

**BUYING BACK THE RIGHT TO HEALTH:
LEGAL AND POLICY FRAMEWORK FOR
FACILITATING ACCESS TO ESSENTIAL MEDICINES
IN DEVELOPING COUNTRIES**

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ABSTRACT

The concept of public healthcare has perennially involved the institution of measures that are necessary for the prevention of large scale epidemics. This preventive approach embodies principles of sanitation, water purification and more recently vaccination. However, the advent of new strains of viruses and an unprecedented increase in the susceptible population has expanded the ambit of primary healthcare to include effective treatment. Especially in developing countries, treatment through affordable medicines is considered fundamental to the achievement of public health goals. Thus, there exists a humanitarian obligation on the international community and the respective governments of nations, to provide effective medication to those who cannot afford it, in the larger interest of maintaining a sense of equity in the sustenance of human life.

This paper analyses relevant international treaties and domestic judicial interventions that could effectuate positive change in the formulation of international trade and intellectual property policies, with regard to healthcare, at national as well as an supranational levels. The paper argues for the transfer of the decision making powers, with regard to the distribution of drugs, from the private pharmaceutical industry to the governments of countries. This, it argues, would result in a shift in prioritization from profit making motives, to the universal realization of the right to health.

Keywords: Healthcare, intellectual property, human rights

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1. INTRODUCTION

“One third of the world’s population still lacks access to essential drugs while in the poorest parts of Africa and Asia, over fifty per cent of the population does not have regular access to the most vital essential drugs.”¹ - M.Scholtz

This recent declaration of the World Health Organization (WHO) brought to light the deplorable status of a rapidly accelerating global health crises that currently plagues the developing world – the lack of availability of life saving medication.² It provided the necessary jolt of pragmatism and highlighted the imminent need to take affirmative action in order to save the lives of millions of people across the globe. This has in fact resulted in a shift of the concerns of production and supply of medicines; from merely an economic driven intellectual property domain, towards the ambit of the preservation of basic human rights. The issues of drug pricing funding innovation, foreign investment and economic growth in developing countries will now have to be read in context with the obligations of the governments to provide basic access to healthcare to their most impoverished citizens.

There are numerous reasons for the lack of accessibility to essential medicines. Notably, the single most relevant cause is the unreasonable pricing of drugs, which places some of the most vital medicines completely out of the reach of large populations living in the developing world. These exclusionary prices are often the result of a stringent regime of Intellectual Property protection that seeks to safeguard the research, innovation and development of unique processes by pharmaceutical companies. While this is a fair incentive to encourage further study and recover costs, there is a definite need to balance this protection of individual ownership with a larger interest of sustaining life through the realization of the overarching right to health.

Significant efforts have been undertaken to reconcile these conflicting interests through international instruments of law and policy, including but not limited to treaties, regulations and nuanced recommendations. International negotiation, in this regard, has been focussed on the protection of

1 M.Scholtz , ‘International Trade Agreements and Public Health: WHO’s Role’ (Conference on Increasing Access to Essential Drugs in a Globalized Economy, Amsterdam, November 1999).

2 World Health Organization, Template for Selected Model Indicators for Studying the Impact of Globalization and TRIPS on Access to Medicines (WHO/EDM/PAR/2002.1,2002, 25–35, 27).

individual effort while at the same time affording governments the requisite flexibility to take necessary measures to create effective healthcare systems. The WHO has begun to advocate that “generic production of drugs should begin upon patent expiration” and that “preferential pricing is necessary for lower income countries”³

With a view to effectuate positive changes in the formulation of trade and intellectual property policies, with regard to healthcare, at a national as well as an institutional level, this paper analyses relevant international treaties and domestic judicial interventions. In doing so, it advocates the transfer of the decision making power, with regard to the distribution of drugs, from the private pharmaceutical industry to the governments of countries. This, it propounds, would result in a shift of prioritization from profit making motives, to the universal realization of the Right to Health. These internationally endorsed policy decisions would inculcate self sufficiency, through the development of capacity building mechanisms such as generic production and compulsory licensing, in the developing world. It would thus effectively put an end to the trend of relegating the needs of the underprivileged to the contours of charitable dependency and staggered donations.

This paper is divided into five parts. After this introduction, part II of this paper provides a background on the existing conflict between the protection of individual effort and institutional innovation and the need to make socially beneficial knowledge universally accessible. Part III explores the shortcomings in the existing efforts to institute a system of affordable and accessible healthcare. Part IV reflects upon the emergence of an enforceable Right to Health; from what used to be a mere privilege. It does this through an analysis of executive policies, legislative initiatives as well as judicial intervention that aim to facilitate the fulfilment of humanitarian obligations in effectuating the Right to Health. Finally, part V provides recommendations at a domestic as well as an institutional level, which would allow governments of countries to create effective instruments within which their most vulnerable populations would be able to enjoy an unfettered access to affordable healthcare.

3 *ibid.*

2. THE CRUX OF THE CONFLICT – INDIVIDUAL OWNERSHIP V. PUBLIC INTEREST

There exists a continuous conflict between two factions of international law, “soft law” and “hard law”. At the crux of this deliberation lies the seemingly opposing tenets of the perambulatory clauses of relevant treaties that emphasize the need for equity and universal social justice; and the specific provisions that propound the principles of free trade and entitlement to individual property. International law leaves the conciliation of these two divergent interests up to the state machinery, thus creating an environment of uncertainty and discord in balancing the preservation of individual rights with the needs of larger populations.⁴

For example, subjecting governmental policies that infringe upon individual rights to judicial scrutiny would relegate placing these conflicting interests in higher hierarchy to individuals who harbour specific views of judges, which may not resonate with the interest of the masses. If a court finds that the only way a particular policy can fulfil a governmental objective is through the restriction of individual rights, then it will have to deliberate upon a scheme of prioritization which effectively upholds one at the cost of the other.⁵ Robert Alexy reiterates the need for a mutually beneficial process of reconciling these diverging interests through his endorsement of tests of suitability and necessity. These focus on issues of facts; such as whether a particular measure does in fact result in the achievement of pre determined goals and if there are less restrictive ways of achieving similar results.⁶ The test of proportionality, however sheds light on a normative concern; primarily of whether gains to the public justify the interference with an individual right.⁷

There have been a multitude of international platforms, established to create a conciliatory environment within the construct of which the resolution of these incongruous appendages can be realized. These include the World Intellectual Property Organization (WIPO), World Trade Organization (WTO), the Joint United Nations Programme on HIV/AIDS (UNAIDS), United Nations. However, as long as the primary interest has remained within the domain of trade and intellectual property rights, the primary legal framework within which multilateral negotiations have taken place have

4 T.Alexander Aleinikoff, ‘Constitutional Law in the Age of Balancing’ (1987) 96 Yale Law Journal 943.

5 Stephen Gardbaum, ‘Limiting Constitutional Rights’ (2007) 54 UCLA Law Review 789.

6 Robert Alexy, *A Theory of Constitutional Rights* (Julian Rivers tr, Oxford University Press 2002).

7 *ibid* 67–8.

been the treaties and custom instituted by the WTO. The following sections aim to provide a background to these negotiations and delve into the crux of the debate, thus strengthening the arguments put forth by the developing world in its bid to sustain the lives of its most impoverished citizens.

A. The Social Cost of a Stringent Regime of Patent Protection in the Developing World

The World Trade Organization Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), sets out minimum standards for the preservation of intellectual property rights, including patents for pharmaceuticals. It includes within its ambit safeguards to prevent the abuse of protections under a stringent patent regime in the form of relevant flexibilities. In practise, however it fails to directly outline the circumstances under which these safeguards can be utilized and the procedure for invoking them. The fourth ministerial conference, held in 2001 in Doha, Qatar adopted a declaration with respect to the public health related aspect of TRIPS. The declaration clarified the position of the agreement and empowered countries to take requisite measures for the protection of public health. This was an important milestone in the evolution of the access to public health as it essentially placed the right to health above considerations of the protection of individual property.

In addition to the increasing cost of research and development that goes into the production of vital medicines, placing them out of the reach of the developing world; there has also been a substantial decrease in international investment in the pharmaceutical industry in developing countries. As a result of this, the capacity of developing countries to produce their own medicines or even generic substitutions of patented drugs is abysmal. The global pharmaceutical market comprises of less than 10 per cent of consumers from developing countries.⁸ Consequently, drug companies recuperate only a minute fraction of their research and development costs from the developing world.

