obligation on protectable subject matters and minimum standards effects thrust of inventions protected under the patent law, particularly in the field of medical. Regarding general remarks, usually, two schools of thoughts on the patent system exists therein one group favors monopolistic patent protection on

[4] Ibid p.10
[5] *Significance of balance between technology transfer and enforcement of IPRs.* Zahid, Nasir Mahmood. March, 2012, IP Community.15, APIC-Japan, p.59.
[6] WTO website

the plea that it will stimulate continuous inventions in pharmaceutical sector and it is vital for survival of human being against life-threatening diseases.[7] The second group opined that patent system is major hindrance to access lifesaving drugs as it put away patented medicine out of affordability cycle of general masses. This group also intersects the views with basic fundamental human rights and supply of indispensible life protecting drugs (5; 5).[8]

In view of correlation between trade and patent system generated in the TRIPS, the market is affected with innovations proportionally with grave results. Inventions having potential for commercial exploitation may radically transform specific sector with everlasting impact. Minimum protection criteria available in the TRIPS Agreement for the protection of patent rights are obligatory to comply for each member states in World Trade Organization. Beyond these obligatory provisions, sufficient space of flexibilities is available for each member in national legislation on patent law in term of certain fields and conditions wherein room is critical in view of economic importance (6)[9].

To utilize the space of flexibilities available in TRIPS, sound skills to structure national legislation on intellectual property, mechanism development and systematic policy formulation for coordination with stakeholders are basic tools for using specific relaxation in the TRIPS. A well-coordinated system is indispensible to utilize flexibilities in the field of health sector which are very tricky in nature in view of human rights and enhancing bilateral trade. Regional cooperation can support meaningfully to handle these situations and the technically handicap human resource of these regional countries can also be

[7] Ibid, p.61

[8] Thomas Pogge, Matthew Rimmer, Kim Rubenstein. *Incentives for Global Public Health-Patent Law and Access to Essential Medicines*, 2015.

[9] Weiss, Pia. *Patent Policy Legal-Economic Effect In National And International Framwork,*. 2010.

trained to use TRIPS flexibilities in order to public health. In view of patent protection level impact on life-saving drugs, the regional cooperation is important for playing role in helping developing countries to use the flexibilities and overcome obstacles imposed by patents. (7 p. 4).[10]

Furthermore, the common apprehension for countries particularly situated in the south of the globe is for affordable essential medicine. The use of different viable regional frameworks can provide a tremendous opening to improve access to essential medicines and facilities. This regional approach would allow each developing state to maximize the benefits with availing TRIPS flexibility through joint sharing of technical expertise and facilities. The regional joint cooperation leads political unity which will exist in certain mechanism essentially to overwhelm opposition at domestic and foreign level to surrender the applicability the flexibilities for health of public and related objective in socioeconomic structure.[11]

It is also worth mentioning that the magnitude of the extension of patent protection for pharmaceutical products and processes is critical in combating diseases. Determination of scope and consensus on interpretation of the flexibilities in the agreement was remained a challenge that can be used to enhance the accessibility and obtainability to life saving patented drugs. Later on this critical challenge was resolved by Doha Declaration which established a relation between public health conditions and the level of patent protection for pharma products and justified the use and extent of the flexibilities in the TRIPS Agreement to this objective (7 p. 4).[12]

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[10] Sisule F. Musungu, Susan Villanueva, Roxana Blasetti. *Utilizing Trips Flexibilities For Public Health Protection Through South-South Regional Frameworks.* 2004.

[11] Ibid, p.34

[12] Weiss, Pia. *Patent Policy Legal-Economic Effect In National And International Framwork.* New York USA, 2010 p.27.

The TRIPS Doha Declaration regarding public health issues and the flexibility for mobility of the drug has stepped in right direction to best use and ensured public health. An important element is of sustainable measures to maximize a space for flexibilities and to counter overwhelming patent protection for pharmaceuticals products and processes. In the backdrop, critical supply of life-saving drugs guides to explore flexibility and limits exclusive rights in the shape of patent protection. (8)[13].

Importantly, the obligations of Doha Deceleration are equally applicable on all Member States on access to medicine irrespective of their development level to take advantage of the flexibility and facilitate availing flexibilities for health purposes. Despite the provisional actions that have been taken in this course, still further clarity will be required to stimulate the incorporation and practice of flexibilities which can be elucidated in the form of principles and guidelines for the implementation of flexibilities in public health (9)[14].

## 1.2. International framework of flexibilities and Exceptions

The meaning of "flexibility", as used in the preamble with Article 66.1 says that "*given the needs and the specific needs of the least developed countries that are members, their economic, financial and administrative constraints, and their need for flexibility to create reading, must have a viable technological base*", these

[13] Hestermeyer, Holger. *Human Rights and the WTO: The Case of Patents and Access to Medicines.* s.l. : Oxford University Press, 2007 p.312-313.

[14] Oh, Cecilia and Sinsule. *The Use Of Flexi`bilities in TRIPS By Developing Countries: Can They Promote Access To Medicines?* Geneva Switzerland : World Health Organisation and South Center, April 2006.

members no obligations other than Articles 3, 4 and 5, for a certain period to implement the provisions of the Agreement (10)[15].

As per TRIPS agreement wherein patents are all available for "inventions, products or processes," and minimum time period 20 years from the filing of a patent application. Addition of process patents in enhances space of patent was of particular interest to the pharmaceutical industry. Article 28[16] provides that "*the patentee has the exclusive right to manufacture, use, offer for sale or the patented product to sell (in the case of a product patent) or manufactured from the patented process product (in the case of a process patent) , the patentees have "qualified" for an exclusive right to import*" (11)[17].

Regarding the measures, three types of flexibilities are available in the TRIPS agreement which can be named as preventative, remedial, and enforcement. Preventative flexibilities are supposed to be the policy options to ensure broadly that patents do not hinder access to affordable medicines. Article-7 stipulates objectives of the instrument whereas Article-8 specifies principles which provide flexibility primarily for the member states. 'Exclusion from patentability' generates ample flexibility about new use of known substances, methods and processes give an ample space for member states in health sector. Furthermore criteria for patentability regarding examination of pharmaceutical patents are also important tool of preventive measure. In addition, the measures to mitigate frivolous patents and opportunities for evergreening of patents are also important steps in this direction. One significant aspect, option of pre-grant and post-grant

[15] *WTO Agreement on Trade-Related Aspects of Intellectual Property, Article. 66.1*
[16] Ibid, Article.28
[17] Sykes, Alan O. TRIPs, Pharmaceuticals, Developing Countries, p.27

opposition system also allows opportunity member states to adopt a type of opposition mechanisms in their best interest (12)[18].

Secondly, remedial flexibilities are a set of exceptions admissible in the certain conditions. Exceptions to rights conferred under Article-30 and use without authorization of the right holder under Article-31 are vital forms of remedial flexibilities. A series of remedial flexibilities are included in the TRIPS Agreement to meet existing and emerging needs to secure access to affordable medicines such as compulsory licenses and government use orders, regulatory exceptions and parallel importation. Significantly, a provision was also added in Article-31 on the basis of paragraph-6 under Doha Deceleration to ensure access to medicine for those countries which have not manufacturing capacity.

Thirdly, Part-III of the TRIPS Agreement stipulates obligations for enforcement actions which also offer an ample space for the Members to enforce patent rights in terms of civil remedies and availing a choice of criminal remedies. This part sets minimum standards for enforcement measures and grants leverage for adoption of certain flexibilities in terms of border measures on exports, criminal remedies in certain forms of intellectual property and other procedures (13)[19].

Another important Article 27 that can afford nations the opportunity to develop to reduce drug prices wherein an important qualification for the exclusive right is available. This Article read with Article 6 of the TRIPS on exhaustion of right, "*the nothing enable in this Agreement be, are used, the question of the exhaustion of intellectual property rights*". This refers obscurely worded provision whether a patentee holds the rights for the resale of a product once it exercised through the

[18] Busche, Jan. *WTO - Trade-Related Aspects of Intellectual Property Rights*, 2009, p.42

[19] *UNDP-Good Practice Guide: Improving Access To Treatment By Utilizing Public Health Flexibilities In The WTO TRIPS Agreement.* NY USA: December 2010, p.9

market stream, or whether the original sale introduced, rights holders "exhausted" its rights.

To extent of minimum substantive standards, these were settled at the time of the Uruguay Round negotiations at then current level of developed countries and reducing the margin of maneuver was the result of the addition of new minimum substantive standards in TRIPS final version. With this Addition, the policy space for the developing countries was reduced significantly. These developing countries are in pursuit of a better understanding of this set of rules, to be able to terminate the consistently in the TRIPS agreement to implement and take advantage of the available options or spaces, which can be used in accordance with their national policy decisions. These available options lead toward the concept of flexibilities in the form of exceptions, exclusions and other room in the certain provisions (14)[20].

The Doha Declaration was marked as a turning point in international trade therein trading system should also be compatible with public interests especially in health sector. The Declaration laid founding principle of public benefits and made notable progress wherein WTO members were allowed to get due advantage of flexibilities in the TRIPS Agreement regarding protection of public health and improve accessibility towards medicines.[21]

As a ground reality, Article 31 (f) stipulates that a compulsory license must be issued primarily for the supply of the domestic market of Member State. A number of countries those didn't have a substantial manufacturing industry in pharmaceuticals remained unable to take suitable benefit of the provisions related

[20] *The Implementation of the TRIPs Agreement.* Vandoren, Paul. s.l. : Journal of World IP (1999), Vols. Vol 2, page 27.

[21] ibid

to compulsory licensing in the TRIPS agreement. Although members could issue compulsory licenses to import but this step was limited to the import from countries where the pharmaceuticals were patented or their protection term had expired. In the case when the generic productions of vital medicines from new manufacturing sources are increasingly, the resolution of this problem was of extreme importance to Members' efforts to ensure access to affordable medicines to meet the health requirement of their public (15)[22].

Whereas the matter of patents related to flexibilities is complex in the multilateral legal framework and their statutory implementation at the national and regional level therein four parts can be settled for it i.e. the multilateral charter for patents; execution of multilateral agreements on patents; explanation of flexibilities and endeavored academic grouping and recognizing a group of application flexibility.[23]

It is important to mention that formulation of legislation to implement does not mean that policy decisions in regard of the flexibilities are effectively reflected in the patent law, though, the capability gained by developing countries in this process to utilizing space is significant in this direction. The use of flexibilities by a large number of countries is salient in the different areas including compulsory licensing, parallel imports, regulatory review exception and transition periods. Nonetheless these outcomes, a deserving focus is need for those countries those are still away from making full use of these flexibilities (16)[24].

