PATENT MONOPOLY: A PRESENT DAY IMPEDIMENT TO HEALTHY LIFE

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I. INTRODUCTION

Rights going by layman's interpretation are the interests that are protected by a statute. They are fundamental elements of any civilization. For a society to thrive in a chaos free manner various rights must be protected by the state. But in certain circumstances, one can come across conflict between different rights that are justified by law. One such major and extensively debated clash of rights is Right to Health and Patent Monopoly. The former is one of the basic right that every state must protect for proper growth of the society while the latter ensures that an inventor's interest are sheltered and he should get the reward for putting up his intellectual efforts. Various international and national conventions and seminars have discussed this issue. Two different types of right involving varied stakeholders whose interest is harmed.

The problem of high prices has been observed by the international community in the context of treatable infectious diseases such as HIV/AIDS and malaria. For example in 2000, for a triple-combination antiretroviral (ARV) treatment, the price of the lowest branded treatment was about US$ 10,439 for a year's supply.[214] Introducing more recent drugs in anti-AIDS combination therapy because of the emergence of resistance to older treatment would increase the annual cost of treating an adult for one year in a developing country from US$ 99 to US$ 426. Since every patient on therapy today is expected to need these newer therapies at some stage of their treatment, the increase in cost will have awful consequences for AIDS programs.

The high price tag meant patients living with HIV/AIDS would not be able to afford treatment and would be condemned to death. Globally, for instance, costly anti-retroviral drugs do not reach the almost 90% of HIV/AIDS patients living in the poorest 10% of the world's countries.[215] The unaffordable prices of drugs are often the result of strong intellectual property protection.

The main reason why cheaper generic alternatives were possible for older ARV products is that there were no patents in some developing countries with vibrant generic pharmaceutical industries. India, for example, free from product patents for medicines in pre 2005 era, used to manufacture and supply generic medicines to the rest of

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[214] See Médecins Sans Frontières, "Untangling the Web of Price Reductions" (July 2007) available at www.accessmedmsf.org.
[215] John A. Harrelson, *TRIPS, Pharmaceutical Patents, and the HIVIAIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion,* 7 SPG WIDENER L. SYMP. J. 175, 176 (2001).

the world.

A lot of fundamental questions need to be answered: Is there any conflict between patent rights protection and access to medicine? How does the conflict arise? What is the substance of the conflict? Does responsibility for a substandard public health system lie on the government? But who is responsible for the violation on such human right of access to medicine, and what is the remedy? What are the options for resolving the conflict and how to find a balance between pressing public health needs and legitimate private intellectual property interests? How to build up human rights-based approach into intellectual property law to mitigate the suffering?

In 2006, the Report of WHO's Commission on Intellectual Property, Innovation and Public Health (CIPIH) [216] observed that "Where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding."

Access to medicine constitutes an integral part of right to health, which is set out in fully many treaties and instruments. Right to health has undergone remarkable normative development and clarification in recent years.

II. RIGHT TO HEALTH

Like the right to life, the right to health entails negative as well as positive obligations. As a fundamental right, on one hand, the right to health is an individual right in that it requires the protection of the physical and mental integrity of the individual and his dignity; on the other hand, it is also a social right in that it imposes on the state and society the collective responsibility for the protection of the health of the citizenry and the prevention and treatment of diseases. To fulfill right to life requires a duty to avoid depriving people of the substance of their rights, to protect people against deprivation of life, and to aid them when they are deprived of their right to life.

A broad interpretation of the right to life- arguably the most basic human right, to which some international tribunals have granted *jus cogens* standing-should include access to life-saving medication if withholding such treatment would otherwise deprive life.[217] The Universal Declaration of Human Rights (UDHR) establishes "the right to a standard of living adequate for health and well-being including medical care and necessary social

[216] See http://www.who.int/intellectualproperty/report/en/index.html
[217] Alicia Eli Yamin, *Not Just a Tragedy: Access to Medications as Right Under International Law,* 21 B.U. INT'L L.J. 325, 330-31 (Fall, 2003).

services."[218]

The Constitution of the WHO, for example, provides for the "enjoyment of the highest attainable standard of health" as a fundamental right, with health defined as a "state of complete physical, mental and social well-being."[219] On May 18, 2002, the World Health Assembly adopted a resolution entitled "ensuring accessibility of essential medicines", which called upon the WHO, among other things: to pursue all diplomatic and political opportunities aimed at overcoming barriers to access to essential medicines, collaborating with Member States in order to make these medicines accessible and affordable to the people who need them.[220]