The medicines produced by most pharmaceutical giants remain cures for diseases that plague the developed world. Strains of the HIV virus which are responsible for a majority of deaths in the African continent or diseases such as Tuberculosis, Dengue, Malaria and the often fatal Human African Trypanosomiasis or Sleeping Sickness are still left untouched by most pharmaceutical companies. Human African Trypanosomiasis (HAT or

⁸ Susan Sell, *Private power, public law: The Globalization of Intellectual Property Rights* (Cambridge University Press 2003).

sleeping sickness) is a parasitic disease that is transmitted by the tsetse fly, and endangers the lives of almost 60 million people in sub-Saharan Africa.⁹ The countries most affected by the endemic are largely politically unstable and lack the requisite healthcare facilities to diagnose and treat the disease, thus making its containment a herculean task.¹⁰ The treatments currently available are outdated and can be used to treat the disease only at specific stages. Pentamidine, a drug from 1941 and Suramin date even further back to 1921 and are effective in treating only the first stage of the disease.¹¹ They have to be injected directly into the blood stream and can be quite expensive to administer.¹² They do not however, cross the blood brain barrier and are ineffective in treating the disease in its advanced stages.¹³

Between 1949 and 2009 alternative measures of treatment did develop but they have proven to be just as ineffective in treating the disease.¹⁴ Melarsoprol, an arsenic derivative was administered to patients in the second stage of their illness. With an almost 50 per cent rate of failure, it killed close to five per cent of all patients who receive it.¹⁵ Similarly, Eflornithine, administered to patients in the 1990s, was relatively well tolerated but was difficult to administer without the trained medical personnel and constant hospitalization that the countries tethered on the brink of poverty could not afford to provide.¹⁶ Nifurtimox-eflornithine combination therapy was added to the essential Medicines List of the WHO in May 2009.¹⁷ Developed and administered by Medecins Sans Frontieres (MSF) in war torn areas it proved effective in treating approximately 48,000 cases in across six countries.¹⁸ In the context of challenging diagnostic specifications, unstable environments and the rampant spread of the disease, the MSF has put forth relevant concerns regarding the need for focused research and development into developing alternative and durable treatments that contain this endemic disease.¹⁹

9 Medecins Sans Frontieres (MSF), *Human African Trypanosomiasis - Fact Sheet* (MSF 2009).

10 Medecins Sans Frontieres (MSF), *Human African Trypanosomiasis- Fact Sheet* (MSF 2009); and Medecins Sans Frontieres (MSF), *MSF Activity Report 2008* (MSF 2008).

11 Medecins Sans Frontieres (MSF), *Experience Treating the Most Neglected of the Neglected Tropical Diseases* (MSF 2008) <<http://www.doctorswithoutborders.org/sites/usa/files/MSF-NTD-Briefing-Paper.pdf>> accessed August 12, 2014.

12 *ibid* at 7, pp 2,3.

13 *ibid* at 7, pp 1.

14 World Health Organization, *Trypanosomiasis, human African (sleeping sickness)* (Fact sheet N°259 March 2014) <<http://www.who.int/mediacentre/factsheets/fs259/en>> accessed August 12, 2014.

15 *ibid* 10.

16 *ibid* 10.

17 cf Médecins Sans Frontières (n 11) 8 pp 1.

18 *ibid*.

19 cf Médecins Sans Frontières (n 11) 8 pp 2.

Another such disease that has attracted the attention of the international community due to its rampant spread is malaria. The resurgence of Malaria in sub-Saharan Africa has been attributed to the mutation of the parasite, making it more drug resistant.²⁰ A Swiss pharmaceutical company developed the first fixed dose Artemisinin-based combination therapy (ACT). Observably, due to the exorbitant price of the drug, it remained inaccessible to the poorest regions of the world and was thus ineffective in curbing the rampant spread of the disease.²¹ The United States Government, The World Bank and The Global Fund to fight AIDS, TB and Malaria have undertaken significant efforts to aid in the containment of the disease through the Roll Back Malaria partnership (RBM) and have attempted to provide infrastructural guidance to developing countries to help fund the treatment of their most vulnerable populations.²² The rising demand for Artemisinin has incentivized producers to promote it individually as a form of monotherapy.²³

The WHO has condemned this practice as the widespread exposure to this drug could in fact accelerate the resistance of this parasite to artemisinin.²⁴ Moreover the research into the development of a new anti-malarial drug has come to an absolute standstill.²⁵ Public health facilities in Africa are still inadequate and fall short of requisite standards of healthcare and drug administration.²⁶ As a result of this, people resort to the private sector, which has been infiltrated with substandard and artemisinin monotherapy drugs due to the practically nonexistent post market surveillance of the private sector drug industry in low income countries.²⁷ Countries plagued

20 UNICEF & World Health Organisation, *World Malaria Report 2005*. <http://www.rbm.who.int/wmr2005/html/exsummary_en.htm> accessed August 12, 2014.

21 World Health Organisation, *Guidelines for the Treatment of Malaria* (September 2006)

<<http://www.who.int/malaria/docs/TreatmentGuidelines2006.pdf>> accessed August 12, 2014.

22 Arrow KJ, Panosian CB and Gelband HN, *Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance* (National Academies Press, Washington DC, 2004).

23 Rational Pharmaceutical Management Plus, Management Sciences for Health, Sponsored by the Global Fund, USAID and RBM, *Changing Malaria Treatment Policy to Artemisinin-Based Combinations: An Implementation Guide* (December 2005) <http://www.rbm.who.int/docs/mms/act_implementationguide-e.pdf> accessed August 12, 2014.

24 World Health Organisation Press Release, 'WHO calls for an immediate halt to provision of single-drug artemisinin malaria pills' (19 January 2006 <<http://www.who.int/mediacentre/news/releases/2006/pr02/en/index.html>> accessed August 12, 2014.

25 Roger Bate, 'Malaria: Poor Drugs for the Poor' *CFD Bulletin* (June 21, 2007) <www.aei.org/publication26383/> accessed August 12, 2014.

26 Amin AA, Zurovac D, Kangwana BB, Greenfield J, Otieno DN, Akhwale WS and Snow RW, 'The challenges of changing the national malaria drug policy to artemisinin-based combinations in Kenya' (2007) 72 (6) *Malaria Journal* <<http://www.malariajournal.com/content/pdf/1475-2875-6-72.pdf>> accessed 12 August 2014.

27 Roger Bate, 'On the Trail of a Cure, Reality and Rhetoric on Treating Malaria' *American Enterprise Institute Health Policy Outlook* (22 March 2007) <http://www.aei.org/publications/pubID.25834/pub_detail.asp>.

by the endemic still lack structural reforms in their healthcare systems and remain largely dependent on donors, a trend that vitiates any attempts to institute self regulating, capacity building mechanisms within the region.²⁸

Thus, the research and development involved in the synthesis of drugs to cure diseases that affect the poorest countries has effectively come to a standstill. This can be attributed to the lack of investment by drug companies in the markets of developing countries for the fear of not being able to recover adequate returns on their investment.²⁹

B. Deconstructing the Argument of Incentivising Innovation Through Rigid Patent Protection in Developing Countries

Medecins Sans Frontieres(MSF) in consonance with a number of other non-governmental organizations have opposed the argument that an increased patent protection would in fact enhance the availability of drugs in developing countries.³⁰ They contend that a stronger regime of patent protection would only result in an increase in the number of patented drugs, the outcome of which would be an increment in the overall cost of healthcare. These drugs will still remain out of reach of most people in developing countries, thus widening the disparity between the production and distribution of effective medication.³¹ Further, the enforcement of stringent measures under the TRIPS will be detrimental to the indigenous production capacity as it would hinder the manufacture of generic drugs and irreparably damage an important industry upon which a majority of the population depends for quality, efficient and most importantly, affordable healthcare.³²

The impetus to innovation, research and development that is said to have been effectuated through a stringent patent regime has remained confined to the private sector of developed countries, from where definitive profits are recoverable.³³ Consequently, developing countries which have a low level of disposable income are often excluded from the ambit of potential research studies as pharmaceutical companies prefer not to invest

28 *ibid.*

29 *cf* Sell (n8).

30 Ellen't Hoen, 'European Parliament Committee on International Trade Hearing on TRIPS and Access to Medicines' (Medecins Sans Frontieres (MSF) Access to Essential Medicines Campaign, January 18, 2005) <<http://www.accessmed-msf.org/documents/ETHatEPhearing.pdf>> accessed September 4, 2014.

31 *ibid* 1.

32 Bonita de Boer, 'TRIPS, AIDS, and Generic Drugs' (AVERT.ORG, January 19, 2005) <<http://www.avert.org/generic.html>> accessed September 4, 2014.

33 *cf* Hoen (n6) 6.

in the synthesis of drugs that treat life threatening diseases plaguing the developing world as the monetary returns from this is minimal.³⁴ Only one per cent of the 1400 new medicines created in the last 25 years treat tropical diseases such as AIDS, malaria and tuberculosis despite thousands of people succumbing to them every year.³⁵ The endorsement of a stringent regime of patent protection as a means of incentivizing innovation thus stands on feeble foundations; as proved from the preceding empirical data, which suggests that the increase in patent protection measures over the last twenty years has not been accompanied by an equivalent increase in the rate of drug innovation.³⁶

There exists a two pronged permeation of the obligations imposed by the TRIPS into the tenets of Domestic legislation of individual countries. This occurs firstly through the regulatory legal processes of trade and economics within the construct of which the requisite policy is formulated and secondly, within the larger context of the *laissez faire* laws of the market, which tend to prioritize intellectual property ownership over public interest. Within these two interlinked spheres of State regulation and libertarian assumption, is encumbered the standing ethical obligation to protect the rights of individuals who may not have the capacity to claim such rights themselves. Thus, a large portion of the developing world depends on the ability of their respective governments to provide access to these drugs through their state sponsored public health systems. These government systems had, up until recently, relied almost entirely on the availability of less expensive domestically produced generic drugs in their respective markets. Further, they used the presence of these drugs in their competitive market spheres as a viable bargaining standpoint; on the basis of which they negotiated for significant price reductions of patented drugs produced by pharmaceutical companies endeavouring to break into the slowly emerging developing market.