[22] Verma, S.K.*TRIPS Agreement and Access to Medicines.* Tokyo Japan : Kansai, 2011, p.7
[23] ibid
[24]WHO Bulletin:Has the mplementation of TRIPS Agreement in Latin America and the Carribbean Produced intellectual property legislation that favors ublic health?. Nov. 2004, Vol. 82 p.67

A multi-dimension review of the flexibilities' effects and practicability was expressed as an excuse to denial to legitimize with the obligations of TRIPS. A focus was viewed wherein flexibilities deemed as the solution to all problems. The extensive deliberations on all aspects of the flexibilities are caused due to its attaching characteristic with fundamental human rights and political responsibility in health sector (17)[25].

Due to diversified approaches, flexibilities were defined as a set of basic rights, measures to safeguards and a combination of options that can be exploit by member states in the implementation of the TRIPS Agreement. Vagueness in the provisions is also a source to build another perception on this idea which lead toward creating new options (18)[26].

To classify the flexibilities, it can be differentiated on the grounds (i) material that qualifies for protection (ii) protection level (iii) mode of IP application and (iv) the matters of management. Conceivably the utmost beneficial method of combining flexibilities takes into account the fact that the member states can use them: (i) in process of attaining the right (ii) the explanation of the areas for law enforcement and (iii) in implementing of the law (19)[27].

Flexibilities in TRIPS regarding patent are mostly focused towards health issues, concentrating these areas, the member states attain some freedom and can adjust to their patent laws in order to fit in their peculiar legal systems, preferences in health sector and compatibility with priorities of development. More importantly, the members had the opportunity to take certain measures to neutralize the effects

[25] Council, TRIPS. *Document IP/IC/W/296, Paragraph 5.* Geneva : WTO, 29 June 2001.
[26] Deere, Carolyn, *The Implementation Game* Oxford University Press, 2009. p-68.
[27] Loon, See Ng-Loy Wee. *Exploring Flexibilties within the Global IP Standards* , 2009. Vols. 2, p.162-164.

of the exclusive rights with promoting competition and facilitate for access to medicines. There were several flexibilities integrated in the agreement in the form of measures that can be utilized to reducing prices and increasing the accessibility of medicines without a negative impact on future R & D activities (20)[28].

Structuring the national legislation, there are several ways through which national interests can be secured in TRIPS compliant legislation enactment in parallel to fulfilling obligations. It can also be transposed in the visions and principles in befitting manner whereas the structure of definitions can effectively limit the scope of the concept of provision in accordance with the obligations and desired future space. The construction of language in such provisions gives right means of implementation keeping in observation of its advantage and flexibility. The various options for attaining certain results and goals require a practical approach in legislation with plausible authority and mechanism for implementation. The flexibility a given step to include in the national law to secure national interest must be integrated in a way that it will be compatible with a flexibility given to the provisions and principles of the agreement[29].

[28] Ghanotakis, Elena, *Access to Medicines for Developing Countries* Journal of World IP (2004),Vol.7

[29] Ibid, p. 87

# Chapter 2

# Flexibilities and Exceptions in Context of Public Health

## 2.1 Preventative Flexibilities

To introduce ways for facilitating access to affordable medicines in view of pharmaceutical patent protection, the member states have many forms of possible flexibilities in respect of preventive and remedial ways which can be utilized to counter the fallback negative effects of patent protection for ensuring availability and improving access to medicines at affordable prices. Pharmaceutical patents have not been granted in an automatic way to all drugs that are already protected under patent in other countries of the world. Patents are territorial rights which are granted by a state under a certain patent law. The patent law can be formulated within allowed limits under TRIPS but it has a flexible range on some subjects. Mostly preventive measures are exercised prior to grant of patents or executed

during the examination of the patent. These flexibilities can be implemented rapidly and are capable of at least other corrective measures.[30]

### 2.1.1 Exclusion from Patentability

Under Article 27 of TRIPS, certain provisions are available regarding exclusion wherein member states are allowed to avoid patentability in the specific areas. As per Article 27.3(a), the member states may exclude the areas in respect of diagnostic, therapeutic and surgical from protection under patent. The member states can control expensive treatment of patient by excluding this area from the patent ability (21)[31].

Furthermore a provision is available under 27.3 (b) in which the member states are also allowed to "*exclude plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes in the field of protection patent*" The area of plants and animals, which is more sensitive for agro-based countries, has no obligation for protection under patent law because member states are free to give protection under sui generis law or under patent law. [32]

The exclusions are also available for certain inventions from patentability if their commercial use is against of "public policy" that would undermine public order or morality, including the life or health. The public policy exception, when all transactions involving the particular area in violation of public order, not only to patent monopolies. (22)[33].

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[30] Ibid, supra note 6
[31] TRIPS Article 27.3
[32] Ibid,
[33] 13. Carlos Correa, *Intellectual Property and International Trade: The TRIPS Agreement.* The Netherland Kluwer Law International , 2008. p.230-31

### 2.1.2 Setting and Applying Strict Patentability Criteria

In TRIPS agreement, Article 1 provides for "*implementing provisions for the freedom of the Member States appropriate method to determine their own legal system and practice*." [34] In the Article 27.1, three parameters are set for patentability criteria wherein the invention must be examined in accordance to novelty, inventive step and industrial applicability. Whereas no specific meaning is elucidate in the agreement so the member states are free to interpret these parameters which give them a policy space in determining their national legislation on patent (23)[35].

In addition, a note is available under the Article 27.1 wherein interpretation of "inventive step", terminology used in the European countries is equal to a term "not obvious" used in USA and the member states are allowed to interpret a term "industrial application" as a same meaning to "useful". The terms "non-obvious" and "useful" set a bottom-line threshold making much more patentable inventions whereas the term of inventive step and industrial application assured that there are fewer new molecules discovered. [36]

On the basis of new use and secondary characteristics, the pharma companies attempts each time to extend the terms of patents on existing drugs. There is no binding provision for the member states to allow the new use or secondary characteristics in their patent legislation. Member States may exempt grant of

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[34] Ibid, supra note 25
[35]UNCTAD-ICTSD: Resource Book on TRIPS and Development, 2005, p.352
[36] Ibid,p.353

patent on grounds of new uses of same inventions for lacking to meet patentability criteria under novelty, inventive step or industrial application[37].

It is pertinent to mention that the spread of secondary characteristics in pharma sector is termed as "evergreening" wherein right-holder try to prolong patent term only by presenting minor changes in the making of the products or to claim through new uses for existing drugs. Such new use leads to 20 years more term therein it can be a de facto addition in term of existing patent. It ultimately thwarts competition in generic pharma industries for facilitating to lower price of the products in the market. By adopting strict patentability criteria, such dummy inventions can be restrained and developing countries may exclude secondary characteristics from patentability and restrict the possibilities of "evergreening" (24)[38].

To protect a certain sectors of industries, many developed countries included criteria of new forms and / or new uses for existing substances in patentability although it is not suitable for developing countries to extend monopoly rights in the form of patents without contribution of substantial invention. Some developing countries showed specific measures to avoid patents on new forms and new uses. India in such countries is a good example that has this type of provision in its patent act (25)[39].

It may also be added that a new form of a known substance is a simple discovery which does not result in substantial improvement in already determined substance efficacy or a mere discovery in connection to a new property or new use for a

[37] Ibid,p.354

[38] *Generic Drug Entry Prior to Patent Expiration* . Washington: US Federal Trade Commission , 2002.

[39] Report on: Prescrire International Commission on Intelectual Property Rights. *Integrating Intellectual Property Rights and Development Policy.* London : DFID , 2002.p.67-68

known or mere using a known process substance, machine or apparatus. Unless such claimed processes give outcome in the form of new product or new uses be the purposes of description of this substance which differ significantly in properties with regard to efficacy[40].

A report of European Commission apprised about a substantial decline in the number of new drugs was observed during 2000 doubled to 2007 patent applications for pharmaceutical products. 87% of the applications were in the process of "secondary" patents registration i.e. that covers several additional functions such formulations, salt forms, methods of treatment, etc. (26)[41].

It is pertinent to mention that different studies and research were undertaken in other countries including United States of America and France and the same aforesaid observations were found regarding share of new use or secondary characteristics (27)[42].

### 2.1.3 Preventative Measure—India's Section 3(d) and the Novartis Case

During formulation of TRIPS compliant patent law in India, a new provision was introduced on patentability criteria by insertion of Section 3(d) in patent law that "*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*". Under this provision, mere new

[40] Ibid,p.70

[41] Paper, DG Competition Staff Working. *Pharmaceutical Sector Inquiry Prelimnary Report.* European Commission (EC) , 2008. P.109

[42] Report of Prescrire International *: Floundering Innovaton and Increased Risk-Taking.* France , ,2005,14(76)p.68-73.

use of existing drug is not supposed as an invention and it is not patentable as per the Indian Patent Act (28)[43].

The Section 3(d) is a source to counter renewing patents in the name of "evergreening". Evergreening practice is used when a drug manufacturer avoids expiry of patent term with getting a new patent on the basis of minor improvements to an old medicine. This practice allows manufacturers to get a new term for their patent without substantial improvements in a drug. These improvements may include such as new forms or new uses of a drug, combinations, or formulations of already known medicines. On the basis of Section 3(d) of Indian Patent Law, Indian Supreme Court gave a famous decision on patent for beta version of Glivec (cancer treatment drug) produced by Novartis in which Novartis filed its patent application on grounds of efficacy (29)[44].

In the said Novartis Glivec case, the Indian Supreme Court has set the bar for patentability. That bar already has become role-model legislation for other developing countries which are striving for a balanced system towards patent granting. This patent granting without balanced approach is touching the issue of human rights on plea of access to life saving drugs especially in developing countries. In 2008, Philippines passed a law which named as *Cheaper Medicines Act* that almost copies exact wording of the Indian phrasing in patent law. Other developing countries including Pakistan, Sri Lanka, Vietnam, Malaysia, and Bangladesh are also in process to consider such provision of Section 3(d) in order

[43] (d), Section 3. *Text of Indian Patent Law*

[44] *Finding the patent balance: the Novartis Glivec case and the TRIPS compliance of India's Section 3(D) efficacy standard.(Agreement on Trade-Related Aspects of Intellectual Property Rights).* **Turrill, Zoee Lynn.** 4, s.l. : Georgetown Journal of International Law, Summer 2013, Vol. 44. P.4

to have greater flexibility in patent law in parallel to fulfilling TRIPS obligations. [45]

### 2.1.4 Developing Patent Examination Guidelines from a Public Health Perspective

TRIPS flexibilities may be utilized appropriate changes in national patent law, in addition, adoption of more stringent patent examination guidelines can be a source to filter the process of examination of applications for pharmaceutical patents in national patent offices. An effective guideline for the examination of pharmaceutical patents from a point of view of public health is important to protect interests of masses.[46]

### 2.1.5 Patent Oppositions (Pre-grant and Post-grant)

Opposition mechanism in patent system exists to protect valid rights of interested parties on grounds of determining novelty in the inventions as well as allowing patent offices to inspect whether an invention has the requisite level of novelty, industrial applicability and an inventive step. Additionally the opposition procedure also takes a look into quality of patents that may prevent many problems (30)[47].

