UNIVERSITY OF ZAMBIA
SCHOOL OF LAW

I recommend that the obligatory essay prepared under my supervision

BY

PRECIOUS GOMA.

Entitled: **PATENTS, THE TRIPS AGREEMENT AND ACCESS TO PHARMACEUTICAL DRUGS AND HEALTH CARE IN DEVELOPING COUNTRIES.**

Be accepted for examination. I have checked it carefully and I am satisfied that it fulfills the requirements relating to format as laid down in the regulations governing Obligatory essays.

MR.G.M KANJA---------- 21/11/03

(Supervisor) Date

OBLIGATORY ESSAY

ON

PATENTS, THE TRIPS AGREEMENT AND ACCESS TO PHARMACEUTICAL DRUGS AND HEALTH CARE IN DEVELOPING COUNTRIES.

BY

PRECIOUS GOMA

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DEDICATION

TO MY FAMILY

FOR BEING THE MOST CONSTANT PEOPLE IN MY LIFE AND
FOR GIVING ME UNCONDITIONAL LOVE.
YOU GUYS ARE SIMPLY THE BEST.
THANKYOU AND I LOVE YOU.

ACKNOWLEDGEMENTS

This has definitely been a journey and it is not over, its just begun...so for that and all its lessons, I first and most importantly thank the most high for being my footprints and carrying me through even when I did not know where to start or what to do. Thank you for all your blessings.

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My family, thanks for the wonderful things you have done for me and thanks for leading me in the right direction. I LOVE YOU!!

Grace, am eternally grateful for your inspiration. Most people never know unconditional friendship but you have given that to me.

Namangolwa, thanks for being my partner in "crime".

To all my friends, you know who you are, thank you for all your love and support; it really means a lot to me. I have learned many things and shared learning experiences that make me a better person.

To all those left out, Please include your names here.....

I care!!

CHAPTER ONE

INTRODUCTION

The mind of human being harbors innovative ideas which on certain circumstances are not common in every human being and may be attributed to the individual so exercising his mind. Thus these ideas are seen to belong to an individual just like any other form of property. Therefore like most property needs to be protected by the owner, this kind of property also needs to be protected by the owner, hence it being classified as Intellectual Property especially that it is a product of an individual's intellect activity.

Intellectual property relates to human activity precipitated by individual skill and Labor either expressed for its own sake or upon some material either in an art form or a functional thing such as a newly invented mechanical device.

According to Merville, intellectual property is a form of property concerned with newly created things that necessarily are unique. However, far from being against the public interest, the creation of these new and useful or artistic things or of new processes is of the essence of life itself, which constantly renews itself in nature, producing in a way, new forms of life which represent an advance on what has been in the past.[1]

[1] Merville L.W Forms and Agreements on Intellectual Property and International Licensing 3rd ed Sweet & Maxwell, London 1979 pp5

Intellectual property denotes the legal rights, which emanates from intellectual activity in industry, scientific, literary and artistic fields. In other words intellectual property is the generic term used to designate the subjective rights that various legal orders grant to the creators of immaterial assets of intellectual origin

Those immaterial assets may be of two kinds, namely either literary or artistic creations or distinctive signs and inventions. Intellectual property therefore establishes the protection of ideas and designs in Art and Technology, in Industry and in Trade.

Industrial property relates to objects that can be used in Technology and Industry. Industrial creations that contribute to an environment of intellectual or aesthetic enjoyment are characterized by their usefulness and serve a particular economic purpose.

It is therefore important to focus on patents as a means of protection for inventions. An invention may be defined as an idea that purports to solve a technical problem. [3]This accounts for the social function that has been attributed to inventions as factors promoting development and as essential components of an economic organization. Patents, for their part, are the titles conferred by the state that attest the grant of exclusive rights to the inventor for the exploitation of his invention.

The patent is the reward or inducement that the state grants the inventor for his contribution to the solution of a problem in technology or industry. It is an arrangement between the state and the inventor whereby the latter decides to disclose and publicize his inventor to society, in exchange for which the state assures him that no one thereafter will be able to copy it without his consent.[4]

Even though, there is no world consensus on whether or not patent rights should be called a monopoly with some saying that they should and other emphatically contradicting them, one thing that is acknowledged in the effects, in economic terms, that patent provisions have in a particular economic environment. Perhaps the most widely discussed effect is the higher prices charged for patented products.