Article 6(1) of the International Covenant on Civil and Political Rights (ICCPR) establishes a right to life, which could require states' affirmative efforts to enable "conditions that permit, at a minimum, survival and promote dignity and well-being."[221]

The Committee on Economic, Social, and Cultural Rights (ESCR) has interpreted health as addressed in the International Covenant on ESCR to be "a fundamental human right indispensable for the exercise of other human rights" and concluded that "every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity."[222] ICESCR expressly addresses the right to health under Article 15 which guarantees all individuals the right to the benefits of scientific progress, which could include access to break-through medications. [223] Its General Comment No. 14 (Comment 14) specifies that the right to health under Article 12.1 is not simply a right to be healthy but rather a requirement that a state provide "a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health."'[224]

The right to health has four interrelated and essential dimensions, whose application depends on the conditions prevailing in a particular country: availability, accessibility, acceptability and quality.[225] *Availability:* public health-care facilities, goods and services, as well as programmes, be available in sufficient quantity within the

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[218] *Universal Declaration of Human Rights,* pmbl., G.A. Res. 217A, U.N. GAOR, 3d Sess., U.N. Doc. A/810 (1948).

[219] Constitution of the World Health Organization, *opened for signature* July 22, 1946, 14 U.N.T.S. 185, 186, pmbl., *available at* http://whqlibdoc.who.int/hist/officialrecords/constitution.pdf (accessed July 30, 2014).

[220]Ensuring Accessibility of Essential Medicines, WHA55.14, May 18, 2002, available at http://www.who.int/bg/ebwha/pdf-_files/WHA55/ewha5514.pdf (accessed July 30, 2014).

[221] *Supra note* 3.

[222] General Comment No. 14: The Right to the Highest Attainable Standard of Health, U.N. Committee on Economic, Social and Cultural Rights, 20th Sess., U.N. Doc. E/C.12/2000/4, para. **1** (2000), *available at* http://www.law.washington.edu/courses/kuszler/H540-SpO5/Documents/ general_comment_14.pdf (last visited on July 30, 2014)

[223] *International Covenant on Economic, Social, and Cultural Rights,* G.A. Res. 2200, U.N. GAOR, 21st Sess., Supp. No. 16, at 49, U.N. Doe A/6316 (1966), 993 **U.N.T.S.** 3, 6 I.L.M. 360, *available at* http://www.unhchr.ch/html/menu3/b/acescr.htm (last visited July 30, 2014)

[224] *Id.* at para. 8.

[225] "General Comment No.14, "The right to the highest attainable standard of health: 08/11/2000", New York: United Nations Committee on Economic, Social and Culture Rights, 22nd Session, Agenda item 3, Doc. E/C.12/2000/4, 2000, para.12.

State party. *Accessibility:* accessible to everyone without discrimination, within the jurisdiction of the State party. *Acceptability:* be respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements. *Quality:* be scientifically and medically appropriate and of good quality.

In case of *F. Hoffman-La Roche Ltd. & Anr* v. *Cipla Limited,*[226] the Delhi High Court in India refused to injunct the defendant to manufacture Roche's patented lung cancer drug "Tarceva" on the ground of public interest and right to life. The court has stated that right to life of the end-users of the life-saving drugs will outweigh the right to exploit a patented drug vested by the patentee.

This right is enshrined in the Constitutions of DPR Korea, Indonesia, Maldives, Nepal (interim Constitution), Thailand and Timor-Leste. All these Constitutions employ the local equivalent of the English language word *"right"* in describing people's entitlement to health care and in some cases also to underlying determinants of health. The constitution of Timor-Leste is the only constitution where the words "right to health" is included. The constitutions of Bhutan, Bangladesh, India, Myanmar and Sri Lanka do not recognize the *right* to health as a fundamental right but, nevertheless, compel the state to provide health services or in some cases, more indirectly to improve public health. Also that a denial of access to life-saving medicine for people infected with HIV in Costa Rica, is infringement on their right to life.[227]

In the case *Minister of Health* v. *Treatment Action Campaign*, [228] the South African Constitution Court held that the Constitution requires the government to "devise and implement within its available resources a comprehensive and coordinated programme to realize progressively the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child-transmission of HIV. [229] This case establishes a conceptual and remedial framework for judicial review and enforcement of the obligation to ensure access to healthcare and other Economic, Social and Cultural rights.