Both types of oppositions namely pre-grant and post-grant in patent system can tackle the issue of deficient means and material in patent offices to oppose a patent application wherein third parties are allowed to share information on prior art and other concerned information. Physical evidence as well as the testimony of

[45] Ibid. p.7
[46] Ibid, supra note 6
[47] *Improving patent quality through Pre-Grant opposition in Thailand.* **Puasiri, Wanwipar.** s.l. : Journal of International Commercial Law and Technology, 2013, Vol. 8(4), p.1-2

experts is also salient to determine novelty at the time of filing a patent application. [48]

Pre-grant opposition is a legal process wherein third parties have opportunity to oppose an application of patent soon after its publication in patent gazette or electronic publication but before the grant of a patent. The disclosure of inventive step is happened to the public at the time of publication in the gazette. In case of a pre-grant opposition offer, the patent office needs to manage publication in a betting manner to minimize the chance that others will file similar inventions before the applicant obtained a patent.[49]

Post-grant opposition is a purely legal procedure in which third parties are allowed to oppose the grant of a patent within a specific period after grant of patents. There are a number of countries including China, South Korea, Brazil, Pakistan and India where patent registration use the post-grant opposition mechanism.[50]

Major issue with this post-grant opposition system is that it is applied through legal process initiated in the court of law which put into a long cycle inapt for commercial matters in certain occasion. Due to this length process of redressal in care of bad patents, the patent holder enjoyed monopoly unjustly. This is also of peculiar concern in India where protracted nature of the judicial process exists. On the other hand, pre-grant opposition has shortened route and more cost effective resulting in a faster disposal of cases in contrast of the post-grant proceedings (31)[51].

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[48] Ibid, p.5
[49] Ibid, p.5-6
[50] Ibid, p.7-8
[51] *Comparative Study of Pre-Grant and Post-Grant Patent Opposition in India* . **Neeti, Shikha.** s.l. : http: ssrn.com/1503188, November 10, 2009. P.2-3

### 2.1.6 Role of Civil Society in Patent Opposition

IP issues in health related matters overlap with human rights in which public basic rights become concern of civil society and state government. Due to vital connections of pharmaceutical patents with access to medicine and public health, the rights granted under patent law affects living of nationals and their basic rights. Role of civil societies is emerging in the world in opposition mechanism under patent system (32)[52] .

Groups of civil society challenge a patent granted by the Office of Thailand Patent Office on important ARV Didanosine. Despite the strong position of patent owner (Bristol-Myers Squibb) wherein civil society groups lacked in standing to challenge a patent but Thailand authorities have allowed the civil society to challenge in accordance with the Doha Declaration (33)[53].

After the successful example by civil society groups in Thailand to challenge patent for Didanosine, effective role of civil society groups is rising in countries such as Brazil, India and China therein they have filed opposition on patents on essential drugs and challenged their validity. In particular, a large number of patent oppositions filed by both groups of civil society and generic companies in India to take full advantage of the opposition trials (34)[54].

## 2.2 Remedial Flexibilities

[52] **Maskus, Keith E.** *Private Rights and Public Problems- The Global Economics of Intellectual Property in the 21st Century.* Washington DC : United Book Press, September 2012 p. 16

[53] **Organisation, World Health.** *WHO Bulletin.* 2006. P.9

[54] http://www.msf.org/en/article/role-civil-society-protecting-public-health-over-commercial-interests-lessons-thailand

In view of patent right for medicines, there are certain ways which allows developing countries to address negative consequences of granted rights under patent law for public and research. Mainly these flexibilities including compulsory licenses, parallel importation, matters to patentable subject matter, provisions on exceptions to patent rights, data protection provision and provisions on exhaustion of rights, competition and control of anticompetitive practices (35)[55].

Compulsory licensing is recognized as a key instrument that can limit the exclusive rights of the patent holder in view of public need to fulfill certain objectives of national policy, in particular, it is a last approach to ensure the availability and supply of medicines at affordable prices. Doha Declaration is salient instrument in securing interests of developing countries in life saving drugs. Article 31 of the TRIPS Agreement sets out a number of conditions and fulfilling formalities for the grant of compulsory licenses (determination in way of case by case; prior negotiation with the patent holder, compensation etc.) but does not limit the grounds upon which such licenses may be granted. Although Article 31 refers to some of the possible reasons (such as emergency and anti-competitive practices) for the issuance of compulsory licenses, it leaves the member states full autonomy to stipulate other grounds, such as non-work and public interest (36)[56].

Issue of access of life saving drugs is interesting due to its crosscutting with fundamental rights in parallel to IP rights. A focus was given on exhaustion of rights and parallel importation, Patentability and optional exclusion to address this issue whereas use of exceptions to patents rights and enforcement due to their importance in protecting from abuse of rights are also salient. National policies

[55] Deere, Carolyn. *The Implementation Game.* London : Oxford University Press, 2009. Vol. p.75-78.

[56] *https://www.wto.org/english/tratop_e/trips_e/healthdeclexpln_e.htm.*

can be developed in important areas of utility models, disclosure of origin of genetic material and prior informed consent, and traditional of flexibilities in intellectual property especially in health of public is of great knowledge[57].

### 2.2.1 Compulsory Licenses and Government Use

A compulsory license is a license issued by a judicial or administrative body to a third party to exploit an invention without permission of the patent holder. This type of license has usually connoting lack of consent of the patent owner in this process. The concept of compulsory license, however, has a long history of operation in needs. One of the first legal instruments to incorporate the concept was the United Kingdom (UK) Statute of Monopolies of 1623. Internationally, compulsory licenses are recognized and provided for in the Paris Convention of 1883, the Paris to Uruguay Round by 1994 when TRIPS Agreement was adopted, the provisions for compulsory licenses had become a typical feature in patent laws (37)[58].

A number of countries have provisions in their national legislation that allow the government or third parties under definite conditions and situations to use a patented invention without the endorsement of the right holder. These provisions differ from other exceptions, since the right to payment is an important element of the balance between the interests of the right holder and other broader interests. These are considered as an instrument to prevent abuses of the exclusivity inherent in patent rights. They are regarded as significant tool which enable

[57] ibid
[58] *https://en.wikipedia.org/wiki/Compulsory_license.*

governments to respond for national security and taking actions in national emergencies (38)[59].

There are certain conditions for invoke compulsory licensing including evidence of prior unsuccessful request for a voluntary license, non-exclusive license and the obligation for compensation. There are also specific situation wherein the termination of licenses, export restrictions and granting of licenses to third parties are salient[60].

Despite these terms and conditions, TRIPS agreement still provides a sufficient room for flexibility in legislation on compulsory licensing. Compulsory licensing keeping as a policy mechanism can be used to meet a number of situations including unreasonable high prices of medicines, anticompetitive practices by pharmaceutical companies, Failure to supply in the market with the necessary medicines by right owners, emergency public health situations and the need for a pharmaceutical industry base[61].

Eexistence of a statutory provision regarding compulsory licenses is an important instrument to ensure a fair exercise of patent rights which is a support to concluding a successful voluntary license under reasonable conditions or inducing competition. Practice of compulsory licenses was analyzed as a tool to improve access to medicines in Africa wherein four of the countries that have tried in domestic production, and was only in one case, a compulsory license granted effective in Zimbabwe. In remaining three cases, voluntary license were granted in Kenya, South Africa and Ghana. It cannot be measured nor discounted to what

[59] Watal, Jayashree. *Intellectual Property Rights in the WTO and Developing Countries* . 2001. Vol. p.238.
[60] Ibid, p-239
[61] Ibid, p.245

extent the provision of applying a compulsory license enhances the negotiating position of the licensees to be voluntary (39)[62].

The member states must comply with Article 31 of the TRIPS Agreement regarding the circumstances which are to be met in the grant of compulsory licenses. It also refers to some of the probable grounds for compulsory licenses, without exhausting all possibilities. Under Doha Declaration on the TRIPS Agreement and Public Health, each member has right to grant compulsory licenses and the independence to determine the grounds upon which such licenses are granted. The grounds for granting compulsory licensing generally are including status of non-working or insufficient working of the patented invention, alarming unfair and anticompetitive practices, public interest regarding public health, securing national security, facing national emergencies and other circumstances of extreme urgency, failure to obtain a voluntary license on reasonable terms within a reasonable time and dependent patents and other titles that relate to the protection of inventions[63].

The decision of the General Council of 30 August 2003 also bounded the member states on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, therefore, some national laws provide specific provisions to implement this decision. In addition, a number of countries have laid down vivid provisions in their national laws which entitle the government or a third party authorized by the government to use the patented invention in certain situations without the permission of the patent holder. In some countries, such public use is permitted where serious public interest abused, such as national security, food, health or the development of other vital sectors of

[62] Cornish, W.R. *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*. s.l. : Fourth Edition . Vols. p.295-296.
[63] ibid, p.297

the economy. There is a variation in the mechanism for the granting of compulsory licenses wherein some states has complex mechanism like Pakistan whereas other states have liberal and easy way (40)[64].

The differences between national laws on this issue have made the work complex and difficult. Its main goal is to show the more or less frequent use of a given reason for a compulsory license. However, the dividing line between a compulsory license on the basis of the public interest and the public use for reasons of public interest is not always easy to determine if no explicit information has been provided on the subject.[65]

### 2.2.2 Parallel Importation and Exhaustion of Rights

Patent rights are territorial in nature, which means that each patent provides its owner the exclusive right to exploit the invention in the country or countries where the patent was granted limits. Under Article 4bis Paris Convention, one aim of the invention is to be patent protection in several countries, creating rights that are independent from each other whereas Article 28 of the TRIPS Agreement the rights granted reckon those rights. They include among them the "right of importation" because the exclusive right derived from patents can import the patented product from another country affected (41)[66].

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[64] **Correa, Carlos M.** *IMPLEMENTATION OF THE WTO GENERAL COUNCIL DECISION ON PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH.* Geneva : World Health Organization (Department of Essential Drugs and Medicines Policy), 2004, p.12-14

[65] Ibid, p.18

[66] **Yetunde Okojie ( Associate at SPA Ajibade & Co)** Parallel Importation and the Exhaustion of Rights Principle under the TRIPS Agreement and the Doha Declaration. P.5-6

Parallel importation is a situation wherein a third party without the authorization of the patentee, any product manufactured abroad marketed abroad by the patentee, the licensee or another lawfully compete with imports or products made locally by the patent owner or its licensee. First Sale Doctrine, the practice is based on the principle that the patentee was paid by the first sale of the product and further control over the resale of the product irrationally restrains trade and competition. After payment, the rights holders are anticipated to have exhausted their rights. As per Article 6 of the TRIPS Agreement, as endorsed by the Doha Declaration, the Member States are free to select their own exhaustion regime without challenge.[67]

TRIPS Article 28 has a footnote on right to prevent importation: "*like all other rights conferred under this Agreement regarding the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6* ". This means that the probability of imposing the exclusive rights of patents against the importation of authentic products varies with the form of exhaustion of rights assumed by the country where the importation takes place.[68]

The doctrine of exhaustion which is linked to the matter of parallel importation therein patent protected product (product manufactured by a patented process or patented product) was positioned on the market by the right holder or with his consent, the rights of patentee in respect of this product are accomplished. This constraint ensures free movement of products (42)[69].

