



## Reduction of Economic Burden on State Exchequer by Using Various International Legal Flexibilities under TRIPS Agreement 1994 of WTO

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### ABSTRACT

During budget year 2016-17, public spending on procurement of medicines in Pakistan surged 29% touching an exorbitant figure of PKR 7.5 billion (Health Budget, 2016-17). Volume of provincial expenditure on medicine almost doubled rising to PKR 1.02 billion from 0.67 billion in last budget year 2015-16. Growing sum of public spending on medicine procurement has many factors such as poverty, money devaluation, indigenous production incapacity, and less developed standards of research and development. Apart from all enumerated above, global pharmaceutical patent protection regime under TRIPS Agreement, initiated by WTO, plays a pivotal role increasing public spending on procurement of medicines in developed and least developed countries. This work presents ways for reducing economic burden on state exchequer by exploiting maximum possible flexibilities under WTO regime to procure cost effective medicines. The work will be done in three parts; explaining Pakistan role and status in global pharmaceutical patent protection regime, existing challenges, and potentials for the country to save public spending on health using international legal agreements under WTO

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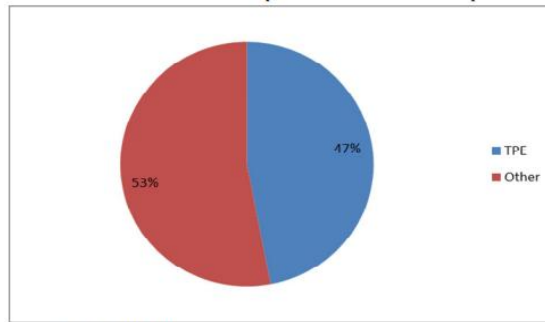
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### 1. Introduction

Economic fragility in Pakistan is one of the existence issues. Besides weak economic conditions, health remains a major challenge but gets very marginal support from public funding (Hestermeyer, 2008). Moreover, half of budget on health disappears in procurement of life saving medicines in public sector. Cost of medicines in Pakistan and around the world is increasing after adoption of TRIPS Agreement under WTO aspirations in 1994. The agreement obliges member states to protect global patents that ultimately give an edge to international pharmaceutical companies an advantage in setting and maintaining prices of medicines. Developing countries like Pakistan often struck themselves in two contrasting obligations. First is in the shape of Millennium Development Goals (MDGs) to ensure various global standards of life with a great focus on protection of health. Secondly, international obligations under TRIPS Agreement call for protection of global pharmaceutical patents which ultimately results in

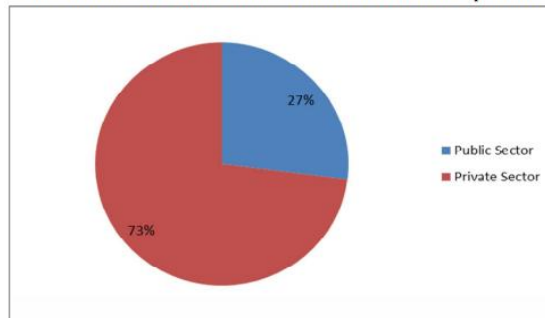
high prices of essential lifesaving medicine. Resultantly, a tangible portion of very meagre public spending on health is dumped on procuring essential medicines.

Share of Total Pharmaceutical Expenditure in Total Health Expenditure



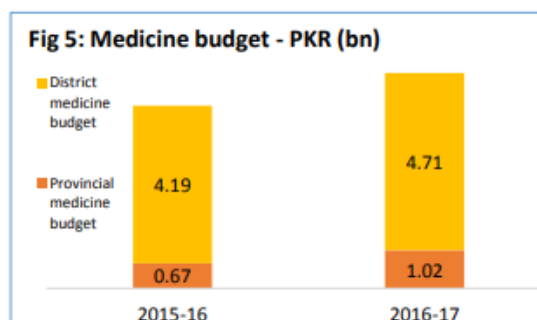
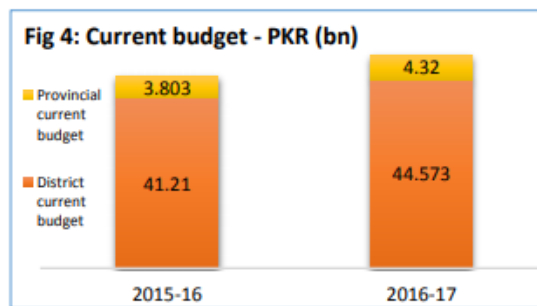
Source: NHA 2007