A number of studies have used models depicting the behaviours of firms and consumers to stimulate the loss of welfare through a stringent regime of patent protection in developing countries.³⁷ India is a primary example of

34 *Id* at 2.

35 Oxfam Briefing Report, *Cut the Cost - Patent Injustice: How World Trade Rules Threaten the Health of Poor People* (February 2001) <http://www.oxfam.org.uk/what_we_do/issues/health/downloads/patentinjustice.pdf> accessed September 4, 2014.

36 Wesley A. Cann, Jr., 'On the Relationship between Intellectual Property Rights and the Need of Less Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply under a Theory of Progressive Global Constitutionalism' (2004) 25 U. PA. J. INT'L ECON. L. 755.

a low-income developing country which did not recognize patents till 1995 and in fact led the bloc of countries opposing the TRIPS. The consumer behaviour of the Indian market is reflective of the disease profile in numerous low income countries across the world.³⁸ The domestic Indian pharmaceutical industry was the largest producer for domestic drugs in 2002, followed by Brazil.³⁹ These markets were initially dominated by multinational subsidiaries in the early 1970's, but soon became self sufficient, with the introduction of numerous domestic players by 2001.⁴⁰ The collective share of foreign subsidiaries in domestic retail sales in India was 75-90 per cent in 1970; which by 2000 had declined to approximately 28-35 per cent.⁴¹

Under the new patent regime, Indian companies engaged in the production of drugs, for which patent applications were submitted in the period between the signing of the TRIPS agreement in 1995 and its formal recognition in domestic law on 1st January 2005, can only continue the production of these drugs if they pay a royalty to the patent holder.⁴² As a result of this, many of the products manufactured by domestic firms in India or Brazil would cease to exist in the market as it would simply no longer be profitable for them to continue producing these drugs while paying a royalty to the patent holder.⁴³ As a result of the withdrawal of generic drugs from the market, consumers will be forced to buy the branded counterparts at significantly higher prices. In the absence of domestic competition, the prices of products offered by the patent-holders will rise.⁴⁴ This is especially problematic in cases of epidemics where potentially life-saving medication would not reach the consumers in low income developing countries in time or even if they did they would be sold at unaffordable prices, thus being ineffective in containing the spread of the disease.⁴⁵

Prior to the institution of this regime, drugs were rarely launched by the

37 Jayashree Watal, 'Introducing Product Patents in the Indian pharmaceutical sector - Implications for prices and welfare' (1996) 20 (2) *World Competition* 5.

38 Lanjouw, Jean O. and I. Cockburn 'New Pills for Poor People? Empirical Evidence after GATT' (2001) 29(2) *World Development* 265.

39 A. Subramanian, 'Putting some numbers on the TRIPS pharmaceutical debate' (1995) 10(2&3) *International Journal of Technology Management* 252.

40 *Ibid.*

41 cf WHO (n 14).

42 cf MSF (n 13).

43 Rozek, R.P. and R. Berkowitz, 'The effects of patent protection on the prices of pharmaceutical products-is intellectual property protection raising the drug bill in developing countries?' (1998) 1(2) *Journal of World Intellectual Property* 179.

44 *ibid.*

45 M.Ganslandt, K.E. Maskus, and E.V. Wong, 'Developing and Distributing Essential Medicines to Poor Countries: the DEFEND Proposal' (2001) *The World Economy* 45.

multinational patent holder and were instead introduced into the market by the domestic firms. For example the launch of Ciprofloxacin in India was through the domestic firm Ranbaxy, in 1989 instead of Bayer, the international patent holder.⁴⁶ Consequently, when Bayer did enter the market much later, it had to lower its prices to compete with the established market share commanded by Ranbaxy.⁴⁷ Multinational companies often delayed their entry into the markets of developing countries (where the prices of their products are naturally capped by a much lower disposable income) after having negotiated upon higher prices in the markets of developed countries.⁴⁸ The foregone profits from this delayed entry were miniscule compared to the additional profits they made in the global market of the developed first world.⁴⁹

The newly instituted patent regime ensures that the patent holder can make exorbitant profits in developing markets, in addition to their already existing returns from developed markets.⁵⁰ The trade off for these additional profits is however, the suffering of thousands of individuals who belong to the poorest countries and simply cannot afford the market price attached to their Right to Health; a cost that can no longer be borne by the Governments of these countries as well. These additional profits are almost never invested in the research and development of effective cures to combat diseases such as Malaria and Tuberculosis as the countries in which these diseases are the most prevalent do not provide a sufficient profit motive to incentivize private sector investment through pharmaceutical conglomerates.⁵¹

As contended previously, there are virtually no profits to be made from instituting stringent patents on new drugs or processes that could treat diseases in developing countries, as the majority of the population would not be able to afford the patented medication anyway. The loss incurred by instituting stringent patents in developing countries is two-fold. It does not encourage innovation, development or research to treat diseases in the developing world and yet places an additional burden on individuals who

46 Geetanjali Deshmuh, Dr. S.S.Sahasrabudhe, 'India's new product patent regime: an analysis of Ranbaxy's R&D's expenditure and business strategies in the post-TRIPS period' (2012) 1(11) International Journal of Social Science and Interdisciplinary Research 36.

47 *ibid.*

48 Patricia Danzon, Richard Y. Wang, and L. Wang 'The Impact of Price Regulation on the Launch Delay of New Drugs' (2005) 14 (3) Journal of Health Economics 269.

49 *ibid.*

50 Cf MSF (n 19).

51 U Suthersanen & G Dutfield, *Innovation without Patents: Harnessing the Creative Spirit in a Diverse World* (Edward Elgar 2007) 35.

cannot afford to pay for the exorbitantly priced drugs that aid in battling life threatening diseases.

The WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH) in April 2006 confirmed that “in a market that has limited purchasing power, patents are not a relevant factor, in stimulating research and development or bringing new innovations into the market”⁵² Thus the development of effective public healthcare is thus dependent on the common but differentiated range of purchasing power of individuals, determined by whether they belong to low income developing countries or profit making developed countries.⁵³ This is evident from the table below⁵⁴ which makes a comparison of the share of the therapeutic segments in retail sales in a developing country, in this case India, with that of the world market. This proves that the disease most prevalent in a developing country does not attract the highest sales in the global market and therefore pharmaceutical companies would much rather focus their research on improving drugs that command the highest sales in the global market made up of mostly developed countries as opposed to synthesizing drugs that are most needed in developing countries.⁵⁵

Table 1 represents a comparison of the expenditure on public healthcare in developing and developed countries.⁵⁶ It indicates a much lesser portion of the GDP being apportioned to healthcare expenditure in low income developing countries than in developed countries. This indicates that the capacity of the government to improve upon its healthcare infrastructure, accessibility and support to the lowest income groups is directly related to average per capita income and consequent purchasing power of individuals within that country. The greater the per capita income of the country, the more the government invests in providing healthcare to its citizens. In low income developing countries, the burden of healthcare costs is largely borne by citizens. Thus, a stringent regime of patents would in fact only increase this burden without providing tangible benefits in terms of new and effective

52 World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health, *Framework Paper* (July 2004) 1< www.who.int/intellectualproperty/documents/en/Framework.paper.pdf.> accessed May 13, 2014.

53 Musgrove, Philip ‘Public and Private Roles in Health: Theory and Financing Patterns’ (World Bank Discussion paper presentation, Washington D.C, 1996).

54 Pinelopi Koujianou Goldberg, ‘Intellectual Property Rights Protection in Developing Countries: The Case of Pharmaceuticals’ (NBER and BREAD, Princeton University, 2009); based on the Alfred Marshall Lecture (European Economic Association’s Congress joint EEA-ES-EM meetings, Barcelona, 27 August 2009).

55 *ibid.*

56 *ibid.*

cures, as concluded from the previously established trend of pharmaceutical companies ignoring developing countries in terms of research for new drugs.

Table 1
Comparing the Indian pharmaceuticals market to the world market:
Shares of major therapeutic segments in retail sales

Therapeutic segment	Share of retail sales (%)			
	World: 2001		India: 2000	
	Rank	Share (%)	Rank	Share (%)
Cardiovascular system	1	19.6	4	8.0
Central nervous system (CNS)	2	16.9	6	6.7
Alimentary tract and metabolism	3	15.3	1	23.6
Respiratory system	4	9.5	3	10.4
Anti-infectives	5	9.0	2	23.0
Musculo-skeletal	6	6.1	5	7.3
Genito-urinary	7	5.7	9	3.1
Cytostatics and immunosuppressants	8	4.0	13	0.1
Dermatologicals	9	3.3	7	5.6
Blood and blood-forming agents	10	3.1	8	3.9
Sensory organs	11	2.1	10	1.6
Diagnostic agents	12	1.8	12	0.1
Systemic hormonal products	13	1.6	11	1.5
Others including parasitology	.	2.3	.	5.4

Source: World sales shares from IMS World Drug Purchases—Retail Pharmacies, IMS Drug Monitor, 2001. Indian domestic sales shares based on authors' calculations from ORG-MARG retail pharmaceutical audit.