[67] Ibid, p.1-3
[68] Ibid, p.7
[69] **Watal, Jayashree.** Parallel imports and IPR-based dominant positiuons: where do India's interest lie?, in Intellectual property: trade, competition, and sustainable development. 2003, *p.204-205*

The countries where the law provides national level of exhaustion, the rights of the patent owner are exhausted only in respect of goods which have been put on the market in the country with his permission. Intellectual Property Rights Commission in its report on the positive practical implications therein a restriction on parallel importation may have in facilitating access to medicines at lower prices to those who are in greatest need (43)[70].

In principle, there will be limitations on the free movement of products once placed on the market by a manufacturer. Nevertheless in practice, the exclusive purpose of confirming that the products at minimum prices can be accessed, and only to those who need the lower prices, it may be compulsory to derogate from this general principle. Therefore, a vital element in instituting a differential pricing is that markets need to prevent low priced products undermining high priced market (44)[71].

A system of regional exhaustion wherein once goods are released with the consensus of the patent holder in any country member of a regional market or union, the rights of the patent owner are exhausted and the goods may be imported into other countries of the regional market or union, and trading of these products do not create an offense[72].

The development of the doctrine of regional exhaustion is rooted in the European Union to a groundbreaking decision of the European Court of Justice in the early 1970s wherein a distinction was made between the existence of property rights of intellectual and the exercise of these rights, mainly, the exercise may be affected

[70] **V. Fink, Carsten.** *Entering the jungle of intellectual property rights exhaustion and parallel importation, in Intellectual property and development. Lessons from recent economic research.* Washington : Fink e Maskus, 2005. P.183-184

[71] Report of Commission on IPRs: *Integrating Intellectual Property Right and Development Policy.* London , 2002. p.103

[72] ibid, p.104

by the prevention against the agreement restrictions on the free movement of goods (45)[73].

According to system of international exhaustion, the products which are placed on the market by or with the consent of the right holder in the world that will a result of the rights of the patent holder being exhausted in the country. Goods imported into a state where having a system of international exhaustion of rights cannot be thought it a violation as long as they were put on the market, originally, by the proprietor or with his consent. (46)[74].

Under TRIPS Article 6, the member states are free to adopt level of exhaustion (i.e. national, regional or international) in accordance to its general provisions on principles of national treatment and most-favored nation treatment. A country may take decision regarding the level of exhaustion which is appropriate for national objective and it is thought a matter of political consideration. Furthermore, it is necessary to decide what steps will be in the chain of production and distribution of goods those require the license holder's right regarding the manufacturing, first sale doctrine, subsequent sales and other reports, export and import (47)[75].

The countries, such as Japan or the United States, have not enacted explicit legislative provisions on exhaustion, leaving it to jurisprudence to conclude the development of this issue. The present situation shows that nearly the same

[73] Case *GmbH v Metro-SB_Grossmarket, GmbH&Co, Case 78/70* . s.l. : Deutsche Grammophon, 1971.
[74] *Centrafarm BV et Adriaan de Peijper V Sterling drug Inc. Case 15-74.* s.l. : ECJ, 1974.
[75] Cornish, W.R. *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights.p.123*

numbers of countries are with three types of exhaustion namely national exhaustion, regional and international[76].

### 2.2.3 Research Exemption

Article 30 of the TRIPS Agreement establishes the general basis for exceptions to exclusive rights under the Agreement. The exceptions to patent rights should be limited and should not unjustified conflict with a usual exploitation of the patent. The legitimate interests of the patent owner should not unreasonably prejudice there should be taking account of the genuine interests of third parties. Although there is not explicitly mentioned in the agreement, exceptions for research and experimentation and early working exceptions are the widely accepted pursuant to Article 30 of the agreement with implications for public health (48)[77].

In some countries, like the United States, these exceptions have traditionally been judicially determined whereas in others, such as Japan, they are statutory rights. The exception of research and experimental use is to ensure that scientific research to produce new knowledge is encouraged and is not disadvantaged by patents. It is a longstanding exception which is justified on the grounds that one of the main objectives of the patent law is to assist the propagation of knowledge, promotion of innovation and thus facilitate the advancement of science and technology.

The early working exception, on the other hand, refers to a situation where a potential competitor uses an invention without consent of the patent owner to undertake actions compulsory to obtain regulatory approval and registration of a generic product before the expiration of the patent term. The exception is intended

[76] ibid, p.126

[77] Eisenberge, Rebecca *Patents and the Progress of Science: exclusive rights and experimental use.* S. s.l. : Chicago Law Review, 1989, Vol. 56 p.1107.

to ensure that generic versions of the product are available on the market nearly or within a reasonable period of patent expiry. The effective implementation of the exception differs from country to country[78].

Proponents of the research exemption base their arguments on a wide range of reasons, starting with the idea that the exception for experimental use is implicit in the patent system and for no other reason it will be able to explain the benefits of the patent system places on the free availability of the disclosure of the invention. It was argued that practical considerations have also been advanced therein much research is cumulative in nature where negotiating and concluding multiple patent licenses before any actual research takes place could result in significant transaction costs (49)[79].

Opponents of exception viewed that it has a negative impact on innovation with argument that the efficient allocation of resources requires researchers to pay the full cost of inputs they use, including knowledge developed by other researchers. (50)[80].

Wherein the first element, some countries make reference to "*acts for the purposes of experimental use*" or "*acts done for experimental purposes relating to the subject of the invention*", Second element, the law of some countries requires that relevant activities with respect to experiment, research, or technical be "*without commercial intent or profit*". In other countries, the provision explicitly

[78] Ibid, p.1109

[79] OECD report, Research Use of Patented Knowledge: a review, STI working paper 2006.

[80] *Report on Patents and Experimental Use.* s.l. : Advisory Council on IP of Australia, Oct 2005.

states that the exemption experimental use is applicable for acts anticipating a future commercial exploitation. [81]

The nature of innovation has changed that many research tools have direct commercial application in diagnostics or treatments, so they qualify for patent protection, but at the same time they are crucial to further research. Any scientist who would examine the genetics of breast cancer needs the BRCA-1 test that is patented. Working out on this point, research tools gain importance and relevance, especially in areas such as biotechnology. The appropriate scope of the exception should be cautiously designed to avoid incompatibility with Article 30 of the TRIPS Agreement, to the extent that any exception should not be "*unreasonable conflict with the normal use of the patents*" (51)[82].

Many experts and scientists argued that liberation from general research is important to promote innovation and improve the function of the patent system. Others claimed that there is very little empirical evidence is the need to demonstrate an exception such as to search engines.[83]

### 2.2.4 Limitation on the Grant of New Use Pharmaceutical Patents

Pharmaceutical patents with new use relate to patents granted for new applications for already known products. New pharmaceutical uses are either the first pharmaceutical use or the second pharmaceutical use wherein the former case relates to a situation in which a new pharmaceutical use is discovered for a product without previously known pharmaceutical use. In this situation, the product is used for the first time in the pharmaceutical industry. In later case, it is

[81] Ibid
[82] *Protecting the Public Domain of Science: Has the experimental use defense arrive?* R., Dreyfuss. 457, s.l. : Arizona Law Review, 2004.
[83] ibid

noted that a product already known to have one or more pharmaceutical uses has a further pharmaceutical use although it is not related to the prior known use (52)[84].

The countries have the opportunity to define the scope of the concept of invention under their national laws to exclude new uses from patentability. Proponents of new use patents justify them on the basis that the discovery of a new use may require the same level of investment and creativity as in the case of a new product, however, this applies in very limited circumstances. The innovation in the pharmaceutical industry for which patents are claimed varies considerably. [85]

Protection of new uses, particularly second medical indications, is commonly used for anticompetitive purposes because it is mainly for extending the patent period and blocking generic entry. The patent portfolio companies have been able to impede the entry of generic drugs by modifying existing and claiming patents on them. In the US, the modification of existing drugs enables companies to extend their patent protection over existing drugs or by patenting new features of the old medicine or getting three years of exclusivity under the provisions of the so- called Hatch-Waxman Act. This problem can become very critical in the countries where the law of pharmacy does not permit generic substitution and or prescription generic.

### 2.2.5 Regulatory Review Exception

In the majority of countries, various entities have the power to authorize the commercialization of certain regulated products. This is true for pharmaceuticals, but this phenomenon is not unique to this sector whereas other sectors such as

[84] **Hoen, Ellen F M 't.** *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of WTO Declaration on TRIPS and Public Health.* s.l. : AMB, 2009. P.34-36

[85] ibid

plant protection products, herbicides and pesticides, feed, flavoring substances and medical equipment are highly regulated. (53)[86]

The complexity of the related administrative processes those have increased in recent times. It varies from one country to another or from one sector to another, or even within the same sector, depending on many factors. For example, the authorization of a new drug is much more complex than the authorization for an "equivalent".[87]

There are the two major issues where is first from the standpoint of the right holder, it may suffer a net loss for the effective duration of patent protection, for the protection period of 20 years starts from the patent application. Secondly users' prospects of competitors, there is an interest that this administrative process for marketing authorization begin within the period of patent protection, despite the fact that the production and marketing must wait until the patent expires.[88]

These two aspects, patent extension for compensation of the time of the patentee lost waiting for marketing authorization and the use of the patented product for submission for regulatory authorization while the patent is still in effect, are under observation together in an exercise to find a balance between conflicting interests. But in many cases, countries have taken steps in relation to one of the two issues in a separate manner.

The review regulatory exception is also known as the "Bolar exception", after a famous case Roche Products vs Bolar Pharmaceuticals in USA during 1984 wherein Federal Circuit Court of Appeals ruled that the research exemption did not cover Bolar acts to perform equivalency tests for the regulatory approval of

[86] Abbot (2001), p.21
[87] ibid
[88] ibid

generic drugs before patent expiry corresponding owned by Roche. Despite the fact that Bolar Pharmaceutical's use was not considered covered by the general research exemption, and consequently he lost the case (54)[89].

To address concerns, this case was brought before the Congress of the United States. It was decided that there was no place to prevent manufacturers of generic pharmaceuticals to start preparing and obtaining regulatory approval for their generic products because it would delay the entry of generics on the market for an important period, extending the period of effective protection beyond the patent term. Subsequently, an explicit exception was introduced as section- 271 (e) (1) in the USA Patent Law. The regulatory review or Bolar exception was included in the national laws of many countries. Some countries do not have this provision as it is considered within the scope of the general research exemption and in other cases has been developed by case law (55)[90].

The scope of the regulatory exception varies among national laws as in some countries, the exception covers the regulatory approval of any products, while in some other countries, it is limited to certain products. The use of patented product must take place in the country where regulatory approval has to be requested, while in other cases, it is sufficient that the product is imported. In other countries, reference is made to the possibility of exportation wherein possibility of requesting marketing approval in other countries included.