Share of Public and Private Sectors in Total Pharmaceutical Expenditure



(Zaidi, 2011)

Health budget of Pakistan has always been very small in comparison with other neighbouring countries. Moreover, increase in health budget is also at snails speed as budget for year 2016-17 was up for only 9 percent in comparison with last year. While at provincial level, it surged only 14 percent and districts added mere 8% to their existing spending on protection of health, one of the basic rights (Constitution of Pakistan, 1973). One may understand plight of health in Pakistan where half of its spending on health goes to procurement of medicines. During year 2016-17, as quoted already, half of the volume of total budget was consumed for medicines and rest of half supported all other expenditures on health including salaries, maintenance of hospitals, procurement of medical appliances and equipment, and emergency services.



(Health Budget, 2016-17)

Aforementioned statistics demonstrate public spending on procurement of medicine which constitutes a lion's share out of total spending on protection of health in Pakistan. Issue of rise in public spending on procurement of medicine went serious after adoption and compliance of TRIPS Agreement in compliance with WTO standards. In year 2000, Pakistan was supposed to comply with international commitments under TRIPS Agreement and Patent Ordinance 2000 was promulgated by a presidential order and patent law in Pakistan went very aggressive in protecting global intellectual property standards in various fields of patents especially pharmaceutical patents (Mahmood, Kazmi, 2008).

Patents monopoly rights in the field of pharmaceutical products were not applied till 20<sup>th</sup> century for the reason that it may impact upon public health. Even prior to adoption and enforcement of Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), patent monopolies protection in the field of pharmaceuticals was only taken in the developed countries and by the way of international treaty its enforcement was anticipated. It made pharmaceutical industry content by introducing many provisions of patent protection by the Agreement, on the other side, the developing countries and NGOs looked at them as major blow to Right to Public Health and access to lifesaving drugs around the world (Rakesh, 2000). Advent of *Trade Related Intellectual Property Rights Agreement* which was signed in 1994. It has changed global setup on pharmaceutical patent and has drawn impact on developing and least developed countries. New challenges to comply with global technological standards of patent protection as intellectual Property rights are leading towards economic burden (Pogge, 2008, p76). Pakistan, one of the signatory of TRIPS Agreement and one of developing countries is facing many economic issues while protecting global patent protection standards. The situation has become intricate as adoption and enforcement of recent international instruments along with protecting national population from health challenges by ensuring availability of essential lifesaving medicines to population is one of very significant national issues where Malaria, Cancer, TB, and other life-threatening issues need state attention (Abbas, 2013).

This paper will contribute in qualitative manner towards issue of over burden on state spending on procurement of medicines. Fundamental issue is scarcity of national funding on health and its better management through using international legal flexibilities provided in global pharmaceutical patent protection regime under WTO. This work will be divided in three parts. First part will introduce reader with domain of globalization of pharmaceutical patent protection. Second part will assess the impact of globalization under TRIPS Agreement and last part embarks on explaining international legal flexibilities those may be utilized to reduce economic burden on health budget by procuring cost effective medicines.