In India, with 260 million citizens still below the poverty line and without the fundamental assurance of healthcare, the right to health clearly acquires great importance in Indian scene. In India, the government's concern for health and safety of its people is indicated by the legislations enacted for health care. Recently, Article

[226] *F. Hoffman-La Roche Ltd. & Anr.* v. *Cipla Limited*, FAO (OS) 188/2008.
[227] A.E. Yamin, "Not Just a Tragedy: Access to Medication as a Right under International Law", 21 Boston Univ. ILJ (2003) p.326
[228] Constitutional Court of South Africa, Judgment of the case "*Minister of Health v. Treatment Action Campaign*", Case CCT8/02, 5 July 2002. Available at: http://www.law-lib.utoronto.ca/Diana/TAC_case_study/MinisterofhealthvTACconst.court.pdf
[229] Alleged violation of the following sections of the South African Constitution: Section 27:"Everyone has the right to have access to a) health care services, including reproductive health care; The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights". Section 28(1)(c):" Every child has the right to basic nutrition, shelter, basic health care services and social services".

21 of the Indian Constitution has been interpreted to incorporate the right to health in right to life[230] and hence this right having now acquired a constitutional status through judicial activism, can be judicially enforced. The Directive Principles of State Policy provide against the exploitation of weaker sections of society[231], including children[232], and mandate the state to raise the levels of nutrition, the standard of living and improve public health[233].

In case of Vincent Panikulangara vs. Union of India,[234] the Supreme Court of India on the right to health care observed:

"Maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community and on the betterment of these depends the building of the society of which the Constitution makers envisaged. Attending to public health in our opinion, therefore is of high priority-perhaps the one at the top".

The Indian Supreme Court has interpreted Article 21 of the Indian Constitution in the Marshallian spirit[235] and has broadened its scope repeatedly, relying on general legal doctrines, international conventions[236] and fascinatingly, the Directive Principles of State Policy, thus making some of them enforceable. The Courts in India have shown keen interest in protecting the health of people in the society and have accepted it in clear-cut manner that administrative as well as judicial wings of the State are under a duty not to adopt an indifferent attitude in this respect[237].

III. PATENT PROTECTION

i. Introduction

[230] *Bandhua Mukti Morcha vs. Union of India*. AIR 1984 SC 802.
[231] Article 39(e): "that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength."
[232] Artilce 39(f): "that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity and that childhood and youth are protected against exploitation and against moral and material abandonment."
[233] Article 47: "The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purpose of intoxicating drinks and of drugs which are injurious to health."
[234] **Vincent Panikulangara vs. Union of India.** AIR 1987 SC 990: 995. p. 995
[235] *McCullah v. Mayland*,
(1819) 4 Wheel 17 US 316.
[236] *Vellore Citizens' Welfare Forum v. Union of India*, (1996) 5 SCC 647; *People's Union of Civil Liberties v. Union of India*,(1980) 2 SCR 913 are some of the cases in
which Indian Courts have relied on the International Conventions
[237] *Municipal Corporation of Delhi v. Suraj Ram* (1995) 2 Cr. L.J. 571

The patent system was originally devised on a balance between the fairness of rewarding innovators and society interest. Patents were granted as means to promote the industrial advancement of the nation.

In the U.S., the drugs have been patentable as chemical products since 1925 when the chemical patents came into use. The US recognize two different forms of patent: the producing process of drugs may be patented independently of the chemical formula for the drug. Until 1984 the U.S. patent law treated medical discoveries in the same way as other innovations, and no special treatment was reserved for drugs.[238] In most of the continent Europe, until recent years only the process of producing a drug could be patented. In Italy, pharmaceutical products and processes were not covered by patents until 1978; the same was in the Switzerland for processes until 1954 and for products until 1977.[239]

In France, the patent law of 1844 excluded drugs from patentability until 1960, to ensure the patents of health products would not be used for purely commercial purposes. This exclusion did not extend to processes of preparation of remedies, which were patentable.[240] During the period of World War I, the explicit recognition of pharmaceutical process patents was enshrined in 1944 French patent law.[241] Later, limited patents for pharmaceutical products were finally introduced in France.[242]

From the history of patent medicine, we can find that pharmaceutical products considered to be goods unlike any others were crucial. Thus the government took into account the social value of patentability of medicine and grant patent cautiously to balance the society's requirement. The rules and laws of patent law have traditionally been designed to achieve optimal balance between two ends: the reward of innovation and the social benefit related to patent monopolies. Even if today, except to consider promoting technology innovation, the general benefits of the public to enjoy right to health should not be ignored.