### 2.2.6 Limiting the Extent of Test Data Protection

As the negotiating history of the TRIPS Agreement states that the suggestion of the United States to introduce data exclusivity was rejected by developing

[89] https://en.wikipedia.org/wiki/Roche_Products,_Inc._v._Bolar_Pharmaceutical_Co.
[90] https://www.law360.com/articles/454560/scope-of-statutory-research-exemption-remains-unresolved

countries during negotiations. Developing countries should avoid, if possible, adopting schemes of data exclusivity because it is not mandatory under the TRIPS Agreement. The data exclusivity systems are very likely to have a negative impact on access to affordable generic medicines to national markets. It is estimated that data exclusivity will also discourage generic manufacturers to apply for registration of their medications given the costs of test data and low margins of generic production. (56)[91]

National health authorities generally require data as a condition for registering the quality of test results on the submission of new drugs in order to analyze safety and efficacy, as well as information on the composition and physical and chemical properties of the product. The originator regulators do not require companies seeking registration of generic versions of the original product to repeat a study that was carried out by the original manufacturer but to rely on bioequivalence tests to grant a marketing authorization.[92]

Article 39.3 covers such obligations in the case especially where trade secret data is subject to government agencies to obtain marketing authorization where it imposes two obligations on governments to protect data on new chemical entities collected with great effort against unfair commercial use and to protect such data against disclosure except when necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. The Agreement does not define "unfair commercial use" giving member states considerable policy space in this area.[93]

[91] Corea (2002), p.16
[92] Ibid
[93] Ibid, supra note 78

Some developed countries including the United States and some EU countries argued that Article 39.3 of the TRIPS Agreement requires countries to create a data exclusivity regime. In these countries, data exclusivity was adopted long before the TRIPS Agreement as USA in 1984 and EEC in 1987. However, it cannot be covered by the TRIPS Agreement, especially considering its basic principles set out in Article 8 in connection with the Doha Declaration.[94]

Members, by requiring, as a condition of approving the marketing of pharmaceutical or chemical products for agriculture that utilize new chemical entities, the submission of undisclosed test or other data, the origin of this which involves a considerable effort, shall protect such data against unfair commercial use. Furthermore, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use. Drug regulatory authorities operate independently of the patent office and are anxious to ensure that drugs and medications are safe to use and compatible with quality standards before they are made available on the market.

Test data protection requires special provisions in many jurisdictions, even though the approach differs from jurisdiction to jurisdiction. In some developed countries such as the United States and the European Union (EU), the regulations provide for the exclusive use of test data from the originator company for a limited period, while in other countries such exclusivity is not an established and common medicines can be registered by relying on test data available on the company's health authorities when the information is submitted.[95]

### 2.3.7 Control of Anti-Competitive Practices

[94] ibid
[95] ibid

TRIPS Agreement envisages a balance between the promotion of technological innovation, transfer and dissemination of technology, in addition to the balance to enjoy the benefits that users and producers of technology. These balances are included in a number of provisions in the contract. In the objectives and principles of the Agreement, the basic concept of the balance of the TRIPS is contained. (57)[96]

The principles on which the balance is to be achieved are, firstly, that the members of the drafting or amending legislation may take the necessary measures to protect public health and nutrition, and take measures to the interests of the public areas of vital importance to their socio-economic and technological development. Second, they may take the necessary measures to prevent the abuse of intellectual property rights holders or hand them to practices which unreasonably restrain trade or adversely affect the international transfer of technology.[97]

The second principle, in particular, should read the interpretative principle in favor of prevention is considered to be necessary for the promotion and misuse of the measures on competition monopoly position of patent holders also engaged in anti-competitive licensing arrangements. [98]

Trademarks and copyrights rules can be used to prevent competition in the pharmaceutical market. For example, on the basis of the rules of the trade mark, the pharmaceutical companies have tried to prevent the rules for generic prescription drugs or generic substitution. However, this is contrary to Article 16

[96] Corea (2000), p.13
[97] ibid
[98] Ibid, supra note 78

of the TRIPS Agreement, which only requires countries to protect trademark holders against the use of their trademarks, where there is a likelihood of confusion. [99]

Article 40 of the TRIPS Agreement explicitly establishes contractual relations control of anti-competitive practices in licensing. The exception of measures aimed at improving the competitiveness of the pharmaceutical market in that country may take in accordance with Article 8 (2), the countries may also take other measures to control in granting pharmaceutical companies. Imposing the prohibition on exclusive terms such as retention clauses preventing challenges to the validity of the patent and compelling packaging, they can reduce the concentration of market power and improve competition in the pharmaceutical market.

[99] ibid

# Chapter 3

## Limitations for Developing Countries

There are two level of concern; firstly putting in place related constraints and the getting facilitation from TRIPS flexibilities whereas the second level contains restraints on the design and implementation and help of the legal actions, such as those relating to the production of local innovation and medicines. As the legal system have been put in place to ensure substitute path of drugs either with domestic production or imported with a purpose of ensuring supply of life saving drugs.

Second level has core hindrance having lack in local pharmaceutical research and manufacture capability. Furthermore it also includes inadequate technical

arrangement and capacity regulation of medicinal products; difficulties in introducing effective medical management and procurement systems; bilateral and against the use of other political stresses flexibility in the TRIPS Agreement; deficiency of capacity to deal with restraining practices and abuses of patent rights; and problems in retrieving pricing and patent position evidence.

### 3.1 Limitation of Technical Expertise

To materialize the utilization of flexibilities, the member states must have enabling provision for availing flexibilities in their national legislations. Unexpectedly, many developing countries are still without the proper provisions in their domestic laws. Flexibilities available in TRIPS Agreement and provisions of these flexibilities available in their national laws are two altogether different things. National law and practice will prevail in the end both in terms of providing access to medicines and to create a domestic framework within which the TRIPS rules are interpreted. One of major reason that a number of developing countries don't have the flexibility of TRIPS Agreement into national legislation is only due to their limited capacity and expertise in this specific area (58)[100].

It is pertinent to mention that nearly all the national patent system in developing countries were inherited from colonial period subjugation to advanced nations and those don't have formulated with support of the advanced nations to meet international obligations. These all are based on expertise of developed part of the world. Most of the technical assistance that has gone into these countries is concerned with compliance and not availing flexibilities to promote public health and access to medicine[101].

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[100] **Love, J.** *Compulsory Licensing: Models for StatePractice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord.* Consumer Project Washington DC : s.n., 2001.p.13

[101] ibid, p.15

Another core issue is lacking in techno-legal expertise on these matters and depends totally on the foreign expertise of developed nations. Developing countries are often not taken aware by their counterparts around the world. More importantly, developed countries are quick to provide assistance in specific areas with examples of best practices but how to protect patent rights is not in their priority to formulate a guidebook or technical aid, such as the widespread use of the United States of compulsory licensing or use of the competition law to curb the abuse of patent rights and serve other benevolent purposes (59)[102].

The lack of expertise has augmented the possibility of granting frivolous patents or filing baseless application. The vital utilization of exceptions is totally dependent on the internal expertise[103]. In developing countries, patent examiners routinely rely on the issuance of developed IP offices like USPTO or EPO prerequisite for the granting of the patent right, despite the fact that their patent law excludes certain subject that may be permitted under the advance countries like US and European patent laws, in the area of business methods and computer programs[104].

### 3.2 Inadequate Pharmaceutical Domestic Capacities

Sufficient research and manufacturing capacity is very limited in developing member states generally but particularly in pharmaceutical sector. This is a challenging for these countries to enlarge their capacity in domestic research.

[102] *Access to Medicines and Public Policy Safeguards under TRIPS.* **Balasubramaniam, K.** s.l. : Multi-Stakeholder Dialogue on Trade, Intellectual Property and Biological Resources in Asia, 2002, p.32

[104] ibid

Increasing investment in basic science, research and development and technological innovation is one of the important action in right direction (60)[105].

The growth of technology is increasingly salient tool for development and also attaining central space in competitive advantage. Because this is the era of technologies-based economies. This also raises the question of standards in developing research into medicines, manufacturing and maintain quality. Quality in medicines and diagnostics equipment is uncompromising due to its sensitivity. Developing countries face vital difficulties that may prevent the quality research & development in these countries or lacking cooperation among the developing countries. Manufacturer of pharmaceutical products includes a series of functions as of the purchase of materials, processing, production, packaging, quality control, release, and storage of medicines and related control.[106]

As explained by United Nations Industrial and Development Organization, there are different categories of the countries in view of level and situation of pharmaceutical industry as : 1) no production facilities and totally depend on imported finished products; 2) a small-scale local production of sterile or non-sterile formulations; 3) mixture of domestic production and imported intermediates; 4) production of imported intermediate products and production of local materials and 5) production of active substances and the processing needed to produce pharmaceutical dosage forms (61)[107].

Pharmaceutical manufacturing depends on number of important segments including ratio of domestic R & D to gross domestic product (GDP) due to technology-driven factor in pharmaceutical industry and second important factor

[105] Kaplan, 2003 p.16-17
[106] Ibid, p.29
[107] Balance et. al p.47

is the size of the household. These two factors may enable the pharma company to take benefit of the national economy scale and taking opportunity of product variation and development. Third factor is regarding level of income in the national market and fourth factor is a dependable domestic arrangement and services at reasonable prices. The fifth factor concerns with the practice of local production and their enforceability to ensure the competence and dependability in the market. The last factor is related to the configuration of the pharmaceutical industry hurdles to trade (62)[108].

Although there is no convincing evidence regarding these factors, how a country attain capacity to produce pharmaceutical products. Importance of each of the identified factors is not clarified how these factors will alter the type of production in question. Various factors are likely to interplay depending on whether the output is at low-end in manufacturing and repackaging or at high-end manufacturing. It is also salient that whether the production of raw materials or finished products. It is said that the production capacity of a negative impact on developing countries' ability to use certain flexibilities in the TRIPS Agreement, such as compulsory licensing for public health purposes (63).[109]

### 3.3 Lack of Technical and Infrastructural Capacities for Medicines Regulation

Inadequacy of technical and infrastructure capacities in regulation of medicines one of limitation for developing country to avail health related flexibilities. The

[108] **Reichman, J. and C. Hasenzahl.** *Non-voluntary Licensing of Patent Inventions: Historical Perspective, Legal Frameunder TRIPS, and an Overview of the Practice in Canada and the USA.* Geneva : Issue Paper 5, ICTSD and UNCTAD, 2003., p.32

[109] Ibid, p.55

countries generally require all medicines on sale in its territory will be registered locally although most of these countries are lacking in taking review the safety, efficacy and quality of medicinal products intended for the national market. They are still dependent on foreign authorities to make the compulsory standards and to make the necessary analysis (64)[110].