## **2. Compliance of WTO standards under TRIPS Agreement**

United States of America (USA) remained the main force behind adoption and compliance of TRIPS Agreement in 1994. Further, enforcement of the agreement was contested by US to protect her national pharmaceutical industry. Some writer believe that giant pharmaceutical companies such as Pfizer, Sanofi Aventis, GSK, and other led influencing US government to enhance their profitability through protection of pharmaceutical patent globally. Persuading enforcement move, US government, started contacting Pakistan government through Dispute Settlement system of WTO for complying and amending its existing laws in accordance with TRIPS Agreement. Fundamental focus of US was pharmaceutical and agriculture sectors and it was claimed that existing intellectual property laws especially patent protection is not adequate and does only protect process patent ignoring product patent. Furthermore, US stance, in WTO, specifically claimed that level of protection provided by Pakistan is in contravention with Article 70.8 and 70.9 of national commitments towards TRIPS Agreement. Based upon arguments forwarded by US, it was declared that level of protection for intellectual property rights is not adequate. Moreover, representatives of Pakistan accepted the US stance of non-compliance of TRIPS obligations on state and ensured making Patent and Design Act in consistency with global intellectual property protection standards. Later on, an amendment was introduced in Patent and Design Act of Pakistan in 1997. This amendment basically introduced mailbox facility and also started granting exclusive rights of marketing in patents.

Pakistan's efforts for making laws TRIPS-compliant were not appreciated by global pharmaceutical companies and it was alleged that nothing on ground is changed as the amendment was only theoretical giving no advantage to global patents. Moreover, law on patents remained same in case of grant of rights to process and not to product. Product patent were not introduced in Pakistan till 2000. Novel formation of molecules was also not considered under patent grant. Responding to all these criticism and political pressure from US government, Patent Ordinance 2000 was promulgated. This ordinance went a step ahead that what was required by TRIPS Agreement and global patent protection standards. The ordinance introduced product patent along with process patent, giving an extra edge to global patent holders on pharmaceutical products. Moreover, life of patent is set as 20 years without consideration to patent ever-greening and factors related to delay in entry of generic medicine to market. To sum up, this paper introduces various flexibilities provided under TRIPS Agreement that may ease prices of medicines procured by state funding reducing economic burden on exchequer.

### **3. Maintaining Lower Prices for Medicines; Statistics from Pharmaceutical Industry in Pakistan**

After inception in 1947, Pakistan was not doing well in pharmaceutical industry with only one pharmaceutical establishment and later it developed with the pace of 5% annually. In Asia, Pakistan secures 10<sup>th</sup> position in pharmaceutical industry volume and per capita annual medicine distribution is at US 10. This figure is very small in comparison with average volume of USD 142 for other countries in region (Mehmood; Kazmi, 1988, p. 694). Pharmaceutical industry in Pakistan has maintained its unique feature of low prices for essential medicines. Apart from all pharmaceutical regulations, many studies reveal that health care has not been priority at state level. This is demonstrated through annual public spending on health (Zaidi; Aleem; Rashidine, 2013, p.635 ).

On the same analogy of developing countries, Pakistan faces many issues regulating pharmaceutical patents. In January 2010, problem of fake medicine was surfaced by interior minister declaring 50 percent of total volume in market as fake or unacceptable to standards of public health. Resultantly, government introduced very strict regulations by upgrading Drug Act. Many malpractices including fake medicine discourage international pharmaceutical companies in introducing their developed and effective products in pharmaceutical market of Pakistan. Apart from all these challenges, it is encouraging that trends of growth in Pharma-industry of Pakistan are positive with a prediction to reach total of PKR 290 billion in 2019. (Health Report, 2010).

### **4. Access to Medicine in Pakistan; Regulations for the Pharmaceutical Industry**

Drug Act 1976 is fundamental legislation in Pakistan to regulate pharmaceutical industry. Fundamental state organ with an authority to regulate under different laws is Ministry of Health. Issues related to pharmaceutical regulation such as pricing, market competition, maintenance of standard medicines, control over fake drugs, and other ancillary matters are regulated under Drug Act of Pakistan by Ministry of Health. Registration of medicine also falls under preview of Ministry of Health and to the day, 40,000 medical brands have been registered and 14,000 out of them are molecules (Das, 2005, p.33-52). During 2009, Ministry of Health used its powers and cancelled 4,000 registrations of imported drugs resulting from objection raised by local pharmaceutical manufactures. This step was aimed at protecting prices of medicine's (Muzaka, 2011, p.77).