The Indian Patents Act, 1970 was enacted to replace the Indian Designs and Patents Act, 1911, whose purpose was to encourage development of the domestic pharmaceutical industry and make lifesaving drugs affordable for common people.[243] The monopolistic control of the MNCs in Indian drug market created pressure by making it

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[238] Michele Boldrin and David K. Levine, "*Against Intellectual Monopoly*", Cambridge University Press, 2008, Ch. 9, P. 2.
[239] *Id.* at P.3
[240] Maurice Cassier, "*Patents and public health in France: Pharmaceutical patent law in the making at the patent office between the two world wars*", History and Technology, Vol. 24, No. 2, June 2008, p.135.
[241] *Id.*
[242] *Supra note* 27.
[243] N.R. Ayyangar Committee Report on the Revision of Patents Law (1959) as cited in Shamnad Basheer, India's Tryst with TRIPS: The Patents (Amendment) Act 2005, 1 INDIAN J.L. & TECH. 15 (2005) available at http://www.nls.ac.in/students/IJLT/resources/1_Indian_JL&Tech_15.pdf (Last visited on July 28, 2014).

import life-saving drugs like penicillin from abroad.[244] Therefore, the need of the hour was to reduce the dependence on MNCs and protect public health by making drugs accessible to people. India was able to achieve all these objectives through the Indian Patents Act, 1970. It abolished patents in pharmaceutical products and provided patents on processes for a short period of time.[245]

Section 3 of the Act categorically states that an invention which is contrary to well established principles of natural laws or the intended use of which would be contrary to law or morality or injurious to public health are not inventions for the purpose of granting patents. The basic philosophy of the Indian Patents Act is embodied in Section 83 of the Act:

Among other things, the, discovery of scientific principles, inventions injurious to public health, a method of agriculture or horticulture or the treatment of human beings, animals or plants are not considered as inventions and therefore are not patentable.

ii. TRIPS

The TRIPS widen the scope of patentable subject matter including pharmaceuticals. The minimum standards mentioned in the TRIPS agreement ensured the protection that the patent shall be granted for any inventions, whether product or processes, in all fields of technology under the conditions that they are new, involve an inventive step and are capable of industrial application without any discrimination to the place of invention or to the fact that products are locally produced or imported.

TRIPS also gives due importance to protection of public health. In this regard, Article 8 provides that "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".

Many developing countries hold that the standardization of the different national legislations that results from the ratification of the TRIPS agreement does not take into account the relevant differences between developing and developed countries, and the TRIPS agreement is unbalanced in that it favors developed countries and transnational corporations, but it is not helpful or even harmful to their own interests, since their domestic firms lack of the capacity to innovate this field. The patent provisions in TRIPS have been subjected to much criticism

[244] Linda Lee, Trials and TRIPS-ulations: India Patent Law and Novartis AG v. Union of India, 23 BERKELEY TECH. L.J. 281 (2008).
[245] Martin J. Adelman & Sonia Baldia, Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India, 9 VAND J. TRANSNAT'L L. 507 (1996).

for failing to reach an appropriate balance with respect to patent protection and access to life-saving medicines in developing and least-developed countries. It was also criticized that the provisions in TRIPS Agreement are more in favor of owners of intellectual property to facilitate global trade.

Public health and legal scholars have suggested that developing countries might improve the potential negative effects of TRIPS on access to medicines by exploiting TRIPS "flexibilities", which provide some room for plan in designing patent laws. TRIPS flexibilities include, for example, the ability to delay entry into TRIPS and to grant compulsory licenses in public health emergencies. Other flexibility is the scope to define patentability standards. While countries cannot, under TRIPS, exclude entire fields from patenting, they do have the right to determine what types of applications merit patent protection. This is potentially important since developed country patent offices commonly grant patents on "incremental" innovations in pharmaceuticals. Such patenting is sometimes characterized as "evergreening," since such patents are often filed late in the product lifecycle and are used to temporally extend patent term.