This argument is strengthened by the data provided in the second part of Table 2 which collates the leading causes of the burden of disease in a developing country, in this case, India and compares it with that in the United States. The vastly differing figures prove that the healthcare needs of the developed world are vastly different from those of the developing world. An intuitive conclusion to this would be that pharmaceutical companies tend to invest their resources in the development of drugs for which they would get the highest returns as the prices of their drugs sold in the developed markets would not be capped by the limited purchasing power of individuals.⁵⁷ As a result of this they would be able to recover their costs of production more efficiently if they focused their research and innovation on developing cures for diseases that plague the developed world as opposed to those that plague the developing world; the market strength of which would depend on the affordability of drugs produced.⁵⁸

57 Mazzoleni, Roberto and Richard R. Nelson, 'The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate' (1998) 27(3) Research Policy 273.

58 *ibid.*

Table 2

Comparing the health sector in low-income and developed economies

	India	Pakistan	Canada	U.S.A.
Information on health expenditures				
Total health expenditures as % of GDP	4.9	4.1	9.1	13.0
Per-capita total health expenditures (US \$)	23	18	2058	4499
<i>Public health expenditures as % of total</i>	17.8	22.9	72.0	44.3
<i>Private health expenditures as % of total</i>	82.2	77.1	28.0	55.7
<i>Out-of-pocket expenditures as % of total</i>	82.2	77.1	15.5	15.3
Top ten leading causes of burden of disease in 1998: all ages				
India		U.S.A. and Canada		
Cause	DALYs (000)	Cause	DALYs (000)	
Acute lower respiratory infection	24,806	Ischaemic heart disease	2,955	
Perinatal conditions	23,316	Unipolar major depression	2,511	
Diarrhoeal diseases	22,005	Alcohol dependence	1,736	
Ischaemic heart disease	11,697	Road traffic injuries	1,670	
Falls	10,897	Cerebrovascular disease	1,651	
Unipolar major depression	9,679	Osteoarthritis	1,029	
Tuberculosis	7,578	Diabetes mellitus	1,017	
Congenital abnormalities	7,454	Trachea/bronchus/lung cancers	996	
Road traffic injuries	7,204	Dementias	940	
Measles	6,474	Self-inflicted injuries	858	

Sources: World Health Report, WHO (2002).
DALY stands for "Disability-Adjusted-Life-Year".

The pharmaceutical industry thus recuperates its costs and meets its profit making goals from developed markets and does not require developing markets to sustain itself. This has been further analysed in the following section

The Real Cost of Innovation – The Recovery of Production Costs Primarily From Developed Markets

Patents confer onto producers exclusive rights to the market in order for them to recover the costs that they might have incurred during the research and development of a particular product. The knowledge, using which the particular product was made, can be used only by someone who is authorized to do so by the patent holder. This protection of patents is afforded by society on to the holders of patents on the premise that without this guarantee of market exclusivity there would be no incentive to innovation. Thus, the State runs on an assumption that a stringent regime of patents would pay off in the long run as a result of the development of new prototypes that stimulate technical efficiency and effectuate scientific progress. However this assumption ignores the higher costs incurred through the creation of a monopoly that excludes competition and effectively paves the

path for arbitrary pricing in the long run, thus taking advantage of the desperate need and continuous demand of these life saving drugs. The rationale for a stringent patent regime is thus based on sweeping assumptions that may not actually take effect in reality, especially in the context of developing countries.⁵⁹

The pharmaceutical industry deems patent protection to be an extremely important aspect of recuperating Research and development costs and technological innovation.⁶⁰ They claim that approximately \$800 million is spent on the production of a single drug. Further, flexibilities such as compulsory licensing and parallel imports threaten the viability of the medical innovation system. Evidence suggests that these figures do not reflect actual costs but the opportunity costs of what the money could have earned if it was spent elsewhere.⁶¹ The pharmaceutical industry is largely based in the United States and Europe. In the U.S, extensive tax reductions are afforded to companies engaged in research and development. This recuperates close to 50 per cent of the cost incurred in the production of new drugs.⁶² Further, a number of clinical trials as well as research studies are carried out in government funded laboratories, which are maintained using taxpayer money. Thus, the public funds the research and development of the essential medication that they are often denied access to. The pharmaceutical industry spends 75 per cent less than what it claims to have spent on the manufacture of these drugs.⁶³

The profits made on patented medication in developing countries do not stimulate research and innovation toward developing possible cures for the majority of diseases in these developing countries. An estimated 90 per cent of global health research and development is spent on diseases that affect only 10 per cent of the world's population.⁶⁴ In 2005, Africa accounted

59 J. Stiglitz, 'Knowledge as a Global Public Good' in I. Kaul, I. Grunberg & M. Stern (eds), *Global Public Goods in the 20th Century: International Cooperation in the 20th Century* (1st edn, Oxford University Press 1999).

60 N. Kumar, 'Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries' (2002) 1b Commission on Intellectual Property Rights Background Paper Series 27 <<http://www.iprcommission.org>> accessed May 10, 2014.

61 S. Morgana, P.Grootendorst, J.Lexchine, C.Cunninghama and D.Greyson, 'The cost of drug development: A systematic review' (2011) 100 *Health Policy* 4 <http://moglen.law.columbia.edu/twiki/pub/LawNetSoc/BahradSokhansanjFirstPaper/100HealthPoly4_cost_of_drug_development_2010.pdf> accessed May 11, 2014.

62 H. Grabowski, 'Patents, Innovation, and Access to New Pharmaceuticals' (2002) 5(4) *Journal of International Economic Law* 849.

63 *ibid.*

64 Médecins Sans Frontières, *Doha Derailed: A Progress Report on TRIPS and Access to Medicines* (6/2003) <www.accessmedmsf.org/documents/cancunbriefing.pdf> accessed May 15, 2014..

for approximately one per cent of the global market for pharmaceuticals.⁶⁵ A recent study showed that between 1975 and 1999, only 0.1 per cent of drugs produced were for tropical diseases.⁶⁶

Further, the fear that the re-importation of generic varieties of patented drugs, under compulsory licensing or upon the exhaustion of a domestic patent, might be detrimental to the established market in developed countries is largely speculative. Considering the fact that, products from generic industries in India and Thailand have not flooded developed markets earlier, the likelihood of them doing so post the TRIPS agreement is minimal. Moreover, the strengthening of already established institutional safeguards to prevent this re-importation of generic drugs into developed markets would significantly negate the possibility of this ever happening. The unfounded threat of this possibly accruing in the future and affecting the profits of pharmaceutical companies in developed markets cannot however be used as a valid justification for preventing millions of individuals across the world from accessing their basic right to health.

The WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH) report made a number of valid recommendations to improve the system of intellectual property regulation in order to increase the accessibility of individuals within developing countries to essential medicines. To this effect, the commission encouraged governments, especially those of developing countries, to invoke the flexibilities within the TRIPS Agreement and use them to institute a regime wherein less stringent protections are afforded to patents within their domestic jurisdictions. This would deter pharmaceutical companies from filing patents in low income developing countries as the returns from such a patent would be minimal within the construct of a less stringent regime of patent protection.⁶⁷ There is an outstanding requirement for the international political acceptance of the creation of a global framework of research and development so that the cost and benefits of essential medicines can be equitably distributed. This would instigate the process of effective capacity building in developing countries.

65 J. O. Lanjouw and William Jack, 'Trading Up: How Much Should Poor Countries Pay to Support Pharmaceutical Innovation?' (2004) 3 Center for Global Development Briefs 6.

66 P. Trouiller, *et al.*, 'Drug Development for Neglected Diseases: A Deficient Market and a Public Health Policy Failure' (2002) 359 Lancet 2188.

67 Gabrielle Marceau, 'WTO Dispute Settlement and Human Rights' (2002) 13 European Journal of International Law 753.

68 C. Correa, 'Implementing the TRIPS Agreement in the Patents Field – Options for Developing Countries' (1998) 1(1) The Journal of World Intellectual Property 75.

3. FUNDAMENTAL SHORTCOMINGS IN EXISTING EFFORTS TO CREATE AN INCLUSIVE SYSTEM OF HEALTHCARE

The Adoption of the TRIPS Agreement in 1994 fundamentally changed the legal environment for the production and supply of medicines.⁶⁸ Subsequent to the universally applicable trade regulations promulgated by the Treaty, the members of the WTO adopted the Doha Declaration, notably the first international effort to clarify the presence and applicability of the flexible norms laid out under the TRIPS. The 140 Trade Ministers of countries ranging from the United States to Switzerland were in agreement that the TRIPS “does not and should not prevent members from taking measures to protect public health ... and that the agreement can and should be interpreted and implemented in a manner supportive of WTO members’ rights to protect public health and specifically promote the access to medicines for all.”⁶⁹

The Declaration did however acknowledge that many countries have “insufficient or no manufacturing capacities in the pharmaceutical sector” and thus could in no way be able to capitalize on the provision that allowed for compulsory licensing⁷⁰ within the TRIPS. The Declaration thus failed to expand its ambit to take into account the needs and vulnerabilities of the least developed countries.