Adoption of intellectual property rights globally and especially Pakistan's compliance towards Bern Convention, World Intellectual Property Organisation and other international legal instruments obliges Pakistan to enforce global patent standards. TRIPS Agreement under WTO law enjoys a robust implementation mechanism and violation of it may get economic sanctions upon country. On the other hand, enforcement of global pharmaceutical patent standards leads towards high prices of essential medicines (Khwaja, 2009, p.264). Pakistan, as a state, has been subject of criticism from both state and international organisational level for non-compliance of international patent protection standards. Many efforts of making medicines affordable, accessible, and available for middle and poor sanctions of society

are criticised internationally. Pharmaceutical Report of 2010, on the other hand have presented a grim report on access to medicine in Pakistan. The report says that only rich and affluent class of Pakistan can afford essential medicine and rest of the population is depending on state level sources of medicine i.e., public hospitals. Moreover, as stated earlier that half of the medicines available in market are fake. This leaves poor faction of society without protection of health (Khan, 2005, p.27).

Legal infrastructure of regulating pharmaceutical patents in Pakistan suffers a paradoxical status. Protection of international standards on pharmaceutical patent protection leaves state contravening its commitments towards right to health under ICESCR. Measures supporting accessibility, availability, and affordability of drugs to poor factions of society attract WTO action against the state. (PPMA Report, 2013).

Careful interpretation of International instruments such as *TRIPS Agreement* reveals that a good deal of international legal flexibilities is embedded in the agreement itself. Moreover, this agreement does not obstruct member states' obligations towards health (Mazuka, 2011, p.77). Next portion of this article will explain various flexibilities available in TRIPS Agreement to protect right to health and access to medicine.

### **5. Flexibilities under TRIPS Agreement**

During negotiation at Uruguay Rounds of WTO-led campaign to adopt TRIPS Agreement, developing countries remained sceptical of future implication of the agreement. Fundamental concern was under-developed industry in developing countries. It is worth noting that current industrial progress in developed countries was achieved in the era of absence of strong intellectual property regime where countries imported industrial ideas from other jurisdictions without being blamed of violating intellectual property as it was national subject matter. Industrial progress of China is recent illustration where weak intellectual property regime let its industry flourish in very short time. Gap between industrial progress of developed and developing countries was very wide and based upon reservations forwarded by developing and least developed countries, various flexibilities were included in text of TRIPS Agreement.

Arguments led by developing and least developed countries during TRIPS negotiation based upon already existing obligations towards human rights regime and international commitments under MDGs. Developing countries clearly objected to enforcement of international standards of intellectual property on food, agriculture, and most significantly pharmaceutical products. All of these areas are closely knitted with protection of minimum standards of human rights. Moreover, in case of pharmaceutical patents, access to medicine is integral part of human right to health guaranteed by UDHR, ICESCR, WHO charter, MDGs, and various other international legal instruments. In result of reservations from developing countries many flexibilities were introduced in the agreement but effective utilisation of these flexibilities is not yet achieved. Many efforts are done in this regard and the most significant development related to access to medicine is Doha Declarations in 2001. It states:

*'We affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicine for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for the purpose.'* <sup>(Gopakumar, 2005)</sup>

The declaration recognises and stresses on interpretation of TRIPS Agreement in a way that it protects public health as a matter of human rights in member countries. Meaning of protection of health in this text is taken as access to medicine for the reason of impact of globalisation of pharmaceutical patent on availability and accessibility of essential lifesaving drugs (Das, 2005). In case of interpreting public health and right of state towards protection of public interest, dispute resolution body may consider standards provided by MDGS, WIPO, and UN Resolutions on elimination of malaria, TB, Hepatitis, and AIDS (Gopakumar, 2005). Moreover, further guidance may be attracted from ICESCR and its later

interpretations in various meetings of international community of states (ICESCR1967, Article 12).