The WTO's 2001 Doha Declaration affirmed that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

The domestic-use restriction, for example, withholds the utility of these licensing flexibilities from the very poorest of countries that lack their own manufacturing capabilities. For this reason, the drafters of the Doha Declaration favor an interpretation of Article 6-which explicitly declines to address patent exhaustion-that would allow for parallel imports.[246] Doha agreement provides that a country can issue a compulsory license for a drug that threats a disease causing a severe health emergency in that country without royalties being paid.
As paragraph 3-4 of Doha Declaration states:
"We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices. While reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[247]

Article 27 defines the subject matter that is eligible for patent protection, and the requirements for patentability

[246] Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, 4th Sess., Doha Ministerial Conference, WT/MIN (01)/DEC/2 (Nov. 20, 2001)
[247] The Doha Declaration on The TRIPS Agreement and Public Health", WTO Website; Available at http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html

of such eligible subject matter. As a central provision on patent protection, Article 27 of TRIPS Agreement prescribes that:

"Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. Members may also exclude from patentability- diagnostic, therapeutic and surgical methods for the treatment of humans or animals."

In 1995, when India decided to join the WTO, it was brought to pressure by the western countries to bring its patent law in conformity with the standards enumerated in the TRIPS. TRIPS gave it a 10 year time frame to extend protection to pharmaceuticals.[248] Finally, the Patent (Amendment) Act, 2005 introduced patent protection for pharmaceutical products and thus a TRIPS compliant patent regime came into existence in India.

iii. Developing countries v. Developed countries

This ongoing debate and controversy about patent rights and public health embodies an underlying controversy between developed countries and developing countries regarding the nexus between IP rights protection and public health.

The pre-Uruguay Round negotiations, developing countries actively opposed the inclusion of IPRs (Intellectual Property Rights) in the new GATT Treaty on the grounds that this would lead to higher prices and be detrimental to the development of their domestic, infant; hi-tech industries. Developed countries, however, pointed out that stronger intellectual property protection would serve to stimulate research, which would, in the long run, be beneficial to both firms and consumers in LDCs. The latter argument won the day, and the WTO Agreement that came into effect in 1995 included a TRIPS (Trade Related Intellectual Property Rights) component.

This has been illustrated most dramatically in the context of the global AIDS/HIV pandemic. Prices for the anti-retroviral (ARV) HIV therapy in 2000 exceeded USD $10,000 per person per year, ensuring that treatment could not be extended to the vast majority. Generic competition led to precipitous price reductions, so that today treatment can be provided for less than USD $75 per person per year.[249] This history has contributed to the growing recognition that strong patent law applied to pharmaceuticals in developing countries undermines access

[248] Vijay Yalamanchili, *State of India's Trips compliant Patent Regime*, 26 BIOTECHNOLOGY L. REP. 211 (2007).

[249] For the most recent available worldwide prices, see World Health Organization Global Price Reporting Mechanism, at http://www.who.int/hiv/amds/gprm/en/.

to medicines and compromises the human right to health.[250]

On the other hand, the developed countries criticized that Paris Convention and PCT failed to provide pharmaceutical companies adequate patent protection in developing countries. The developed countries argued that the innovation and R&D costs a lot, whereas countries without strong patent protection free-ride on the innovation, profiting from the knowledge without contributing to the costs of its development.[251] In addition, copying a product in the countries with weak patent protection is legal, which leads to serious piracy in developing countries and the industries' significant economic losses.

The notorious case was the United State's use of section 301 of the US Trade Act of 1974, which designed to force open other country's markets by the threat of depriving trading partners' access to the U.S. market. It was described as "the principal statutory authority under which the United States may impose trade sanctions against foreign countries that maintain acts, policies and practices that violate, or deny U.S. rights or benefits under, trade agreements, or are unjustifiable, unreasonable or discriminatory and burden or restrict U.S. commerce". "Special" 301 is a part of the section 301 remedy that focus on intellectual property rights, requiring that the U.S. Trade Representative (USTR) to go through identifying countries that "deny adequate protection for intellectual property rights".[252] US trade representative to blacklist South Africa under the US Special 301 watch list, which list the countries denying adequate and effective intellectual property protection.[253]

IV. CONFLICT B/W THE TWO AND ISSUES INVOLVED

Domestic poverty levels in sub-Saharan countries alone explain the lack of access to treatment.[254] Surely poverty and under-resourced public health infrastructure are major barriers to access to costly medications. But it is also true that prices remain high and therefore out of reach, because of patent protection.[255] Even if access to affordable generics, increased, no infrastructure exists for proper disbursement and monitoring. The argument goes as follows: without substantial public health infrastructure, patients will not be able to adhere to the treatment cycle, rendering the drugs ineffective and facilitating drug-resistant viral strains.[256]

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[250] UK Commission on Intellectual Property Rights (2002), *Integrating Intellectual Property Rights and Development Policy* (hereinafter "UK CIPR"); CIPIH report.