Process for regulatory approval raised a number of problems that affect how efficiently the flexibilities under the TRIPS Agreement can be used to improve the usability and availability of essential medicines. The registration with speed and competence of the procedure of medicines has a significant impact on the utilization of early-working exception effectively. Slow registration procedure effects the generic benefits of that early work is intended to provide an exception.[111]

Another regulatory issue that arises is concerning to post-marketing surveillance which is lacking area. It is very difficult to authorities to prove the abuse of patent holders in the pharmaceutical market and compulsory licensing is also very difficult on this reason. Lack of advertising regulations can also be a problem with the use of the flexibility of the TRIPS Agreement.[112]

Intense misleading promotion and marketing of brands is reported to badly affect consumers are averse to generics. Generics in developing countries, such as Pakistan, Nigeria and the Philippines have revealed a poor public view of lower-priced medicines. A rule on publicity through mechanisms that set and enforce

[110]**Velasquez, G. and P. Boulet.** *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement, Health, Economics and Drugs.* WHO, Geneva. : Economics and Drugs, DAP Series No. 7, WHO, Geneva., 1999.

[111] ibid
[112] ibid

guidelines to promote the drug which is needed, therefore, to avoid advertising, which may be false, or otherwise misleading impact on the whole society.

### 3.4 Problems in Establishing Efficient Pharmaceutical Management

An effective management and procurement system is another challenge for developing countries in their efforts to improve the availability of essential medicines and pharmaceutical in a smooth way. Introduction of effective management systems for the procurement of medicines can be an expensive and difficult process that requires enormous resources and technical know-how. These problems may be more acute in small states those with an average drug prices are usually high due to lack of economy scale.[113]

The cost of quality and supply chain issues is also high whereas lack of efficiency and cost-effective management and procurement systems therefore influence prices, quality, rational use of medicines, as well as the availability of medicines at large. So flexibility of use of the TRIPS Agreement is in to progress the availability of drugs and the trials of lack of resources and technical expertise to provide operational medical management and procurement systems.[114]

### 3.5 TRIPS-plus Pressures

Usually developed countries tried to achieve their objective through bilateral tools which they could not achieve at multilateral level. Political pressure has attained a vital role in these modern economic rights (65)[115]. Integrating basic issues to

[113] ibid
[114] ibid
[115] *Priced Out of Reach: How WTO Patent Policies Will Reduce Access to Medicines in the Developing World.* **Bailey, M.** s.l. : Oxfam Briefing Paper 4., 2001.

implement flexibilities in many developing countries is the political pressure on these countries to keep away them from using the flexibilities, or even more, putting pressure on them to adopt "TRIPS-plus" legislation and measures. Political pressure may be exerted from sources at internal or external level.[116]

Internal pressure is exerted from the dominant multinational pharmaceutical companies operating in the domestic market. These companies have big resources and lobby power with politicians to secure their interests. Furthermore they implement enormous marketing campaigns that compromise the use of the flexibility of the TRIPS Agreement. But more often than not, political pressure is external, the governments of the countries, particularly the United States government and European Union from the developed.[117]

There are certain forms of pressure including bilateral trade agreements which have an important component on intellectual property rights. For example, both signed bilateral trade agreements of United States with Vietnam and Cambodia wherein compliance in accordance with the requirements of intellectual property including the TRIPS standards was added whereas these countries were not members of the WTO (66)[118].

In certain cases, Vietnam and Cambodia to provide that mandatory issued by used primarily for the domestic market. A more recent example is where an agreement between the United States and Central American countries has been concluded in which along with other things, holds provisions on the patent rights term to compensate for the delay, limit may be annulled patents, and the introduction of a

[116] ibid
[117] ibid
[118] Said, Mohammed K El. *Public health related TRIPS-plus provisions in bilateral trade agreements.* Geneva : ICTSD-WHO, 2010.

system of market exclusivity and test drugs and chemicals used in agriculture, data protection which are not covered under TRIPS requirements.[119]

A another way of pressure building is a unilateral trade pressures such as issuance of special 301 report under US Trade Act 1974 formulated by Office of US Trade Representative (USTR). Under this report, trading partners are classified into different lists as watch list, priority watch list and foreign countries accordingly to IP situation and US trade interests. In the case of drugs, the assessment and classification of data is based as provided by the US pharmaceutical industry. [120]

The US government uses these mechanisms to push the developing countries from adopting TRIPS-plus legislation or to stop flexibility for the exercise of the TRIPS Agreement. It will require a significant political and economic influence of individual governments to resist the pressure which can only be materialized in the form the regional policy.

### 3.6 Difficulties in Encountering Anti-Competitive Practices

Access to medicines requires a viable system of competition to ensuring fair practices. Competition regulations are to curtail the unchecked market power by which the patents can be defined as efforts to increase the exploitation of a patent rights offered by borders. Without properly enforcing competition law, patent right can monopolized the whole system which will be an alarming position for the state government and public (67).[121] Such abuses include monopoly pricing that create a limited access, particularly among the poor; non-price predation,

[119] ibid
[120] ibid
[121] **Lahouel, M., and K. Maskus,.** *Competition Policy and Intellectual Property Rights in Developing Countries: Interests in Unilateral Initiatives and a WTO Agreement.* 1999, p.19

when intellectual property rights are used to bring the inconsistency of the dispute and the proceedings in order to exclude and harass the attainment of competitors and the strategic use of patent portfolios to thwart competition by similar but non-infringing product and the constant blurring of the lines between invention and discovery.[122]

Growth of patent protection in developing countries is increasing continuously and even though Article 40 of the TRIPS allows countries to use processes of competition subject to permitting chances for administrative evaluation and bilateral negotiations to deal with unfair practices. There is very few of the developing countries and least developed countries those have system for competition. Furthermore the high-priced costs of patent lawsuit and the organization of patent and competition system made to obtain a major problem and just resolutions of disputes the validity of the patent or the abuse of patent rights. Insufficient competition policy and enforcement mechanisms are the effect of undermining the chances to take advantage of the TRIPS flexibilities. (68)[123]

Developing countries will not be able to use the TRIPS flexibilities that allow them to use competition law to thwart the misappropriation of patent rights. Another problem is about anti-competitive practices and misuse of patent and related rights is that information asymmetries. Local businesses in developing countries and pharmaceutical industries can manufacture unpatented products without need to resort to compulsory licensing, is not easily reachable information about what drugs patented in the country. This seriously lacks of knowledge does

[122] Ibid, p.18

[123] **Vivas-Eugui, D.** *Regional and Bilateral Agreements and a TRIPS-Plus World: the Free Trade Area of the Americas* . Geneva and QIAP, Ottawa : QUNO, ICTSD, 2003.p.21

not encourage local companies manufacturing drugs for fear of lawsuits patent holders (69)[124].

It has been noted that in small national markets there are not substantial economic encouragements for existing generic drugs business to trial bad patents, unlike the United States, Japan and European markets. It is therefore predictable that a large number of patents in developing countries will be poor, because the countries or competitors do not have the capacity or financial incentives to evaluate and arguing inappropriate claims.[125]

[124] Sykes, Alan: *TRIPs, Pharmaceuticals, Developing Countries, and the Doha 'Solution'.* Chicago Law & Economics, Olin Working Paper No. 140 , February 2002.p.
[125] ibid

# Chapter 4

## Patent Law in Pakistan and Use of Flexibilities

In this chapter, Patent Law in Pakistan is reviewed where it has been found that there is three type of issues in this law with reference to flexibilities for exhaustion of patent right and available Exception as follows: Absence of provisions; Weak provisions and Lack of Effective Mechanisms.

Pakistan is a member of the World Trade Organization and its patent law has been modified to implement the TRIPS Agreement. Current laws contain the following (TRIPS) flexibilities and safeguards: Compulsory licensing provisions for reasons of public health; Bolar exceptions and Parallel importing provisions.

In cases where the public interest of the country is generally formulated, it may be enough to cover the public health needs in terms of ensuring access to medicines. If the public interest ground is not available, it should be able to advise countries to review its legislation to ensure that the compulsory licensing provisions do not unnecessarily restrictive.

## 4.1 Provision on Compulsory Licensing

| Provision | Comments |
|---|---|
| **58. "*Exploitation by a Government agency or third person*** (70)[126]**.-** *(1) Subject to sub-section (2), where -* | |
| *(i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or* | In Subsection 1(i) of Section-58, terms are used in broad way which cannot be materialized until there are certain rules or regulations. |
| *(ii) the Federal Government has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Federal Government is satisfied that the exploitation of the invention in accordance with this sub-section would remedy such practices; or* | In Subsection 1(ii), determination procedure is required in vivid manner and responsibilities of authorities in federal government structure should also be in right order. |
| *(iii) the patent holder refuses to grant a license to a third party on reasonable commercial terms and conditions; or* | In Subsection 1(iii), reasonable term is required to explain and clear under rules or regulations. |
| *(iv) where patent has not been exploited in a manner which contributes to the promotion of technological innovation* | In Subsection 1(iv), a duration specification is required which determined a time period of patent |

[126] Pakistan Patent Law, Section-58

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| *and to the transfer and dissemination of technology,*[127]<br>*the Federal Government may, even without the consent of the owner of the patent, decide that a Government agency or a third person designated by the Federal Government may exploit a patented invention.* | without exploitation. |
| *(2) The Federal Government shall, before taking any decision under sub-section (2), give the owner of the patent arid any interested person an opportunity of being heard if he wishes to be heard.* | Under Subsection (2) of Section (58), Federal Government will hear right-holders and interested persons but it cannot possible until there will be prescribed mechanism between the government bodies. |
| *(3) The exploitation of the patented invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the Federal Government authorization, as determined in the said decision, and where a decision has been taken under sub-section (1), the need to correct anti-competitive practices.* | In Subsection (3), terminology of limit and adequate remuneration is a very abstract and until there will be specification of these, it can't be used. |
| *(4) A request for the Federal* | In subsection (4), there is required to |

[127] ibid

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| *Government authorization shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual license, but that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time:*[128]<br>*Provided that this sub-section shall not apply in cases of –*<br>*(i) national emergency or other circumstantial urgency provided that in such cases the owner of the patent shall he informed of the decision of the Federal Government as soon as reasonably practicable;*<br>*(ii) public non-commercial use; and*<br>*(iii) anti-competitive practices determined as such by a judicial or administrative body in accordance with clause (ii) of sub-section (1).* | affix efforts for getting license or contract with request to federal government but this not applicable in case of national emergencies, non – commercial use and anti-competitive pratices. |
| *(5) The exploitation of a patented invention in the field of semi-conductor technology shall only by authorized either for public non-commercial use or where a judicial or administrative body* | Under Subsection (5), a mechanism is required for using this provision. |