### **6. Compulsory Licensing; Piercing Patent Monopoly for Access to Medicine**

Pharmaceutical patent monopoly is not an absolute right rather international legal system provides certain ways of scrutinising its operation. Compulsory licensing is authority with state regulatory authority that makes it pierce patent monopoly and put product under monopoly open for market competition in case of any malpractice such as non-availability, violation of public interest, or any practice against state policy. Article 31 of TRIPS Agreement defines and codifies compulsory licensing in following way:

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

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

*(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly; (TRIPS Agreement 1994, Article 31)*

Title of this article was suggested as using product under patent monopoly without authorisation of patent holder and this authorisation is only provided to state authority on various conditions. Moreover, this authorisation to state is not un-fettered and is subject to various conditions and limitations. Moreover, patent holder have certain control over negotiation and accruing benefit from state that must be adequate and sufficient against the patent rights. The issue arises when developing countries invoke power of compulsory licensing that brings a great deal of international pressure from international community led by developing nations. Writers on the topic have suggested a name for this pressure as ‘intellectual property politics’ (Cahoy, 2008).

Brazil, South-Africa, India, Thailand, and many other countries have tried to invoke their power of compulsory licensing to protect public interest of their population. All this was done to rationalise prices of medicine against deadly diseases where the population was not affluent enough to afford the treatment. Malaysia and Thailand used compulsory licensing to harmonise prices of drugs treating AIDS and other fatal diseases (Mohara, 2012). Compulsory licensing proved to be effective tool in Brazil and South Africa taking prices of essential medicines down enhancing availability, affordability, and accessibility of drugs. India has used various other methods including check on patentability to help local pharmaceutical industry and low cost of medicine.

Compulsory licensing has remained an effective tool to reduce prices of medicine but on the other hand some countries have not built capacity for production of life saving medicine. It is significant to note that Pakistan imports almost 90 percent of its raw material for pharmaceutical industry from different countries. (Pogge, 2008). Moreover, international intellectual property politics also hinders global and national developments for bringing prices of essential medicine lower (Rashid, 2013). Various tactics such as diplomatic pressure fear of economic sanctions, foreign direct investment, and Free Trade Agreements marginalise operation of compulsory licensing (Jain,2008).

Most significant is technical charter of intellectual property rights especially pharmaceutical patents where developing countries does not have enough legal experts to defend state’s prerogative of using

compulsory licensing and often lose their case in WTO dispute resolution system attracting economic sanctions (Braun). K. M. Gopakumar quotes Prof. Drahos stating:

*“Over the years the steady drip of technical assistance leads to the formation of technocratic trust in the EPO’s system. A strong belief forms that the EPO’s system produce quality results and that belief in turn forms the basis of decision-making y patent examiners in under-resourced developing country patent offices. Technocratic trust thus fosters a circle of decision-making in which the EPO trains developing country examiners to make decisions in their own countries that predominantly benefit foreign companies, including European companies.” (Gopakumar 2005)*

## **7. Principle of Human Rights Supremacy; critical analysis of Access to Medicine**

Patent Ordinance 2000 of Pakistan may utilise using flexibilities under TRIPS Agreement for protecting public interest by convincing international regulatory authorities. Case of affordable medicine is already contested by various countries such as Brazil, South Africa, Thailand, Malaysia, and most significantly India. It is worth noting that Indian legislation on pharmaceutical patents accommodated local industry in growing to great extent with easing patentability criteria. All this was done in accordance with international patent commitment as deciding standards of patentability is sole prerogative of state.