[251] J.H. Reichman, "Intellectual Property in International trade: opportunities and risks of a GATT Connection", Vanderbilt Journal of Transnational Law, Vol.22, 1989, p.22.

[252] "Special 301" was introduced by the Omnibus Trade and Competitiveness Act of 1988, 102 Stat 1107, 23 August 1988.

[253] Patrick, Bond "Globalisation, pharmaceutical pricing, and South African health policy: Managing confrontation with US firms and politicians", International Journal of Health Services, Vol.29, Issue 4, (1999), p.765.

[254] James Thuo Gathii, *The Structural Power of Strong Pharmaceutical Patent Protection in U.S. Foreign Policy,* 7 J. GENDER RACE & JUST. 268 (2003).

[255] *Id.* at 301.

[256] Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The 'Fourth Wave' of Corporate Human Rights Scrutiny,* 25 HuM. RTS. Q. 425, 444 (2003), *available at* http://muse.jhu.edu/journals/human-rightsquarterly/v025/25.2 joseph.pdf (last visited July 30,

South Africa's experience with the AIDS crisis provides a representative example of the deadly combination of poverty and patent protection in the context of public health disasters.[257] HIV/AIDS patients in South Africa would substantially benefit from the increased affordability of generic anti-retroviral drug therapies. But the limited access largely results from patent protections held by multinational pharmaceutical corporations that maintain inflated drug prices and severely restrict the generic manufacture of anti-retrovirals.[258]

The adoption of a process patent regime allowed pharmaceutical firms in developing countries to specialize in the production of cheap, generic versions of non-patent drugs for domestic markets, as well as for export to other countries where similar patent regimes were in place. As a consequence, the price of newly patented drugs is set to rise sharply in the region, imposing a significant social and economic cost on these countries. Product patents, and the legal monopoly rights that they create, enable patent-holding pharmaceutical companies to price above marginal cost, and thereby, to recoup the large, fixed, research and development costs incurred by them in developing new drugs. By affording inventors this right, thus, product patent regimes ensure incentives for future re-search and innovation activity.

Talking of India, its patent system needs to incentivize innovations in sectors like pharmaceuticals which are developing rapidly. At the same time, given the existing level of poverty in the country, high pricing of drugs would deny millions of people access to life-saving drugs. [259] While protecting innovations like new drug delivery systems developed by domestic majors like Ranbaxy is helpful in promoting new research and development, one cannot ignore the fact that liberal interpretation of patentability criteria can have serious effects on public health. Therefore, there is a need to strike a balance between the two conflicting priorities: interest of the inventors who undertake considerable R&D investment on incremental innovation and the general interest of the public which requires restricting the scope of patentability of pharmaceutical substances.

Section 3(d)[260] can help strike this balance by protecting only those new forms of known pharmaceutical substances that represent genuine incremental innovations. However, this would hinge on the interpretation of the term "efficacy". A proper balancing of the two conflicting interests requires that standard of efficacy should be

2014).

[257] Gregor Adams et al., *Consensus Statement on Anti-retroviral Treatment for AIDS in Poor Countries,* 3 (Mar. 2001), *at* http://www.hsph.harvard.edu/hai/conferencesevents/2001/consensus_aids therapy.pdf (last visited on August 6, 2014).

[258] John A. Harrelson, *TRIPS, Pharmaceutical Patents, and the HIVIAIDS Crisis: Finding the proper balance between Intellectual Property Rights and Compassion,* 7 SPG WIDENER L. SYMP. J. 175-77 (2001).

[259] Shamnad Basheer, *The Glivec Patent Saga: A 3-D perspective on Indian Patent Policy and TRIPS Compliance*, available at http://www.atrip.org/upload/files/essays/Shamnad%20Basheer%20Glivec%20Patent%20Saga.doc.

[260] Section 3(d), Indian Patent Act, 1970.

fixed at a reasonable level. A reasonable standard of efficacy entails some level of certainty with respect to the meaning of "efficacy". Therefore, there is an immediate need to amend Sec. 3(d) to provide clearer standards of patentability for pharmaceutical innovations.