It is for these reasons that the patent protection of innovations concerned with chemical, pharmaceutical and food products has been one of the most controversial subjects in industrial property.

The subject of the patent protection of pharmaceutical compositions is vitally important. Equitable and appropriate health care is universally considered as a basic human right, and pharmaceuticals are an integral part of the Modern Health Care System. Essential Medicines save human lives and reduce suffering.

Access to essential drugs is, therefore a critical part of this fundamental human right. Essential drugs are not ordinary commodities. Every effort should be aimed at improving

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[3] Intellectual Property and Human Rights WIPO Publication, 9 November, 1998 pp 68
[4] ibid pp68

access to essential medicines for those who need them, with the aiment globalization of trade; access to drugs becomes a critical issue which needs particular attention.

It is sad to note that diseases such as HIV/AIDS, Tuberculosis (TB) and Malaria have being responsible for millions of deaths worldwide.

Developing countries bear a disapropriate burden of death and illness caused by such diseases. For instance, in Sub-Saharan Africa, where it is estimated to have already caused 2.4 million deaths; a further 25.3 million people in the region are HIV positive.[5]

Such diseases may be treated with modern drugs. For instance, people with TB can be readily treated with a combination of anti- bacterial drugs; although treatment courses are long (even current short treatment courses take 6-8months). While there is no cure for AIDS, modern Anti-HIV drugs can delay the onset of the disease and prevent infections such as TB, the leading infectious killer of people with HIV/AIDS.

In developed countries, the preferred treatment is a triple combination therapy which is taken for a lifetime and can involve complex drug regimes.

It is from this background that a debate over patents, pharmaceuticals (drugs), and fair and affordable access to health care for all is increasingly in the news today.

Access to Pharmaceuticals in developing countries has attracted much recent attention. This is because the developing countries claim that they have been disadvantaged in

[5] Report on Access to Medicines in the Developing World, 18- 20July,2002, p1 ; www.parlament.uk/post/home.htm

accessing drugs and health care because of regulations and rules that are being made in developed countries. The following are some of the arguments that have been put forward regarding patents and pharmaceutical drugs and access to health care.

On one hand there are the pharmaceutical patent's detractors, who point mainly to the increase in the price of drugs and the consequent restriction of access to them for certain factors of population. On the other, it is said the grant of protection will bring about the removal of a local industry that owes its very existence to the possibility of reproducing and marketing the innovations of the transnational pharmaceutical industry, causing an adverse balance of payments effect attributable to the encouragement of drug imports.

The defenders of drug patenting, for their part, base their reasoning on their part on the general assumption that intellectual property protection is an inducement to scientific and technological development. The incentives that will make members of a community decide to invest in research and development of new knowledge are constituted in modern world by patent system has shown itself to be the only efficient means of promoting research and development for the acquisition of new knowledge which eventually brings about an improvement in social and economic well being

This paper therefore aims to take a broad sweeping look at the patenting of pharmaceuticals and the controversy that has arisen between developing and developed countries, to attain this, the paper discusses some issues relevant to the discussion on the

TRIPS Agreement, patents and access to affordable medicines and health care. It is organised in four main chapters.

CHAPTER TWO:

This chapter defines what patents are in detail and what effect patents have on the price of pharmaceutical drugs. This chapter will also include the various theories that try and justify why patents are necessary in this world. In addition the various arguments made by developing countries and developed countries over patents and pharmaceutical drugs will be outlined.

CHAPTER THREE:

This chapter looks at what other factors affect high prices of drugs in developing countries and the lack of access to health care. The chapter will look at socio-economic factors that contribute to the lack of access to drugs and health care of which they have been divided into physical barriers, informational barriers and financial barriers.

This chapter will also look at the TRIPS Agreement and what effect it has especially on developing countries. It will provide arguments from both the proponents and opponents of the TRIPS Agreement. In addition, it looks at some of the limitations on exclusive property rights of patent holders, specifically provided for within the TRIPS Agreement. These include compulsory licences and parallel imports, which can be used to curb anti-competition practices and abuses of intellectual property rights.

Compulsory licences and parallel imports are important tools in the consent of protection public health and promoting access to affordable medicines.

However, narrow interpretations of the TRIPS provisions relating to compulsory licences and parallel imports put forward by some developed country members have led many developing country members to feel restricted in their ability to employ these measures at the national level.

There have also been cases of pressures applied on developing countries in relation to their use of compulsory licences and parallel imports. The cases of the Brazil- US dispute in the WTO, and pharmaceutical companies' legal challenge of the South African government are just two obvious examples of such pressures.