[128] ibid

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| *has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive and if the Federal Government is satisfied that the issuance of the non-voluntary license would remedy such practices.*[129] | |
| *(6) The authorization shall be considered on its individual merits and shall not prohibit-*<br>*(i) the conclusion of license contracts by the owner of the patent;*<br>*(ii) the continued exercise, by the owner of the patent, of his rights under section 30; or*<br>*(iii) the issuance of a non-voluntary license under section 59.* | Under Subsection (6), word of merits has been used which is quit general in nature that can be specified under rules and regulations. |
| *(7) Where a third person has been designated by the Federal Government, the authorization may only be transferred with the enterprise or business of the person or with the part of the enterprise or business within which the patented invention is being exploited.* | Under Subsection (7), authorization of third person is required to be under specific criteria which should be determined under the rules or regulations. |
| *(8) Where the exploitation of the invention by the Government agency or* | Subsection (8) explains authorization for production which will be only for |

[129] ibid

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| *third person designated by the Federal Government is authorized under clause (i) of sub-section (1), it shall be predominantly for the supply of the market in Pakistan.*[130] | national territory. The matter of authorization will required to be structured mechanism under rules or regulations. |
| *(9) Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Federal Government may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.* | Subsection (9) is regarding the variation in decision made by federal government subject to hearing of parties. Variation or alteration is a legal process which can't be possible until specified under rule or regulations. |
| *(10) Upon the request of the owner of the patent, the Federal Government shall, subject to adequate protection of the legitimate interest of the persons so authorized, terminate an authorization if it is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to the decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by it has failed* | Under subsection (10), Federal government may terminate the authorization which led to the decision ceased based on grounds. There is requirement of specific system. |

[130] ibid

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|---|---|
| *to comply with the terms of the decision.*<br>*(11) Notwithstanding the provisions of sub-section (10), the Federal Government shall not terminate an authorization if it is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by it justified the maintenance of the decision.* | Subsection(11) tells that federal government will own its decision and will not terminate the authorization. It needs plausible way under rules or regulations. |
| *(12) An appeal shall lie to the High Court against the decisions of the Federal Government under sub-sections (1) to (9).* | Appeal against decision of the federal government may be filed before High Court. |
| ***59. Powers of Controller in granting compulsory licenses.-***[131] *(1) On request, made in the prescribed manner to the Controller after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, the Controller may issue a non-voluntary license to prevent the abuses which might result from the exercise of the rights conferred by the patent, for example, failure to work.* | Under subsection (1) of section 59, an application can be filed before controller patent in case of failure to work or non-use of the patent in prescribed manner which mean that it should elaborated in the rules or regulation. But in case of absence in rules, this provision in the patent ordinance is dormant. |

[131] Ibid, section-59

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|---|---|
| *(2) Notwithstanding the provisions of sub-section (1), a non-voluntary license shall not be issued if the owner of the patent satisfies the Controller that circumstances exist which justify the non-exploitation or insufficient exploitation of the patented invention in Pakistan.*[132] | Under subsection (2), rightholder justify the controller for non-exploitation of patent invention to counter failure to work or request of non-voluntary license. This process also requires a mechanism under the rules. |
| *(3) The decision issuing the non-voluntary license shall fix-*<br>*(i) the scope and function of the license;*<br>*(ii) the time limit within which the licensee must begin to exploit the patented invention; and;*<br>*(iii) the amount of the adequate remuneration to be paid to the owner of the patent and the conditions of payment.* | In subsection (3), terminology of adequate remuneration and conditions are required to explicitly explain under the rules and regulations. |
| *(4) The beneficiary of the non-voluntary license shall have the right to exploit the patented invention in Pakistan according to the terms set out in the decision issuing the license, shall commence the exploitation of the patented invention within the time limit fixed in the said decision and, thereafter, shall exploit the patented invention* | Under subsection (4), it is explained that non-voluntary license can only be utilized with the limits granted in the decision. |

[132] ibid

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| *sufficiently.*<br>*(5) If the invention claimed in a patent, hereinafter referred to as "later patent", cannot be exploited in Pakistan without infringing a patent granted on the basis of an application benefiting from an earlier filing or, where appropriate, priority date, hereinafter referred to as "earlier patent", and provided that the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the Controller, upon the request of the owner of the later patent, may issue a non-voluntary license to the extent necessary to avoid infringement of the earlier patent.*[133] | Under Subsection (5), the patent controller may grant non-voluntary license of former patent to the owner of later patent where later patent is infringing former patent but has a technical advancement of considerable economic importance. This also requires a mechanism. |
| *(6) Where a non-voluntary license is issued under sub-section (5), the Controller upon the request of the owner of the earlier patent shall issue a non-voluntary license in respect of the later patent.* | This is a correlation clause to subsection (5) but reciprocity manner, wherein owner of the former patent requests for non-voluntary license of latter patent. |
| *(7) In the case of a request for the issuance of a non-voluntary license* | In subsection (7), when rights applied under subsection (5) and subsection |

[133] ibid

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|---|---|
| *under sub-sections (5) and (6), sub-section (3) shall apply mutatis mutandis with the provision that no time limit needs to be fixed.*<br>*(8) In the case of a non-voluntary license issued under sub-section (5), the transfer may made only with the later patent, or, in the case of a non-voluntary license issued under sub-section (6), only with the earlier patent.*<br><br>*(9) The request for the issuance of a non-voluntary license shall be subject to payment of the prescribed fee.*<br>*(10) The provisions of sub-sections (2) to (10) of section 58 shall apply mutatis mutandis for issuance of an non-voluntary license under this section".* (71)[134]. | (6) reciprocally without effecting the main issue. There is no time limit is required.<br><br>In subsection (8), a matter of transfer has been explained that in case of license issued under subsection (5) the transfer can be done with late patents. Where as in case of Section (6), transfer can be done with earlier patent.<br>In subsection (9), the payment of prescribed fee is required which can explained under rule or regulation.<br>The subsection (2) to (10) under section 59 shall apply for non-voluntary license.<br><br>**Note:**<br>No regulations or rules available on the section-58 how it can be utilized therefore it is practically useless and dormant.<br>There is lack of simple, straightforward legislative and administrative processes to put the |

[134] Section-58. *Pakistan Patent Law*

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| | system in place. There is need to review this provision. |

## 4.2 Provision on Parallel Imports and Exhaustion of Rights

If a developing country to adopt international exhaustion, such as Pakistan, the first sale of the patent holder in any country in any parallel run of the intellectual property in the importing country; so that rights cannot be used to impede imports. The parallel import medicine typically purchased by someone other than the holder of the patent; for example, the pharmaceutical wholesaler that initially purchased (first sale) rights or its authorized representatives.

| Provision | Comments |
|---|---|
| *"**Section 30**[135]*<br>*(b) where the subject matter of a patent is a process, the holder of a valid patent may 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.*<br>*(2) The holder of a valid patent shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.* | Section -30 (1)(b) of the patent law envisage the rights of right-owner in view of exclusive rights.<br>Subsection (2) assures the rights of assign or transfer by the succession.<br>Subsection (3) guarantee the |

[135] Ibid, section-30

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| *(3) The owner of the patent shall, in addition to any other rights, remedies or actions available to him have the right, subject to sub-section (4) and section 59, to institute court proceedings against any person who infringes the patent by performing, without his agreement, any of the acts referred to in subsection* | proceedings under section 59 for non-voluntary license. |
| *(2) or who performs acts which make it likely that infringement will occur.*[136] | Subsection is regarding the application filed under mailbox. |
| *(4) Where a person has filed an application in the mailbox, in accordance with subsection(9) of section 13, for protection of an invention relating to a pharmaceutical or agriculture chemical product, exclusive marketing rights shall be granted for a period of five years after obtaining marketing approved or until a product patent is granted or rejected whichever period is shorter, provided that, subsequent to the first January, 1995, a patent application has been filed and a patent granted for that product in any Convention country and marketing approval obtained in such* | |

[136] ibid

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|---|---|
| *country;*<br>*(4A) where a person has made an invention in Pakistan in respect of a process of manufacture of any of the products referred to in sub-section (4) and has obtained a patent for the same and has filed an application in the mailbox for protection of the invention, and has been granted marketing approval thereof, then he shall have the exclusive marketing rights for that product for a period of five years after obtaining marketing approval or until a product patent is granted or rejected whichever period is shorter.*<br>*(5) The rights under the patent shall not extend to-*<br>*(a) acts in respect of articles which have been put on the market anywhere in the world by the owner of the patent or with his consent or by an authorized person or in any other legitimate manner such as compulsory licenses;*<br>*(b) the use of articles on an aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Pakistan;* | Marketing approval can be sought for 5 years on the basis of mailbox application afterwards it will be subject to granted or rejected of patent.<br><br>Under subsection (5) there are certain limitations on which rights of patents cannot be extended as follows:<br>a) Article in anywhere in world;<br>b) Articles enter temporarily in territory of Pakistan or space;<br>c) Acts done for experimental of innovation;<br>d) Acts done in good faith;<br>e) Acts done for teaching purpose;<br>f) Acts for test of innovation;<br>. |

| | |
|---|---|
| *(c) acts done only for experimental purposes relating to a patented invention;*[137]<br>*(d) acts performed by any person who in good faith, before the filling or, where priority is claimed, the priority date of the application on which the patent is granted in Pakistan, was using the invention or was making effective and serious preparations for such use; or*<br>*(e) acts, including tests, necessary for the approval of a product for its commercialization after the expiration of the patent; or*<br>*(f) acts done for teaching purposes in educational or research institutions.*<br>*(6) The right of prior user referred to in clause (d) of sub-section (5), may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business, in which the use of preparations for use have been made"*[138]. | **Note:**<br>**Limited and narrow scope in patent law.** |

[137] ibid
[138] Ibid section 30

### 4.3 Provision on New use

| Provision | Comments |
|---|---|
| ***7. "Patentable inventions.-*** *(1) Any invention is patentable, if it is new, involves an inventive step and is capable of industrial application.*<br>*(4) A patent shall not be granted-*<br>*(d) for a new or subsequent use of a known product or process"*[139]. | This is an important provision to put bar on frivolous patents.<br>This provision is right to protect and promote domestic generic industries. |

### 4.4. International Exhaustion

| Provision | Issues |
|---|---|
| ***30. "Rights conferred by patent.***<br>*(5) The rights under the patent shall not extend to-*<br>*(a) acts in respect of articles which have been put on the market anywhere in the world by the owner of the patent or with his consent or by an authorized person or in any other legitimate manner such as compulsory licenses".*[140] | International exhaustion is right to get benefit from parallel importation. |

[139] Ibid section 7
[140] Ibid section 30

# Chapter 5

## Comparative Analysis of Patent Laws in Developing Countries

At the time of TRIPS negotiation, it is known that a large number of sovereign states did not include product in patent protection for granting exclusive rights in pharmaceutical sectors. Moreover a considerable number of countries even excluded patent protection of process in pharmaceutical. Review of national legislations for patent right apprised regarding different approaches on the question of patent subject matter. General patentability principles do not render of new use of a product as patentable. It may be added that patent for second use which is equal to a therapeutic treatment technique that can also be excluded from patentability.