This has been reflected in the recent case of *Novartis AG vs. Union of India & Ors.*[261], where the Hon'ble Supreme Court of India has upheld the Indian patent office's rejection of the patent application. In 1998 it had submitted a product patent application for the beta crystalline form of imatinib mesylate, the active pharmaceutical ingredient of its branded drug Glivec. Novartis' patent application was rejected under section 3(d) of the Indian Patent Act allowing the generic companies to continue making available the drug at one-tenth of the price of Glivec. The company had claimed that section 3(d) is inconsistent with the TRIPS agreement, in particular, with Article 27 of that agreement, which has to do with patentable subject matter. The Novartis ruling is also important in another significant way- several other developing countries have followed India's lead and have adopted comparable strict patenting standards as a key flexibility under international law. Though India is not the only country to have such a provision, Argentina and Philippines have put in place a mechanism similar to Section 3(d), and other countries are considering such a proposition.

V. AMICABLE SOLUTIONS/ RECOMMENDATIONS

i. Amicable Solutions

Compulsory licensing[262] remains one of the most effective tools in reducing the price of medicines, and has been deployed with particular success in the context of ARVs. As TRIPS came to be implemented in developing countries, and the AIDS pandemic exploded, a growing number of developing countries have successfully used the policy tool of compulsory licensing to lower the price of AIDS (and other) medicines.[263]

A compulsory license is a government license that allows itself or a third party to practice the patent without the patentee's consent. It is an essential and important government instrument to intervene in the market and limit patent rights if a patent owner abuses the rights by, for example, refuse to make the invention available on the market, or offer it at a abnormally high price which potential buyers cannot afford. The grounds for issuing compulsory license without making prior efforts to license fall into two categories --where there is an overriding

[261] (2007) 4 MLJ 1153.
[262] Article 5A of the Paris Convention (1967).
[263] El Said, M., and Kapczynski, A., (2011), Access *to medicines: The role of intellectual property law and policy*. Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, 7-9 July 2011.

public interest to the level of "a national emergency or other circumstance of extreme urgency", [264] or where the compulsory license is used to remedy anti-competitive practices such as high prices result from domination of the market and failure to supply necessary products including drugs at affordable prices.[265]

Taking example of Brazil, its efforts and initiatives are illustrative. In 1996, it adopted a policy of universal access for ARVs by reliance on the production and importation of generic HIV treatments. When Brazil came into compliance with TRIPS, newer ARVs were patented, and paying for them imposed a substantial burden on the national health budget. In 2007, a compulsory license was issued for efavirenz, an important ARV used by most of Brazilians in the national HIV treatment programme. The license led to a substantial drop in price. The results in terms of lives saved or prolonged are striking and self-evident.

Thailand has made perhaps the most energetic use of compulsory licensing among developing countries. Between 2005 and 2006, the Thai government exercised its right to issue multiple compulsory licenses.[266] Two of the licenses covered ARVs (efavirenz, marketed as Stocrin by Merck, and lopinavir/ritonavir, marketed as Kaletra by Abbott). These licenses resulted in substantial price decreases and improvement of accessibility to drugs.

In this context, Parallel importing is an important tool enabling the access to affordable medicines because the price of pharmaceutical is very different in different countries and the parallel import can change the price discrimination in the market, so that more patients may have access to cheaper medicine. It enables the import of patented product from countries where they are sold at lower price into those countries selling the same patented product with a higher price. [267] Parallel import is allowed in the TRIPS Agreement, while the TRIPS Agreement doesn't address this issue explicitly. Article 28 of the TRIPS Agreement grants the exclusive right of import to the patent holder.

ii. Recommendation

Developed countries should commit to an indefinite pause on increased international IP standards, at least as regards medicines. The negative consequences for human health of increased international IP standards are now clear. As a result, developed countries should stop seeking to impose higher IP obligations on developing

[264] The TRIPS Agreement, Article 31(b).
[265] The TRIPS Agreement, Article 31(k).
[266] Open Society Institute (2008), *Playing by the Rules: Using Intellectual Property Law and Policy to Improve Access to Medicines,* available at http://www.soros.org/initiatives/health/focus/access/articles_publications/publications/playing_20080731/playing_20080818.pdf.
[267] G. Velasquez, P. Boulet, *Globalization and Access to Drugs. Perspectives on the WTO/TRIPS Agreement*, 1999, WHO Health Economics and Drugs, DAP Series, No.7, p.22.

countries, where those obligations could affect medicines. Such obligations are sometimes imposed in free trade agreements, and at other times via pluri-lateral initiatives that may influence the availability of medicines in developing countries.