In late August 2003, the members of the TRIPS council addressed the issue of capacity building in the pre-Cancun Agreement. It allowed for the export of drugs produced under compulsory licensing, but only on the fulfilment of certain predetermined criteria. In order to avail of the benefits of the import of drugs produced under compulsory licences, a country must show that it lacks the requisite capacity to produce medicines on its own, even those under a compulsory license from the original patent holder. Further, there also exists a need to prove the existence of a health emergency within the country, which makes it imperative to import drugs produced under compulsory licenses as opposed to original patented ones. This provision has been criticized for obstructing the implementation of mechanisms

69 C. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (1st edn, Third World Network 2001) 54.

70 World Trade Organization, *Doha Ministerial Declaration on the TRIPS Agreement and Public Health* (WT/MIN(01)/DEC/2 14th November 2001); WTO Council for TRIPS, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (IP/C/W/405 30th August 2003).

to better the system of healthcare in developing nations by placing an unnecessary reliance on often subjective and unascertainable criteria.⁷¹

The pharmaceutical industry contends that the export of medicines under a compulsory license would be a violation of obligations under Article 1709(10) of the NAFTA,⁷² as was seen in the case of the strong opposition to Canada's proposal of export of drugs manufactured to cure tuberculosis, HIV and Malaria.⁷³ This is exactly the kind of restriction that saw vehement opposition from developing countries in the pre Cancun Agreement.⁷⁴ The creation of a functioning capacity in order to allow the universal actualization of the Right to Health has often been restricted by the crystallization of legal principles that preclude even the most progressive governments from taking active measures; for the fear of relegating their citizens to the receiving end of harsh trade sanctions imposed by more powerful nations. The principle of *pacta sonda servant* has thus been used to spur the notion of the prioritization of individual enterprise over the Right to Health.⁷⁵

4. THE EVOLUTION OF THE RIGHT TO AFFORDABLE HEALTHCARE

In 2001, the High Commissioner for Human Rights called upon States to embody the provisions of the TRIPS within their domestic legislation in a manner that maintained the balance between the rights of the innovators and the interest of the public as reflected in Article 15 of the treaty, which endorses the flexible application of obligations under the TRIPS. Thus, the recognition of the importance of innovation and the rewards for such innovation comes with the caveat that States may be allowed or rather expected to utilize the flexibilities available within the TRIPS to aid in the realization of their goals of universal public health. The special rapporteur noted that "in accordance with intellectual property treaties, States must establish

71 Carlos M. Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health, Health Economics and Drugs' (2002) 12 EDM Series (WHO/EDM/PAR/2002) 3.

72 Kristen Douglas, Celia Jutras, 'Patent Protection for pharmaceutical products in Canada – Chronology of Significant Events' (2008) Parliamentary Information and Research Service 3.

73 Warren Kaplan, 'Fixed Dose combination (FDC) drugs availability and use as a global public health necessity: intellectual property and other legal issues' (2003) Essential medicines and Health Products Information Portal (World Health Organization) 164 <whqlibdoc.who.int/publications/2003/a86263_part9.pdf> accessed May 12, 2014.

74 Press Release, 'Canada Proceeds with Bill C-9 on Cheaper Medicines Exports: NGOs Say Initiative is Important, and Urge Other Countries to Avoid the Flaws in the Canadian Model' (28 April 2004) <www.aidslaw.ca/Media/press-release/e-press-apr2804.pdf> accessed May 12, 2014.

75 World Intellectual Property Organization, *International Intellectual Property Institute, Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa* (2000).

‘minimum standards of protection,’... surpassing these standards, although profitable in the short term would not however always be compatible with human rights obligations”.⁷⁶

The Universal Declaration of Human Rights mandates the embodiment of the right to health within the domestic legislation of Nations. The International Committee on Economic Social and Cultural Rights (ICESCR) makes the right to health binding on all parties to the treaty. Further, Article 12 of the treaty stipulates “The right of individuals to the highest attainable standard of physical and mental health”. Within the context of the obligations set forth in these treaties it is imperative for activists to strategize a durable way forward to effectuate the crystallization of norms that surround the Right to Health, Life and Bodily integrity; thus making these universally obligatory standards even for countries not party to the specific treaties.

General Comment 14 of the CESCR states that the dispensing of essential drugs, as defined by the WHO Action Program on essential drugs is a “core obligation” of the State under the ICESCR. The Human Rights Council has recently confirmed that the Right to Health includes access to medicines, in a general sense and is not restricted to medicines on the WHO essential medicines list.⁷⁷ Effective healthcare, has through the due course of international deliberation, been recognized as a fundamental right that has its origins in the natural law conception of an all encompassing right to life. This right is not provided by the State but can only be regulated by it through a procedure established by law; one that satisfies the requirements of justice, fairness and equity. The Right to Intellectual Property is not a fundamental right but merely a legal entitlement, granted in order to effectuate economic progress. The protection of this entitlement although justifiable to a certain extent does not merit the denial of capacity building instruments such as the production and importation of essential drugs and vaccinations, which may be essential to the very sustenance of life.

The prioritization of Intellectual Property Rights, an individual economic interest above the right to health is thus inherently problematic as it monetizes a fundamental right, restricting its enjoyment only to a privileged few, capable of affording it. This essentially opens the floodgates to an extremely dangerous situation where the right to life can be bought and sold

⁷⁶ Human Rights Council, *Report of the Special Rapporteur on the right to enjoy the benefits of scientific progress and its applications* (A/HRC/20/26 May 14, 2012) paragraph 59.

⁷⁷ Human Rights Council, *Report on the Access to Medicines, in the context of The Right of everyone to the Enjoyment of the highest attainable standard of Physical and Mental Health* (A/HRC/23/L.10/Rev1 June 11, 2013).

thereby reducing its stature to a mere commodity rather than an intrinsic value, indispensable to the very tenets that define our humanity.

It is thus the prerogative of the governments of Nations to balance the right to Intellectual Property with larger considerations of the preservation of human life. The core obligation of a State is not to incentivize creativity or innovation but to ensure basic necessities such as food, health and education. Additionally, the private interests of individual entrepreneurs should be balanced with the larger social benefits that can be accrued out of such innovation. The end goal of social progress is not the enrichment of a few but the betterment of the majority. “Ultimately, intellectual property is a social product that has a social function. State governments, thus have a standing duty to prevent unreasonably high costs for access to essential medicines.”⁷⁸

A. Discovering Flexibilities within the TRIPS, which Facilitate Access to Affordable Healthcare

The Medicines and Related Substances Control Amendment Act No 90 of 1997 (Amendment Act) was introduced by Nelson Mandela to create a provision for increasing the availability of and access to affordable medicines in South Africa. It endorsed the generic substitution of off patented medicines, transparent pricing of all medicines and the parallel importation of patented medicines.⁷⁹ This was based on a draft text produced by the WIPO Committee of Experts.⁸⁰

This legislation was vehemently opposed by major pharmaceutical companies, backed largely by the governments of the developed world. The Government of the United States espoused the cause of these pharmaceutical companies and threatened to levy trade sanctions against South Africa.⁸¹ Similar Action was taken by the European Union as well.⁸² This resulted in protests and demonstrations by AIDS activists all over the world. The negative attention drawn by the trial towards the major pharmaceutical companies left a huge impact on their profit margins, eventually resulting in a withdrawal of the case. This case for the first time paved the way for developing countries to take a firm stance against their more developed counterparts without facing the repercussions of the same in the form of trade sanctions.

⁷⁸ United Nations Committee on Economic, Social and Cultural Rights, *General Comment 17* (UN Doc. E/C.12/GC/1712 January 2006) paragraph 35.

⁷⁹ *Pharmaceutical Manufacturer's Association of South Africa v. President of the Republic of South Africa* (1998) Case No. 4183/98.