The early working exception is in sense facilitation to using an invention covered under exclusive right granted in a patent for objective of seeking approval of a generic product. It will not be out of place to add here that this sort of

arrangement avoid a gap between patented medicine on high price and generic cheap supply. This exception is provided in pharmaceutical patents that can also be applied in the other sector like agrochemical and such products requiring approval before its commercialization.

Exception for use of an invention in research or experiment is commonly sought under the provision of national patent law compatible with Article 30 of the TRIPS agreement. The scope of provision can be enhanced with suitable construction of provision that may provide a certain space in which this exception can be rightly utilized for work of experiments and research for attaining objective in scientific and commercial purpose, without the consent of right owner.

### 5.1. Comparative Study of Exceptions

Review of a number of patent laws apprised us that national legislation in number of countries has one of the exception from the both to the patent right. Therein exception for use of patent in experiments or in other words it may be termed as research exception. It is found that provision on this exception to facilitate research and experimental work is almost available in the all national legislation on patent around the world. Accurately it can be said that this exception provision is nearly available in all legislation (85 %) in Latin America and Asia but 59% available in Africa.

In addition to the exception for using a patent in research and experimental work, a second exception is available regarding allowing for early working, it is also termed as Bolar exception with a reference of legal case which became a source of this exception in USA. The provision in the national patent law is incorporated to avail this exception wherein domestic generic product producer can be benefited

with this section. After exploring the world legislations, it is found that 61% of the national legislation on the patent are lacking in availing this exception. Therein 32% countries of Latin America have this provision and 31% countries in Asia have this provision whereas majority of legislation in Africa did not have this provision.

A comparative data of five developing countries in term of Patentability Exceptions and Early Working Exceptions is as follows:

| Sr. No. | Country | Exceptions in Patentability New use or 2nd use patents | Exceptions on Early Working | Other Exceptions |
|---|---|---|---|---|
| 1 | Pakistan | New and 2nd use both excluded | No | Experimental Purposes, teaching purposes in educational and research institutes |
| 2 | India (72)[141] | 2nd use excluded, but effects of patent ordinance to be clarified. | Yes | Experiment or research including the imparting of instructions to pupils |
| 3 | Philippine[142] | Not Excluded Specifically permitted for certain new medical applications | No | Private and non-commercial use Scientific research and experiment |

[141] Information of Member States on www.wipo.int, India
[142] Ibid, Philippine

| | | | | |
|---|---|---|---|---|
| 4 | Indonesia[143] | Not explicitly excluded | No | Experimental use, use for research education and analysis |
| 5 | Thailand[144] | Not Excluded | Yes | Broadly worded "Any act for the purpose of study, research, experiment or analysis: provided that it does not unreasonably conflict with normal exploitation of patent and do not unreasonably prejudice the legitimate interests of patent owner" Reverse Engineering of products specifically permitted under Trade Secret Act 2002. |

[143] Ibid, Indonesia
[144] Ibid, Thailand

| | | | | |
|---|---|---|---|---|
| 6 | Malaysia[145] | 2nd use patents allowed | Yes | The rights under the patent shall extend only to acts done for industrial or commercial purpose and in particular not to acts done only for scientific research. |

Pakistan should avail early working (Bolar) exception and it can be very useful for our domestic industry. The Bolar exception has been incorporated in many national laws. It is clearly one of the 'flexibilities' allowed by the TRIPS Agreement extensively recommended to lessen the negative impact that patents may have on access to medicines, particularly in developing countries. In order to derive the supreme benefit from a generic medicine it must be available from day one following patent expiry. In certain markets, generic medicine entry is often delayed, partly by the need to gain pricing and compensation approval. Basic rational is to maintain the balance in the patent system between patent holders and general public.

## 5.2. Comparative Study of Flexibilities

Availability of provision on flexibility in national patent legislation may serve a purpose adequately in view of requirements for public health although its development in the law was not focused to the public health. In the lot of cases, serious lack to invoking compulsory licensing leads to a reality that there is lack

[145] Ibid, Malaysia

of system or mechanism to avail this facility in the form of compulsory licensing. It is essential that there will be a vivid, trustworthy and effective mechanism to utilize this flexibility.

It may be mentioned that difference of viable mechanism and clear approach is the basic requirement to get benefited from the compulsory licensing, this difference is clearly shown in the case of developed countries which are utilizing this flexibility in true sense. It is very salient lesson in this regard which shows a huge difference of system, those states which are rich in system can be only benefited from international mechanism.

In order to get maximum benefits, only availability of provision may not serve the right purpose in this regard without plausible grounds. So in this case, developing states should include reasonable provision in their national laws and stipulate as most of the probable reasons to avoid uncertainty and vagueness. It is pertinent to mention that almost all the patent laws provide compulsory licensing to grant remedy against anti-competitive performs and to enabling to pursue using dependent patents. Small number of grounds will limit the scope for qualifying to avail compulsory license and this is found in number of the national legislations especially in developing countries.

Provision on government use and compulsory license both have the same dependency and use of the patent. There is a line of difference between these two flexibilities wherein government use is limited to ‘public’ and ‘non-commercial’ purposes but on other hand compulsory license can cover private and commercial use both. The specified meaning and scope of ‘public’ and ‘non-commercial’ is not mentioned in TRIPS**.** Where national laws provide for government use or public, non-commercial use of patents, the provisions are usually adequately

broad to provide governments with the flexibility to take necessary acts to meet requirements of public health.

A comparative data of five developing countries in term of Compulsory Licensing Grounds, Government Use and Data Protection is as follows:

| Sr. No. | Country | Exhaustion Regime | Compulsory Licensing Grounds | Government Use | Data Protection |
|---|---|---|---|---|---|
| 1 | Pakistan | International | Failure to exploit<br>This ground may only be invoke 3 year from grant or 4 years from filings. | Yes<br>for public interests, including, health, nutrition or national security, and on finding on anticompetitive practices<br>Patent owner may request hearing to vary terms of the decision authorizing exploitation | No Provision (only common law and Official Secret Act 1923) |
| 2 | India (73)[146] | International | | Yes | No |

[146] Sources www.wto.org and www.wipo.int, India

| | | | | | |
|---|---|---|---|---|---|
| | | | | For national emergencies/ extreme urgency and for public noncommercial use | Provision, discussion are underway |
| 3 | Philippine[147] | National | | No | |
| 4 | Indonesia[148] | No explicit Provision | Failure to exploit. Patent implemented in a manner that 'contravenes the public interest'. Dependent patents These ground may only be invoked 36 months after date of patent issue, and requires a | Yes For national defense or security or security or an immediate need for the sake of public interests | No provision Law is under draft. |

[147] Ibid, Philippine
[148] Ibid, Indonesia

| | | | | | |
|---|---|---|---|---|---|
| | | | court hearing. | | |
| 5 | Thailand[149] | No explicit provision | Failure to exploit domestically.<br>Public demand not being met on reasonable terms<br>Dependent patents<br>This may only be invoked 3 years from grant or 4 years from filing. | Yes<br>For any service for public consumption, national defense, environment preservation or preventing severe food shortages | Yes<br>Under Trade Secret Act 2002<br>No specific provision in patent law<br>Stated in WTO interview that the issue of whether later applicants may rely on previous test data will be determined 'on a case |

[149] Ibid, Thailand

| | | | | | |
|---|---|---|---|---|---|
| | | | | | by case basis’ |

In the case of Pakistan, there is need to develop a simple mechanism to get benefit from compulsory licensing.

# Chapter 6

## Findings and Conclusion

This study finds that the use of TRIPS flexibilities can promote access to medicines on reasonable terms in developing countries. Reviewed laws and practice of developing countries had revealed about incorporation of one or more TRIPS flexibilities. The constraints in terms of technical capacity or political will were found which transpose the situation into failure of usage. There are certain gaps between incorporation of the flexibilities and their usage which require to be addressed for their effective use in developing countries.

Paragraph 4 of the Doha Declaration which is a source not only for a right but also an obligation to the WTO members to understand and implement the way of TRIPS Agreement which supports measures to protect public health and promote access to medicines for all. Whereas August 30 Decision establishes a system of limitation of exports which will be abandoned under a compulsory license

provisions in TRIPS Agreement in order to do the production and export under a s per compulsory license notification and other requirements to prevent the unintended product on the market. As these provisions are not self-executing, it is important that the specific provisions laid down in national laws to enable countries to take advantage of flexibility.

It has been observed that the widespread ambiguity of options, combined with a deficiency of techno-legal expertise is serious dearth of professionalism in the field of intellectual property. The professional expertise are the only way of incorporating the effective provision to domestic needs and acquire maximum scope at the international level. Shortcomings of local expertise in this techno-legal area are the main reason in utilizing benefits from flexibilities and policies of the TRIPS Agreement.

The understanding of these countries in implementing TRIPS and availing flexibility is lacking of practice and limited. An effective cooperation is required among a concerned government bodies and institutions, such as trade, health and industry those were not the part of segment before to coordinate the development of a common policy. In this regard, in addition to responding to these specific problems, there is a need for regulation in implementing good policy regarding the protection of public health in the IP regime. Although the countries are able to take measures in the field of public health, it seems little clear if they will be able to establish such procedures.

Intellectual Property related trade policies of developed countries including United States and European Union and their constant pressure in the shape of bilateral agreements kept away developing countries to adopt suitable policies for health protection. There is need to develop a mechanism and implement

intellectual property national and internationally to facilitate the development and access to medicines in developing countries. Interestingly, intellectual property right enforcement provisions in TRIPS agreement are vivid and enforceable under specific infrastructure whereas there is ample room in developing a system to get benefit from the health related flexibilities and exceptions.

Source of TRIPS-plus measures in the form of IP-related policies and free trade agreements have to fully consider and understood. In this background, the additional steps required to facilitate the inclusion of flexibility in the TRIPS Agreement as part of free trade agreements.

These public health objectives or principles can be a source for clarification that those measures are intended to fulfill. Decision makers in developing and developed countries have to be take measures which are to be considered as a pro-public health. Access to the standards and principles is salient which can guide to implement the legal framework of the Doha Declaration on the TRIPS Agreement and the August 30 Decision.

The main objective of all the flexibilities and exception in the area of health is to ensure speedy mechanism to meet public health requirements in order to supply of life saving drugs with competition of suppliers for affordable price. The enhanced role of World Health Organization is imperative to attain these goals. An effective mechanism among World Health Organization, World Trade Organization and World Intellectual Property Organization for quality lifesaving medicines at affordable prices is needed principally. There is requirement to curtail TRIPS-Plus environment which is aggregating the situation in health related facilities for nationals of developing countries.

Keeping in view of strength of domestic industry, Pakistan should amend patent law to avail early working (Bolar) exception and it can be very useful for our local industry especially generic pharma industry. This exception has been incorporated in many national laws to balance negative impact of patent in view of requirement of generic pharma industry. Basic rational is to maintain the balance in the patent system between patent holders and general public.

In the case of Pakistan, there is also need to develop an effective mechanism to get benefit from compulsory licensing and other flexibilities. A simple, mechanism in place, proper legal and administrative processes are salient to put the system into effect.

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