Developing countries should:

- Adopt robust TRIPS flexibilities into national law as a matter of urgency supported by adequate and user-friendly regulations enabling its utilization easily.
- Coordinate regionally to ensure that they take advantage of emerging ideas about how to creatively implement TRIPS, and to benefit from the power of counter- harmonization.[268]
- Incorporate into their domestic law and utilize provisions on compulsory licensing and government use where cost, supply or other barriers to access to medicines exist.
- Make use of parallel importation, by adopting national exhaustion regimes.
- Retain remedial flexibility and encourage that judicial discretion regarding patent remedies be applied in the public interest and to make decision in favor of health and human rights.
- Reject TRIPS plus obligations that reduce TRIPS flexibilities that may arise as a result of bilateral and pluri lateral arrangements. Notably, since TRIPS-plus demands are ever-evolving, developing countries must remain alert and guard against any new demands made during negotiations which may impact public health.

The pharmaceutical industry can and should take the responsibility to help States to achieve the full realization of the right to health and should work in partnership with them and other actors through its core capabilities of researching, developing and producing medicines and vaccines to address essential medical needs, and helping to ensure their appropriate distribution. Important areas where the pharmaceutical industry can play an important role cover the work of promoting right to health in the following ways:

- Discover and develop new medicines for neglected diseases prevalent in developing countries;
- Help states to build health care capacity, strengthen health systems and improve health education and awareness;
- In terms of patent issues, the company should respect the right of countries provided in TRIPS Agreement;[269]

[268] Kapczynski, A (2009), *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 Cal. L. Rev.

[269] "*Human Rights Guidelines for Pharmaceutical Companies in relation to Access to medicines*", Preamble, , Published in the report to the General Assembly of the UN Special Rapporteur on the right to the highest attainable standard of health, UN document: A/63/263, dated 11 August 2008, para.26-27.

National laws may also permit parallel importation of patented product to purchase or import pharmaceutical products at a lower price if such products are sold at a higher price in their countries. India should engage in international negotiations to ensure the affordability of medical drugs, it must at the same time take steps to strengthen its domestic health delivery system.

VI. CONCLUSION

Without doubt, considerations of availability and access to medical facilities are the paramount challenge in our country. Allowing patent protection for incremental innovation may also be beneficial in dealing with public health concerns.

Firstly, by increasing the number of different drugs in a specific class, it can increase the price competition among those drugs. This would result in decline of drug prices thereby making them accessible to ordinary people. Secondly, it can reduce the cost of healthcare by improving the quality and selection of drugs available to the patients. Further, the presence of multiple drugs within the same class ensures that there are adequate back-ups in case a drug goes out of market. Thirdly, the revenue from incremental innovation can be used to fund development of research intensive "blockbuster drugs" which make new medicines available to the public in the long run. Fourthly, new formulations and drug delivery systems can be developed which are specifically suited to Indian climate.

For instance, use of microspheres for the controlled release of vaccines which make them resistant to extreme heat conditions could greatly help people living in remote areas of India where there is no refrigeration. The importance of these drugs can be gauged from the fact that 60% of the essential medicines on the World Trade Organization's Essential Drug list represent incremental innovation over existing drugs. Thus, it is clear that equating all kinds of incremental innovation with ever-greening, would fail to protect genuine innovations that could greatly benefit millions of people.

The Doha Declaration recognizes the gravity of public health problems affecting many developing countries and least-developed countries. It marks a turning point and a significant milestone on the agenda of providing access to medicine the duty to provide access to essential medicines is clearly originated from the expanded notions of obligations deriving from the right to life. The public health crisis in the world and the very fact of access to medicines needed special attention in intellectual property rights legislation and implementation, and the medicines products need to be treated different from other products. The social goal and measures to protect public interest should be included in the national legislation encompassing public health issues, especially the

access to essential medicines.

Historically international patent norms facilitated the growth of pharmaceutical industries in many countries which lack the capacity to invent and produce drugs, since flexibilities available in the Paris Convention, which means there was no mandate for member states to provide product patent, enable these countries to build their domestic industries and to provide access to medicines at affordable cost. The international norms set up in the TRIPS Agreement are still not uniformed since the TRIPS Agreement is not uniform law. In addition, the problem requires a commitment from all members of international community, including not only the government in developed countries, the international organization, but also the research groups and the media, to provide funding and strategic planning to improve the insufficient medical infrastructure in developing world. Thus, for 'global' diseases, product patents will imply higher prices for new drugs in developing countries, with little or no offsetting dynamic gain, in the form of higher rates of medical research and innovation. In the case of 'poor country' diseases such as malaria id TB, on the other hand, stronger intellectual property protection, while necessary, may not, by itself, be sufficient to induce new, improved and affordable medical treatments for these ailment.