Although WTO has been considered as ‘self-contained’ regime and human rights role in interpretation during various disputes is kept minimum. Many authors argue that international human rights regime is directly relevant to interpretation of public interest. These arguments rely on Statutes of International Court of Justice (ICJ) which describe sources of for settlement of international disputes and adjudication as ‘General principles of law recognised by civilised nations’. This brings human rights relevant to debate of sources of law in WTO dispute settlement. Monistic Theory of international law takes it to next level and states adopting this theory put international above national law. For this reason, universally accepted principles of human rights come relevant to interpretation under Dispute Resolution Body (DSB) of WTO (Marian, 2008). USA is one of the states those adopt international law primacy principle under Monistic Theory of International Law.

For the reason of human rights supremacy as an objective of national laws and also international law, one may claim that in case of conflict between global pharmaceutical patent protection under TRIPS Agreement of WTO and right to health under ICESCR, later will prevail (Vega, 1994). A majority of international community, except USA, is signatory to ICESCR and have made their internal laws consistent with obligation towards this document (Fourie, 1990). Right to protection of health and provision of adequate standards of treatment is integral part of ICESCR but it is unfortunate that US is not part to it. On the other hand, USA is party to ICCPR and perusing its enforcement most vigorously (Fourie, 1990). If analysed critically, access to medicine may be interpreted as integral part of right to life covered under ICCPR. Diseases like AIDS, Cancer, TB, Malaria, and other tropical infection cause threat to life. So, one may state that access to essential medicine forms part of both ICCPR and ICESCR. Moreover, it is duty of states to ensure affordability, availability, accessibility, and quality of medicine in their territories (Hoen, 2002).

## **8. Concluding Remarks**

Although road towards using flexibilities under TRIPS Agreement is but but not impossible to travel through (Gopakumar, 2014). Neighbouring country, India has smartly dealt with concept of patentability granting a grace period for their pharmaceutical industry to grow before triggering its laws equal to global standards of patent protection. Moreover, academic campaign led by Amartya Sen justified state endeavours to ease patent monopolies bringing prices low on principles of human rights supremacy. Pakistan needs to learn from this lesson of using carrot and stick both in regulating pharmaceutical patents and prices of essential medicines. Utilising all available flexibilities under TRIPS Agreement will ultimately save major part of public spending on health. Besides very small budget of health in Pakistan, a good deal of resources may be saved to utilise them other than procurement of medicines. TRIPS

flexibilities will not only facilitate national pharmaceutical industry but will also bring prices of medicine lower in Pakistan.

Fundamental question is to harmonise national challenges with international requirements that will facilitate evolution of patent laws not revolution as adopted in 2000 by introducing a very strict ordinance (Palmer, Mavroidis, 1998). Additionally, paradox of public interest and strong patent protection in TRIPS Agreement may be contested in justifying efforts to facilitate lower prices of medicines in Pakistan (Dadupota, 2005). Preamble of TRIPS Agreement makes it clear that "special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base". Article 8 of TRIPS Agreement further elaborate:

*"1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.*

*2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."* (TRIPS Agreement, 1994)

Using above mentioned provision of TRIPS Agreement of WTO, following measures may be taken and justified by state of Pakistan to reduce a good deal of economic burden spent on procurement of costly patented medicines:

- 1- Patentability criteria are sole prerogative of state and it may be defined in a way suitable to public interest and access to medicine. Indian patent development and academic justification campaign is good illustration in this regard.
- 2- Regulation of price control may also be viewed technically and a due consideration may be given to public interest. Even public spending to procure costly medicine indirectly is paid from the taxes of those who are not affluent enough to buy those drugs.
- 3- Although, compulsory licensing is included in Patent Ordinance 2000 but its usage needs both technical and state level will. Regulatory authorities, IPO may keep a vigilant eye on various lifesaving drugs and advise state authorities in good time to invoke the power of piercing patent monopoly in public interest and later justifying in WTO forums. This needs technical expertise at both pharmaceutical and legal levels.
- 4- Last but not least, Pakistan should be using vigilant system of using all flexibilities provided in international legal framework. Human Rights Supremacy is good argument but as WTO is self-contained regime, it possesses much flexibility.

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