CHAPTER FOUR:

A conclusion will be made and proposals will be put forward on for some of the possible actions that can be made so that developing countries are able to enjoy the same benefits that developed countries have so that they can access drugs/ health care without any difficulties regards of other socio-economic factors.

CHAPTER TWO

Although the term patent was briefly defined in chapter one, it is prudent that the term be properly defined in detail since the paper is centered on patents.

Different scholars have defined patents in different ways. According to Jeremy Phillips and Alison Firth, the word patent is synonymous with monopoly right in an invention.[13]

A WIPO publication defines a patent as a document granted upon application by government office (or a regional office) acting for several countries, which describes an invention and creates a legal situation in which the patented invention can normally be exploited (that is manufactured, used, sold or imported) with authorization of the owner of patent.[14]

Therefore a patent can be said to be a property right granted by government to an inventor to exclude others from making, using or selling an invention fulfilling certain requirements most notably that performs a "useful function".

As can be noted from the foregoing, patents are certainly conjoined to invention. it is therefore necessary to also define an invention.

The WIPO publication defines an invention as a solution to a specific problem in the field of technology. [15]

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[13] Phillips J and Firth: Introduction to Intellectual Property Law (1990) p76
[14] Intellectual Property Reading Material (World Intellectual Property Organisation) Geneva, March 1998
[15] ibid p76

Although it is merely persuasive, the American case of **Hochkiss V Greenwood** [16]laid down the principle that only inventions were patentable and that in order to constitute an invention, a new technology must transcend the everyday efforts of the skilled mechanic.

Before proceeding further into discussions and arguments relating to the patent system, one has to be clear as to what the patent system is. This was clearly explained in a UN Report that states that the patent system is in fact a system of accumulated practices rather than a set of fixed rules. It is practice of international relations in the matter of legal protection of inventions resulting from and governed by both rational legislation defining the treatment to be granted to foreigners and international treaties concerning such treatment.

The patent system has both individual and public justifications. It is however of crucial importance to note that the patent system does not protect each inventor who conceives an invention but rather the first to apply for a patent is given priority.

Most debates have concluded that patent systems tend to concentrate upon their role as a public instrument of economic policy. This view pretends that patents are intended to encourage the making of inventions and subsequent innovative work that will put the invention to practical use and they are expected to procure information about an invention for the rest of the industry and the public generally which might otherwise be withheld for a period that could be crucial.

[16] US Supreme Court 1851 52 US11(How) p248

The economic rationale of patents rests on the proposition that knowledge is an economic commodity over which patent system establishes property rights. The frequency of such notions embodies the orthodox view that "the prospect of obtaining a patent monopoly provides an incentive to invest in research to make new inventions and that the patent system promotes disclosure of one's inventions and thereby enlarges the public storehouse of knowledge".[17]

There has always been a set of thorny issues about the patent system. For example as earlier alluded to, patent holders may capitalize an invention by suppressing their development, even though these inventions would benefit the public, furthermore, the patent system provides incentives to focus on what is patentable and on developing certain superfluous innovations simply to avoid what is covered by a patent.

There are various theories that have been developed to try and explain and justify the patent system. Therefore before discussing the debate that exists between developing countries and developed countries in relation to patenting of pharmaceutical drugs and access to health, it is imperative to discuss the various theories that exist on the patent system. These are:

[17] Kewanee Oil Co V Biscron; US 470-80(1974)

INCENTIVE TO INVENT THEORY

According to this view, without legal protection of patents the quality of innovation would be less than that deemed socially optimum. If it is found on the premises that too few inventions will be made in the absence of patents protection because competitors of the original inventor who have not shared in the cost of the invention easily appropriate inventions once made.[18]

As a consequence, the inventor does not enjoy the benefits that are deservedly his for the costs incurred by the initial investment and development expenditure. This is because the patentee, like other intellectual property right holders can derive no financial benefit except by exploiting it commercially.

The bastion for the enjoyment of the benefits emanating from the grant of patent lies in the fact that with the assurance that his invention will be protected from competitors, the inventor is motivated to invent. In this case, an inventor does not run the risk of his invention being indiscriminately hijacked by competitors.

The most plausible exposition of this theory is that patents serve to bring the private benefit of invention in line with their social value by alluring inventors to use their monopoly position to extract a price that more closely approaches the value that users receive from inventions.[19]

[18] Aldelman, etal, Patent Law p34

In this regard, there is an equitable distribution of resources between society and the inventor.