⁸⁰ *ibid.*

The United States government, post its stance against the South African legislation that sought to increase accessibility, came under severe attack for its lack of commitment towards Human Rights concerns. As a result of this the WTO Ministerial Conference in Seattle was used by President Clinton to announce a revised policy wherein the Trade Representative and the Department of Health and Human Services would look into the health related aspects of the United States trade-related intellectual property law.⁸³ In May 2000, the US issued an executive order to facilitate the access to HIV/AIDS drugs and related medical technology, through the use of compulsory licences in sub-Saharan Africa.⁸⁴

Similarly, the Brazilian AIDS program reduced AIDS-related mortalities by about 50 per cent between 1996 and 1999.⁸⁵ Brazil used the threat of compulsory licensing as a bargaining chip in its negotiation with major pharmaceutical companies in order to facilitate the reduction of prices of essential drugs. Article 68 under the patent law of Brazil allows a patent to be used without the consent of the patent holder.⁸⁶ This model of compulsory licensing has served as an important instrument of empowerment for other developing countries, which may have had the capacity to produce these drugs but lack resources to fund the research and development required for the production of completely new prototypes. Brazil has offered multiple cooperation agreements to aid in the transfer of technology to developing countries for the production of generic varieties of patented drugs.⁸⁷ The United States notably, still maintains its stance that Article 68, allowing compulsory licensing is contradictory to article 27.1 and 28.1 of the TRIPS.⁸⁸

Although the provision for compulsory licensing may have differed from the black letter of the law it was still very much in keeping with the spirit of the TRIPS agreement. Article 5.4 of the Paris Convention,⁸⁹ upon which the

81 Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Pub. L. 105-277, Oct. 21, 1998, 112 Stat. 2681).

82 Dylan Gray, 'Big Pharma's excuse for the monopolies on medicine won't wash' *The Guardian* (February 22, 2013) accessed on August 12, 2014.

83 Susan S. Westin, 'WTO Seattle Ministerial: Outcomes & Lessons Learnt', (United States General Accounting Office Testimony Committee on Finance, U.S Senate, 2000).

84 Exec Order 13,155, 65 Fed Reg 30, 521, 2000.

85 T.Rosenberg, 'Look at Brazil' *The New York Times* (January 28, 2001) 6.

86 Brazilian Patent Law, Industrial Property Law No 9,279 of 14 May 1996.

87 Brazil Ministry of Health, *National AIDS Drug Policy* (May 2001) <www.aids.gov.br/assistencia/aids_drugs_policy.htm> accessed May 16, 2014.

88 World Trade Organization, *Request for the Establishment of a Panel by the United States, Brazil Measures Affecting Patent Protection* (WTO Doc No WT/DS199/3 January 9, 2001).

89 World Trade Organization, *Paris Convention for the Protection of Industrial Property* (21 U.S.T. 1583, 828 U.N.T.S.305 20 March 1883 as last revised at Stockholm July 14, 1967).

TRIPS agreement is largely based, allows for compulsory licensing in certain cases. This has been embodied within Article 2.1 of the TRIPS Agreement. Under Article 31 of the TRIPS the original patent holder receives adequate remuneration under compulsory licences as well. Further, essential drugs produced under compulsory licenses can be exported to countries which have minimal or no production capacity.⁹⁰ The exporting of the drugs produced under compulsory licensing is imperative as it would not only aid in the dissemination of these drugs within the poorest countries but the money saved by the government through the utilization of these drugs as opposed to original patented varieties could be invested in developing the production capacities of these countries as well, thus making them more self reliant. This is a better system than continued dependence on foreign aid as it allows for the poorest countries to create for themselves a system of self sustenance and in doing so negotiate with developed countries on a close to equal footing. Thus compulsory licensing can be an effective tool to overcome barriers such as prohibitive pricing that is largely caused by patent abuse.

The Doha declaration, although instrumental as a compulsory license to endorse a regime of flexibilities within TRIPS towards humanitarian ends, did not clarify the stance regarding the export of drugs produced under compulsory licensing. Article 31 (f) of the TRIPS limits drugs produced under compulsory licensing predominantly to supply in the domestic market. It is imperative that further international action permit the export of drugs produced under compulsory licensing to countries that do not possess the capacity to produce these drugs even after a compulsory license for the same has been obtained. An alliance of NGOs including the Consumer Project on Technology, Essential Action, Medicins Sans Frontieres, Oxfam International, Health GAP Coalition and The Third World Network called upon the WTO members to incorporate a solution to the issue of export of drugs under compulsory licences. They proposed that under Article 30 of the TRIPS,

members may provide an exception to the exclusive rights conferred by a particular patent to permit all acts associated with the production for export to a third country of a patented product or a product produced by a patented process; where the export addresses the health needs in the third country; and the product and/or the

⁹⁰ World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights* (April 15, 1994) Article 31.

process is either (a) not patented; or (b) a compulsory license has been granted or the government has made use of relevant patents in the third country.⁹¹

This solution is both economically viable as well as relatively simple in terms of administration.

B. The Judicial Endorsement of Affordable Healthcare Over Arguments of Economic Sustainability

This part of the analysis focuses on the factors that have shaped the debate on the TRIPS and the right to health through various judicial decisions. These decisions of courts across the world have sought to pave a way forward for the international community to reconcile two opposing factions of human development.

The crux of the debate lies on two levels of argumentation. Firstly, would the reformation of intellectual property laws be more effective in improving accessibility, rather than alternative methods such as price controls and financial aid? And secondly, in light of incentivizing innovation through research and development, would a stringent intellectual property regime aid in effectuating the universal enjoyment of the right to health in developing countries?

The first judicial decision that challenged the existing norm of intellectual property protection was a 2002 decision of the Thai Central Intellectual Property and Trade Court.⁹² The court, in this case, drew a fundamental distinction between medicines and other products, as the drugs in question were fundamental to the sustenance of the life of a human being. This distinction placed medicines above other forms of property and dissolved the solitary claim of an individual institution to make way for a nuanced structure of rights and obligations, one that must be regulated by the State. The court laid down an important precedent in establishing the supremacy of the Right to Health. Further, it made use of Humanitarian considerations to expose the flexibilities within the TRIPS agreement. This was in consonance with the defined objective and construct of the Doha Agreement.

91 World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights* (April 15, 1994) Article 30.

92 *AIDS Access Foundation, Mrs. Wanida C. & Mr Hurn R. v. Bristol-Myers Squibb & The Department of Intellectual Property*, Thailand, The Central Intellectual Property and International Trade Court, Oct 1, 2002.

Similarly, a 2008 Delhi High Court decision concurred with the previously established trend of the affording an exceptional status to life saving drug, hence differentiating them from the pre-mandated rule.⁹³ The Court concluded that in the case of essential medicines, the pay offs for the stringent protection of patents were largely unknown variables as there was no definitive guarantee of investment, research or development in exchange for the same. However, this regime of stringent protection of patented medication placed an obligation on the State to protect individual enterprise at all costs, the fallout of which included “the likelihood of injury to non parties” and “the risk of denial of remedies”.⁹⁴ Thus, it held that “the granting of an injunction to stop the production of a generic variety of a life saving drug would be a prima facie violation of the right to life and liberty, enshrined within Article 21 of the Indian Constitution.”⁹⁵ Similarly, the South African Court of Appeals laid down an important test in the determination of a grant of injunction on the production of generic variety of a patented drug. It held that it was imperative that the “broader public interest” be taken, in light of a “balance of convenience” in assessing whether a preliminary injunction should be issued.⁹⁶

A 2004 decision of a Peruvian Constitutional court upheld the Right to Health as protected under Article 7 and 9 of the Peruvian Constitution.⁹⁷ The Court adjudicated upon the right of HIV/AIDS patients to free antiretroviral treatment. It used the provisions of the Doha Declaration to circumvent the stringency of the TRIPS Agreement holding that “the concerns regarding the effect of intellectual property rights on medicines cannot be left to one side.”⁹⁸

The TRIPS Agreement does not aim to obstruct the duty of the member countries to provide for the health requirements of its citizens. It is imperative that the right to health be construed in the most basic sense as an access to available medication for the enjoyment of a sustained reasonable standard of life. Yet it is obligatory upon the courts of countries not completely diverge from the provisions of the TRIPS and the subsequent Doha Declaration, which aimed to create a modicum of flexibility in the interpretation and application of the provisions of the TRIPS. It is in this context

93 *F. Hoffmann-LA Roche AG v. Cipla Ltd.*, [2008] 148 DLT 598.

94 *ibid.*

95 Article 21, The Constitution of India, 1950.

96 Sandra F. Joireman, ‘Colonization and the Rule of Law: Comparing the Effectiveness of Common Law and Civil Law Countries’ (2004) 15 *Const.Pol.Econ.* 315.

97 *Lori Berenson-Mejia v. Peru* IACHR Series C no 119, IHRL 1502 (IACHR 2004).

98 *ibid.*

that a need for clarity arises as to the nature and extent of this flexibility and whether it is enough to sustain a universal right to health while at the same time encourage research and development and protect innovation.

A 2009 decision of the Kenyan court held that the Anti Counterfeiting Act must be overturned on the grounds that it defined ‘counterfeit’ to include a patent anywhere in the world, thus making generic medicines unavailable in Kenya.⁹⁹ This restrictive definition effectively limited the access to essential medicines, threatening the lives of the petitioners and others infected with the HIV virus. This case brought forth an unprecedented instance of the judiciary stepping in to correct a possible oversight by the legislature and retaining the stance of the developing world of prioritizing the right to health over the protection of intellectual property.¹⁰⁰ A Chilean court reiterated this stance in 2013 holding that a law that allows the pricing of a drug so as to place it out of the reach of the majority of the country’s citizens, effectively violates the right to health, as guaranteed by the Chilean Constitution.¹⁰¹

A case that drew sufficient attention to the needs based stance of developing countries was *Novartis v. Monte Verde*¹⁰² wherein it was argued by the plaintiffs that they must be granted exclusivity of data in accordance with the obligations laid out under the TRIPS. The Argentinian Court held that the objective of reverse engineering was to fulfil the obligation of the State to address the public health demands of an increasingly incapacitated, ailing population. Further the right to health was inextricably linked to the right to life which forms the basis of the Constitutional guarantee of a government.¹⁰³ The court thus used international human rights obligations to lobby for a less stringent regime of Intellectual property protection, especially when it put an individual economic right on a balancing scale with the inherent right to life of all human beings.