CRITICISMS OF THEORY

This theory has not gone unchallenged. It has been argued that once a monopoly in an invention is granted through a patent, it restricts their use thereby reducing the social benefits of patented inventions.

The question for determination according to Aldeman is whether it is necessary to endure the output restricting effects of a patent monopoly in order to stimulate invention. This is especially in issue where alternative views for stimulating inventions at less social cost are available, such as where government or alternative systems award prizes and business to inventors in lieu of a patent.

It has been argued that patent protection is not the magic formula to volume and nature of inventions, and the presence or absence of a patent law is not the principal determinant of a country's technological progress.[20]

It is contended that alternative methods of inducing inventions other than the patent system include, instinct of contrivance or workmanship, reputation, the desire for fame and the sense of altruism as well as intellectual inquiry and curiosity which also lead to discoveries.[21]

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[19] ibid p35

In the same vain, Grudman stated, "what is needed is a stress on technical and scientific training and not on the protection of invention.[22]

Another opposing view to the incentive to invent theory of patent is that inventions arise inevitably with or without government incentive when the state of basic knowledge and other social conditions become favorable.

The contention is that patent protection is not an incentive to invent since according to this view, inventions are a product of necessity.

It has also been argued that competition between rivals in a market place in relation to technological progress may induce inventiveness without there being further incentives.

It is provided that if the problem of appropriatibity is ignored, firms in a competitive market will have greater incentive to invent than would a monopolist because the competitive firms' incentive is equal to the full cost reduction on the competitive output, while the monopolist's incentive is diminished by the set-off of pre-invention monopoly benefits.[23]

A further objection to this is that patents may distort economic activity in ways that undermine efficiency, whereby, inventors may spend too much money trying to develop

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[20] Ojok Bwangamoyi, Patent and Technology Transfer thesis(1976) p 58
[21] Voughman F.C , Patent system: New York, (1925) p16
[22] Grundman, H. The Economic Agreement for Patents and their Valicity for Developing Countries(1970), Indian Economic Journal, Vol XVIII No. 2 p 198
[23] Aldeman etal p36

inventions quickly when the same result could be achieved at less social cost through a less accelerated research effort.[24]

This emanates from the principle patent systems do not protect each inventor who conceives an invention but the first to apply for a patent.

The last critique of the theory advanced focus on persons other than the patentee and contends that the existence of a patent may undermine the incentive of these other persons to make improvements in patented technologies where they are forced to waste time and effort finding duplicate solutions to technological problems in order to avoid infringement.

REBUTTAL TO THE CRITICISMS

Finding duplicative solutions to technical problem in order to avoid infringement is not wasteful if it leads to the development of superior products or processes. This criticism does not hold in that according to the case of **Yarway Corp v Control** [25]inventing around patents requires further research and stimulates progress.

One is therefore compelled to contend, like Professor Clark that a patent system is a stimulant of invention and development.

[24] ibid p 37
[25] OP CIT, p 37

Patent systems provide a framework in which persons can exploit their inventions with a clear conscious that their findings will be protected. Without such a system, there would be no guarantee for the protection of the intellectual property right even where the motive for invention and innovation advanced are present.

Patents by securing protection against indiscriminate and unauthorized exploitation through a monopoly for a fixed period, for an invention, which more often than not involve upfront costs, act as one of the incentives to invent. Owing to the increasingly systematic organization of research and development and the extensive process of education that precedes it. This makes it harder to maintain the view that inventions are there to be discovered and industries that have progressed will evitably make them and so artificial aids are unnecessary.

The incentive theory is focused on enhancing the economic position of the inventor.

INCENTIVES TO DISCLOSE THEORY

A patent gives the inventor an exclusive right to exploit his invention on condition that he discloses the invention immediately and fully to the public. The basic premises for this theory were typified in the case of **Universal Oil Productions Co v Globe Oil and Ref Co**[26]: that in the absence of patent protection inventors would keep inventions a secret in order to prevent competitors from exploiting them, thereby depriving the public of the benefit of new knowledge.

[26] 322, US 471,484 (1944)

This tenet though sound, it has not gone unchallenged. The rationale for the challenge is that if long-term secrecy is feasible, patent protection for a limited period might not be an attractive alternative.

Furthermore, Melmam Seymour puts up a compelling argument that patent systems encourage secrecy and incomplete disclosure of technological information. He asserts that most applications are desired to disclose as little information as possible which is not enough to be useful to the public.[27]

JUSTIFICATION OF THE THEORY

The positive effect of this theory is that patents facilitate disclosure by protecting rights in inventions whereby these rights are not affected by the disclosure that is, the patentee does not lose their exclusive right.

The purpose of disclosure is to inform the public inventions or processes such that it warns researches not to infringe the patentee's right or waste resources on an article which is already protected by the patent.

This is achieved through protection of patentee's rights that encourage full and immediate knowledge that can be used directly (under a licence) or as a foundation for further research.

[27] Seymour, Melman, The Impact of Patent System on Research, US Senate Committee on the Judicial sub-committee on Patents, Trademarks and Copyright, 85th congress, and Session Study No.11 p34-35

INCENTIVE TO INNOVATE

The premise on which this theory rests is that a patent monopoly is necessary to induce firms to invest in innovations, that is, putting existing inventions to practical use.

This is where a firm undertakes to make further improvements on invention to suit consumer demands and needs. With the patent protections offering monopoly profits the firm will be willing to undertake investments. This theory gives existing patents a continuous role in preserving the incentive of patent holders to invest in development during the term of the patent.

THE PROSPECT THEORY

The economic aspect of this theory is anchored on the belief that the patent system promotes efficiency in the allocation of resources to the development of existing inventions by awarding exclusive publicly recorded ownership in new technological prospects shortly after their discovery. This efficiency is promoted through private property rights created by patents and by putting the patentee in apposition to co-ordinate or control subsequent research and development efforts.

DEVELOPING COUNTRIES' VIEWS ON PATENTS AND ACCESS TO DRUGS AND HEALTH CARE.

The impact of intellectual property protection is often a difficult concept for policy-markers in many developing countries to implement. Existing policies in these countries allows or even encourage, copying of pharmaceuticals developed by multinational firms. Some countries have enacted intellectual property protection laws but the enforcement

mechanisms are still rudimentary. Governments in developing countries are apt to be dissuaded from implementing and enforcing pharmaceutical patent due to:[21]

a. concern over destroying the local pharmaceutical industry, which relies on producing copies of innovators' products.

b. A belief that intellectual property protection will result in increased drug prices.

The focus of this debate between developing countries and developed countries is the second issue, which states that intellectual property protection will result in increased drug prices. One commentator asserted that "patent rights typically cause the price of pharmaceuticals to triple of which in turn becomes a nightmare for mast people in developing countries to access the drugs and in general access health care.[22]

However developed countries have the following views on patents and pharmaceutical drugs and access to health.

To begin with, for developed and some newly industrialized countries, the question of access to health care is related to whether the health care system in a country is universal.

Universality is the principle that welfare services should be available to all by right, according to needed, and not restricted by individual ability to pay. This principle is one of the five essential elements of the National Economic Research Associates (NERA)

[21] Richard P. Rozek, The Trips Agreement and Access to Health Care: The Journal of World Intellectual Property(1999) p 813
[22] ibid p 813

prototype for a health care system. It is also consistent with the world health organization's (WH0) goal of "Health for All"[23]

The following are the views of developed countries:

Patents perform an essential role in stimulating the development of essential drugs, including anti-Aids drugs, by offering incentives for investing inexpensive and long-term research and development of new drugs.[24] Without patents existing anti-Aids drugs would not have been produced. Without the patents, new and better drugs that are needed to overcome the increasing resistance of the AIDS virus would not be developed.

At the same time, the patent system also contributes to society as a whole by accumulating and making available human knowledge to fight against the AIDS crisis. The patent system requires significant disclosure of the information leading to the invention of new drugs. Without the patent system, such key technical information would remain unavailable or even a secret.

Many health care researches and drug manufacturers, who depend heavily on such information for their work, would have to reinvent the wheel. Given the severity of the crisis, no one can afford to spare such resources and time. Medical researches rely heavily on previous work in developing better drugs to treat diseases.[25]

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[23] U.K Hoffmeyer and T.R McCarthy, Financing Health Care(1994) Vol.1 p54

[24] www.Wipo.Org/ healthcare htm

[25] Richard P. Rozek: The Trips Agreement and Access to Health Care: The Journal of World Intellectual Property(1999) p814

A robust patent system providing for adequate patent protection is indispensable incentive to creative work and is crucial to establishing and maintaining an attractive commercial environment. An adequate patent system, effectively administered ultimately stimulates domestic innovation, patent system fosters new industries and creates jobs, and it helps attract foreign investment as well.