The outcomes of these decisions, although not binding outside their respective domestic jurisdictions have been instrumental in setting a trend of legal precedent that international courts can draw upon. They form the

99 *PA.O and others v. Attorney General and another* (2012) High Court of Kenya at Nairobi Petition No. 409 of 2009 <kelinkkenya.org/wp-content/uploads/2012/04/Judgement-Petitioner-No-409-of-20092.pdf> accessed May 11, 2014.

100 *ibid.*

101 ‘Chilean Constitutional Court to decide on the constitutionality of the patent linkage bill’, (*Info Justice*, 7 March 2013) <<http://infojustice.org/archives/28883>> accessed May 12, 2014.

102 *Novartis Pharma AG v. Monte Verde SA & Propiedad industrial e intelectual* Sala III, Camara Nacional de Apelaciones en lo Civil y Comercial Federal (Division III of the Federal Civil and Comercial Court of Appeals in Argentina), Case No. 5.619/05 (decided on 1 February 2011).

103 *ibid.*

basis of articulate argumentation in a relatively nascent area of law, one that aims to use the tenets of humanitarian ideals to restrict the pragmatic application of economic regulation. Such a precedent is often instrumental in affording a sense of legitimacy to executive and legislative action of a similar nature. For example, the compulsory license on the HIV medication Efavirenz, instituted by the Brazilian government was recognized internationally as an actualization of State responsibility to “protect and preserve the human right to health.”¹⁰⁴ The formulation of this norm of Intellectual property preservation within the construct of Humanitarian considerations, by courts, has had a massive trickledown effect in civil society as well. The judicial decisions propounded within these cases have in a sense legitimized the institution of public welfare policies that seek to prioritize public interest over the profit driven demands of pharmaceutical companies. They also provide a strong foundation within the framework of which non-governmental organizations and rights based groups can pressurize pharmaceutical companies to afford due consideration to the healthcare needs of the developing world.

5. RECOMMENDATIONS ON THE REFORMATION OF INTERNATIONAL INTELLECTUAL PROPERTY LAW AND POLICY

Embodied within the covenants of the Universal Declaration of Human Rights, is “the Right of an individual to enjoy the protection of moral and material interests that result from scientific, literary or artistic production of which he is the author”.¹⁰⁵ Notably, there is a standing obligation upon governments of nation states to balance this with the “right to share in scientific advancement and its benefits”.¹⁰⁶

There is emerging consensus on establishing that developing countries cannot, in the given economic status quo, expect adequate investment in research and innovation towards cures for diseases that largely plague their populations. This is because it would simply be economically detrimental for large pharmaceutical companies to shift their production from drugs

104 Dr. Pedro Canisio Binsfeld, ‘The Use of compulsory license as patent related flexibility – Brazilin experience in Health’ (2012) 10 Organization Mondiale De La Propriete Intellectuelle 16 <www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_bog_12_ref_u10c_binsfeld.pdf> accessed May 13, 2104.

105 *The Universal Declaration of Human Rights* (December 10, 1948) Article 27 (2).

106 F. Machlup, & E. Penrose, ‘The Patent Controversy in the Nineteenth Century’ (1950) 10 *The Journal of Economic History* 20.

that cure diseases prevalent in developed countries towards the needs of developing countries. The furtherance of humanitarian goals such as the right to health requires human rights law to be used as a lens through which one might interpret and formulate the application of patent law. In the present context, a strong patent regime in developing countries can only increase prices of essential medicines without guaranteeing innovation, and therefore must be reformed.

A. Reforming Intellectual Property Policy at a Domestic Level

At the crux of the issue lies the reconciliation of two broadly opposing consequences of human enterprise. At one end of the spectrum is the encouragement of innovation, research and development through the protection of novel ideas. At the other end, lies the obligation of the State to make socially beneficial novelties accessible to the majority of individuals. While the recognition of individual liberty is imperative to the sustained progress and cultural development of a nation, it cannot be the sole determinant of a policy that affects millions of individuals. It is in this regard that there emerges a need for the reformation of intellectual property law and policy to incorporate the needs of the most vulnerable, especially with regards to essential medicines; while at the same time endeavouring to achieve a minimum standard of protection of research and a reward based incentive for innovation.

i. The Benefits of Establishing a Less Stringent Regime of Patent Protection within Developing Countries

Intellectual property policy, more often than not, is determined as a result of the exertion of power that profitable conglomerates have over the governments of countries. Thus, the consideration of public good is completely overshadowed by commercial interests. This imbalance often transcends domestic policy formulation and permeates into international deliberations between developing and developed countries. A stringent regime of intellectual property protection is largely beneficial to the export markets of developed countries. Consumer nations however, in this case mostly developing countries, do not have enough bargaining power to stand up to and negotiate with these developed countries on close to an equal footing.

The strengthening of IP laws without providing for reasonable flexibilities would effectively restrict the diffusion of socially beneficial knowledge in the developing world, thus incapacitating large populations and denying them the opportunity not only to access essential medicines presently but also sustain themselves in the future. Reverse engineering and production of generic stereotypes have been longstanding methods of this diffusion of knowledge. However, clamping down on these processes hinder the capacity building processes of developing countries.

The reason behind developing countries accepting the TRIPS agreement was the promise of a reduction in the protectionist policies of international trade. Observably, developed countries have wavered on their promises to liberalize their markets to allow for imports on agricultural produce and textiles. Developing countries have had to accept the restrictive provisions of the TRIPS that often prevent their access to essential commodities such as life saving medicines. The international community has recognized this disparity at the Doha and Monterrey conferences where the governments welcomed the “integration of development objectives into the formulation of IP rules and practice, including the need for the WTO to recognize the needs of developing countries and include them in the basic structure of its working program.”¹⁰⁸

The latest World Bank report estimates that most developed countries would benefit from the TRIPS as a result of the enhanced value of their patents. This benefit is estimated at an annual amount of 19 billion dollars in the United States alone. Developing countries would be the net losers with, for example, South Korea incurring losses amounting to 15 billion dollars.¹⁰⁹

The strength of a patent protection can be determined from the scope of the patent and the length of the period for which it was granted. Often the patent extends beyond the basic structure of the invention itself. Extending a patent beyond the scope for which such patent was claimed is in fact detrimental to innovation as it allows the patent holder to own the rights over all aspects of a particular knowledge or process, whose alternative use

107 *ibid.*

108 World Trade Organization, *Doha Ministerial Declaration on the TRIPS Agreement and Public Health* (WT/MIN (01)/DEC/2 November 14, 2001).

109 World Bank, *Global Economic Prospects and the Developing Countries 2002: Making Trade Work for the World's Poor* (ISBN 0-8213-996-1 1 January 2002)143. <<http://sit-eresources.worldbank.org/INTGEP/Resources /335315-1257200370513/gep2002complete.pdf>> accessed May 10, 2014.

or application may have been discovered by someone else. This acts as a disincentive to research and analysis into alternative uses or applications of patented knowledge or processes, thus limiting the depth of scientific study. Thus, narrower patents would allow researchers and innovators to work around existing patents even under a stringent regime. This policy of granting narrower patents also provides an impetus to the production of generic drugs at cheaper costs that work around existing patents and are less vulnerable to challenge in courts.¹¹⁰

An underlying assumption that is used to justify a strong patent regime is that there exists a latent potential of innovative capacity that would be unleashed through stringent patent protection. However in developing countries there is a definite need to build this capacity. This can be done through government investment in research, development and education. The government would have the resources to invest in this research and development only if it is able to save on costs incurred in obtaining essential drugs, required to ensure that the basic health needs of the majority of its citizens are met. Thus, a less stringent patent regime would in fact allow developing countries to invest in research and development and build upon this latent potential of innovative capacity. This potential could eventually be actualized through the development self sustaining health systems, thereby reducing the dependency of the developing world on foreign aid.

ii. Using Flexibilities within the TRIPS to Create Self Sustaining Mechanisms for Healthcare in the Developing World

Article 7 sets forth the primary objectives of the TRIPS Agreement. It essentially provides that the right to intellectual property is merely a means to an end and not an end in itself. It must thus contribute to the mutual advantage of innovators and the general public “in a manner that is conducive to social and economic welfare, and to institute a balance of rights and obligations.” Article 8 provides the requirement for the formulation of laws that “protect public health and nutrition”. Notably, the article also mandates that these laws be in consonance with the specific provisions of the TRIPS. Article 73 allows action in contravention of the TRIPS but in limited circumstances such as during war, emergencies or in furtherance of peace and security. Article 30 permits member States to provide certain

110 J.Sachs, ‘The Global Innovation Divide’, in A. Jaffe, A. Lerner, J. and S. Stern (eds.), *Innovation Policy and the Economy*, vol 3 (1st edn, MIT Press 2003) <<http://www.nber.org/books/innovation3/>> accessed May 4, 2014.

exceptions to the rights conferred by patents. Observably, these exceptions have been interpreted differently by the governments of different countries, thus rendering the effectuation of an equitable regime of patent protection, all the more difficult. The following sections expound upon the utilization of these flexibilities to develop processes and policies which provide the citizens of the developing world, a greater access to essential medicines.