An adequate patent system can also help countries develop and strengthen their own research infrastructures and capacities. It also provides a proper balance between public interest of the inventor.

A patent is not necessarily the determining factor in the price of drugs. The price of drugs depends on a wide variety of factors, including the cost of research and development, production, distribution and marketing. Still, the actual market price is often marginal to the problem of access to drugs. Even reducing the price of HIV/AIDS treatments to cover the costs of basic manufacturing and distribution alone as was recently done in a number of countries hardest hit by the crisis still keeps the cost of annual treatments at between $350 and $600 per year[26]. These prices, which are similar to the cost of generic versions of these, same drugs and make no provision for recouping the cost of research and development are still above the annual per capita incomes of some countries with high levels of HIV/AIDS.

Patents are only one of many factors that influence access to health care and drugs. Many governmental and non-governmental organization involved in the fight against

HIV/AIDS cite socio-economic factors as barriers to access to drugs; indeed, the United Nations Declaration of Commitment on HIV/AIDS notes the importance of strengthening national health and social infrastructure as a key means to prevent the spread of the epidemic.[27]

Many drugs do not even fall under patent protection in some countries. In many African countries where the AIDS crisis is most acute. For example, a variety of Protease inhibitors- a crucial treatment that helps stop the spread of HIV virus from cell to cell within a patient- do not enjoy patent protection, still, they are prohibitively expensive for most patients.

In fact, some 95% of the pharmaceutical products on the world Health Organization's essential drug list- which includes many drugs used to treat various aspects and side effects of HIV/AIDS are now " off patent" meaning that these products are no longer protected by patents, which generally last for 20 years counted form the time that an application is filed. Because of the time taken to process patent application, the actual period of protection is often several years shorter. Yet many of these "off-patent" drugs remain unavailable or unaffordable to most of those suffering from the virus why? The reasons are not to be found in the patent system. The reasons are due to socio-economic factors.

In many cases, patents are but one of the many other factors that influence the accessibility of health care and drugs in developing countries.

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[26] The World Bank,(1998) World Development Indicators, p40
[27] ibid p40

CHAPTER THREE

About 14 million people die each year from infectious diseases, many of which preventable or treatable, such as acute respiratory infections, diarrhea diseases, malaria and tuberculosis[28]. Up to 45% of deaths in Africa and Southeast Asia are thought to be due to an infectious disease.[29] The death toll is unacceptability high in developing countries, even as health indicators show improvements in many countries of the world. This is mainly because of lack of accessibility to medicines by developing countries. The lack of accessibility for the population (respectively, for certain population segments) in developing countries that are stricken by health crisis must be seen as an extremely complex combination of social and economic factors. These factors can be divided into three main categories:

1. PHYSICAL BARRIERS:

Physical barriers to health care exist in developing countries in the form of a lack of access to health care facilities or personnel. The primary physical problem is providing health care to people who live in remote, rural areas. The elderly and the mentally or physically handicapped may also have difficulty in accessing health care, even within an urban environment, if there is an inadequate support system.[30]

There are inadequate infrastructures in place in developing countries to meet the level of health care demand:

-the public and private resources available to construct health care facilities are insufficient to meet the needs of the growing population;

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[28] TRIPS and the Primary of Public Health p2 .http//www.iips.org/ DO1
[29] The World Bank,2001 World Development Indicators, p40
[30] The Journal of World Intellectual Property Vol.2 No.5 (2000) p813

-an expanding health care system may be unable to meet the needs of a larger population; for example, South Korea experienced access problems when it expanded coverage; and

-on a more basic level, roads, transportation and education in these developing countries inhibit access to health care.

2. INFORMATIONAL BARRIERS: Imperfect information may affect access to health care:

-people may fail to access health care due to a lack of information about the need to treat diseases such as tuberculosis, malaria, hepatitis or hypertension;[31] and

-patients may not know how or where to access health care, particularly in the cases of minorities or immigrants.

-Imperfect information may affect proper and economical use of pharmaceuticals:

-Self-medication by poorly informed patients may lead to ineffective drug utilization;

-Poorly informed physicians in developing countries often treat illness such as diarrhea inappropriately with antibiotics[32];

-Physicians may not always be aware of the most cost-effective therapy. In addition, physician preferences for dosage form may influence the choice of drugs prescribed;

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[31] S.Asch, L. Gelberg, and B.Leake, Access to Health Services and Delay in Obtaining Care for Tuberculosis, Division of Internal Medicine and Health Services Research, UCLA, Los Angeles, California,1994.