A. Parallel Imports

Parallel Imports are a system of cross border trade in a product that is still under a patent without taking the permission of the patent holder. This occurs when there is a significant difference in pricing for the same good, in different markets.¹¹¹ Developing countries should not be made to restrict cheaper imports from developed or other developing countries. To this effect, in order to comply with the regulatory provisions of the TRIPS, developing countries should allow parallel imports only when the patent holders' rights have been exhausted in the country from which the commodity is being imported.

The provisions of the TRIPS, although obligatory in nature can still be superseded by the exercise of the sovereign authority of independent States to formulate their own trade related laws. The Agreement thus allows countries to develop their own laws that establish the subsisting time period of a patent. According to article 6 of the TRIPS the "first sale doctrine" cannot be made subject to WTO dispute settlement. Thus developing countries can capitalize on the benefits of parallel imports through the embodiment of a regime of "international exhaustion". Under such a regime a patent owner loses his right over the patent once it has been put on the domestic market of any country. This allows other countries to import the patented product if it has been put on any such domestic market, anywhere in the world, thus making off patent products available at cheaper prices.

B. Compulsory Licensing

The TRIPS Agreement allows its members to use patented inventions without the authorization of the patent owner, either by the government or through the issuing of compulsory licenses. The grounds on which compulsory licenses may be granted are not restricted by the TRIPS except in the areas of non working or dependent patents. As long as certain proce-

111 *Roussel Uclaf v. Hockley International*, [1996] R.P.C. 441.

dural conditions are followed compulsory licenses may be allowed on multiple grounds including public health, national interest and food security. The conditions required for the use of compulsory licenses are prescribed within Article 31 of the TRIPS. Article 5 of the Paris Convention confers onto nations the right to take legislative measures to grant compulsory licenses.

Compulsory licensing is an extremely effective instrument through which developing countries can make essential patented medication more accessible to its citizens. It is thus imperative that developing nations establish a strong framework of laws and procedures as well as the infrastructural facilities required to give effect to compulsory licenses. According to article 31(f) of the TRIPS a compulsory license must be “predominantly for use in the domestic market”. This is problematic as there are a number of countries which have no manufacturing capacity and cannot issue a compulsory license to a foreign manufacturer due to the territorial nature of patents. An amendment to this provision, so as to exclude laws, policies or administrative regulations in the furtherance of public health from its ambit; would be instrumental in the removal of trade related barriers to the actualization of the right to health in developing nations.

Another effective instrument of introducing generic drugs into the domestic market without incurring significant economic losses is the “Bolar exception”. The U.S Drug Price Competition and Patent Term Restoration Act, 1984, in overturning the landmark court decision of *Roche v. Bolar*,¹¹² introduced the concept of an early working exception. This exception makes it legal for a generic producer to import, manufacture and test a patented product before the expiry of its patent. This is done to ensure that the subsequent generic variation of the patented drug complies with the requirements mandated by specific domestic legislation, thus ensuring its quality and efficacy.

The flexibilities afforded by the TRIPS should be utilized by developing countries in the most effective manner possible. It is imperative that the governments of developing countries find an appropriate middle ground and utilize the strongholds and loopholes within International agreements to their benefit. It is also essential that they endorse Internationally recognized norms of patent protection norms which are reflective of a policy of Intellectual property protection that incentivizes originality without excluding certain sections of society from reaping its benefits.

112 *Roche v. Bolar*, 733 F.2d 858 (Fed. Cir., 1984).

B. Recommendations to Improve Institutional Collaboration in Achieving Universal Accessibility to Essential Medicines

The WIPO, due to its existing working relationship with domestic patent offices of governments all over the world, would be able to formulate a comprehensive guide of existing patents on essential medicines. Although the final interpretation of the flexibilities within the TRIPS agreement lies largely with the WTO, the WIPO can play a pivotal role in reconstructing existing perceptions with regard to the flexibilities within the TRIPS agreement and its facilitation of a greater access to essential medicines in developing countries. The WIPO should clarify the existing flexibilities within the TRIPS agreement and recommend their incorporation into the legislations of developing countries.

An example of this would be to advise developing countries against entering into TRIPS Plus trade agreements with developed nations. There is an increasing and yet alarming trend of governments in developing countries being pressurized by the pharmaceutical industry to implement patent legislation that extends beyond basic requirements of the TRIPS agreement. Also referred to as TRIPS Plus, this refers to the efforts on the part of developed countries to lobby for an extended patent protection on certain drugs; beyond the twenty year period. Further, it calls for the strengthening of existing patents, thereby rendering the flexibility afforded by the TRIPS to governments to reduce the stringency in the application of patent protection laws and allow for the permeation of generic variations into the market, virtually redundant. These agreements although seemingly economically profitable remain hugely detrimental to a large percentage of the vulnerable population living in these developing countries.

A number of State sponsored or international programs such as the UNAIDS Drugs Access Initiative have been instrumental in inducing price reductions and attracting investment to better the healthcare infrastructure in developing or underdeveloped countries. This prevents the percolation of essential drugs into the black market and the production of often dangerous counterfeit drugs. Further, these programs assist in the training of healthcare personnel to create an efficient system of dissemination of essential drugs to the poorest and most inaccessible regions.

The European Commission has noted that “the experience with vaccines and contraceptives have allayed fears of impracticality of differential pricing between developed and developing countries”.¹¹³ The Pharmaceutical Research and Manufacturers of America in explaining its rationale behind

differential pricing has stated that different prices for pharmaceuticals make them available to consumers at prices lower than what would be possible if only a uniform system of pricing was made applicable. The difference in pricing across markets (*i.e* lower prices in developing countries and higher prices in developed countries) based on the purchasing power of the target demographic in each country, can in fact increase overall sales, maximize the overall output and serve markets more efficiently. This benefits developing countries by increasing the availability of reasonably priced products and as well as developed countries by lowering prices than what they might have been under a uniform price regime, through the economies of scale.¹¹⁴

The WIPO should collaborate with the WHO in order to establish a joint initiative within the construct of which experts in healthcare as well as intellectual property can develop a basic framework of research. On such foundations the international policies could aid in the universal access to essential medication can be formulated. Lastly, it is imperative that the WIPO facilitates international engagement, deliberation, and coordination between intergovernmental as well as non-governmental organizations in order to accelerate the process of the actualization of the right to health in the developing world.

6. CONCLUSION

The end objective of both international as well as domestic developmental policy is to facilitate economic advancement, accelerated social progress and infrastructural expansion in order to achieve the basic goals of development. One such goal is affording access to primary healthcare to the most vulnerable individuals, who do not have the requisite means and resources to claim the rights that they are entitled to themselves. The economic indicators of development attribute the progress within a country to technological prowess and scientific innovation. In keeping with this theory, a stringent regime of intellectual property protection confers the right to market exclusivity onto individual entities; with a view to incentivize innovation and effectuate development in the long run. Similarly, the promise of focused investment to facilitate research initiatives is used to justify an

113 Martin Foreman, 'Beyond Our Means?: The Cost of Treating HIV/AIDS in the Developing World,' (The Panos Institute, London, 2000) 13 < www.panos.org.uk > accessed May 10, 2014.

114 R. Howse, 'Conference: Linking Trade and Sustainable Development: Roundtable Discussion,' (2003) 18 *American University International Law Review* 1324.

exclusionary price regime of essential medicines in developing countries as well. However, the assumption that the institution of stringent patent laws, especially in developing countries, will encourage foreign investment and aid in the creation of self sustaining healthcare mechanisms, is an inherently flawed leap of faith; one that has been disproved through the course of this paper.

The sustenance of human life is a primary duty of the State, as propounded in the most basic conceptions of the social contract theory of State formation. Numerous international agreements, institutional resolutions and domestic judicial interventions have paved a way forward for the reconciliation of the two conflicting realms of economic regulation and the fulfilment of State obligations. It is in this regard that this paper recommends the utilization of flexibilities within the TRIPS agreement and calls for cooperation amongst nations to establish a durable framework for the creation of efficient systems of healthcare in developing countries. This would provide developing countries with the opportunity to engage in the creation of self sustaining mechanisms to facilitate a greater accessibility to affordable healthcare; thus reducing their dependency on foreign aid. Through the course of this paper relevant conclusions have been drawn with regard to how best to aid in the actualization of the right to affordable healthcare through policy reformation and institutional advocacy. It is essential that these measures are put in place in order to empower vulnerable populations within the developing world to realize this right for themselves.