[32] For Example, one study found that in Nigeria 60 Percent of Children with diarrhea inappropriately received antibiotics: See A. Isenalumbe and O. Osawaru, Polypharmacy: Its cost Burden and Barrier to Medical Care in Drug Oriented Health System, International Journal of Health Service, 1998p335-42

3. FINANCIAL BARRIERS:

Access may be restricted due to financial barriers:

-some countries may not have resources available to provide even rudimentary health care. For example, annual spending on health by ministers of health in some African countries is under US$ 4.00 per capita;

-health insurance may not be available in a region or country, and it may be costly for an individual to purchase private health insurance even where it is available

-some patients are not able to pay the full cost for health care, and there may be relatively high co-payments for health care services, which some patients in developing countries can not pay; and

-Unofficial or side payments to health care providers are prevalent in many developing countries. Having to make such payments to access health care may discourage people from seeking care.

The government may not assign priority or have sufficient resources available to build the infrastructure necessary to improve health status and provide access to health care. Other factors to consider are education, a clean or safe environment, and programme to reduce poverty. There are stronger correlations between health care expenditure per capita and life expectancy[33]. Investments in preventing health problems have a more

[33] International Healthcare News, November 2000, p11

significant impact on a country's health status than investments in treating health problems once they arise.

Having looked at the factors that hinder or rather restrict access to health care and access to drugs, it can be concluded that there are various aspects that contribute to people not accessing health care, The absence of a functioning national health system, insufficient or lacking infrastructure, for example (Hospitals, streets, sanitation, electricity), lack of education and prevention, a shortage of medical personnel and health care. A research conducted by Dr. Attaran and Mr Gillespie White [34]argued that patents do not prevent patients from developing countries from receiving treatment. For example in their research, it shows that most AIDS drugs are patented in most African countries and that only a few AIDS drugs are patented in most African Countries.

They argue that patents are not major barriers to access to drugs in Africa and that the relevant authorities should work to alleviate poverty rather than attack intellectual property rights. They conclude that the central role patent protection plays is solving health problems. Patent protection offers the producers of medicines the necessary protection and incentive to invest in the corresponding research and development needed for new, more effective medicines. Without this incentive, the hundreds of millions of dollars spent developing a product today would not be worth the investment. Medicines must first be developed before they can be accessed. Import duty and other fees for anti-retroviral AIDS medications can make up 5-30 % of the cost in African countries and up

[34] Attaran A, Gillespie-WhiteL. Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa? JAMA. 2001; 286:1886-1892

to 35 % in India[35]. In that sense, patent protection plays an especially important role in the fight against diseases such as AIDS where a cure has yet to be found and, for that reason, great effort is still necessary. Thus, it would be false to reduce the entire problem of access to medicines to patent protection and the TRIPS Agreement, and would detract from a constructive and long-term solution.

The insufficient access to medicines in certain developing countries is due to complex and multifaceted problems that the community of countries affected must address with concentrated action and financial support. Patent protection is not the problem, rather a part of the solution because it is an incentive for the research and development of new, more effective medicines.

Therefore one would conclude that patent protection is not the only problem that causes individuals who live mostly in developing countries not to access health care and drugs but by several inter-linked factors.

TRIPS AGREEMENT, PATENTS AND ACCESS TO DRUGS AND HEALTH CARE.

Even though the debate over patents, Pharmaceutical drugs and fair health care is mostly between developed countries and developing countries, as a specialized agency of the United Nations mandated with managing Intellectual Property issues and standards on an international level, the World Intellectual Property Organization (WIPO) participates in that debate between public health concerns and interest of the patent owner and this balance exists in the patent system.

[35] Felix Addor: Access to Medicines in Developing Countries Patent Protection(2002)p3

It is important to note that a number of member states of the World Trade Organization(WTO agree that the Agreement on Trade Related Aspects of Intellectual Property rights which is administered by WTO also provides the necessary flexibility to achieve that balance and accommodate the needs of countries that are deeply affected by dreaded diseases such as HIV/AIDS. However this view is not shared by the developing countries.

The TRIPS Agreement and patents on drugs

Patent rights are being extended around the world through the provisions of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Proponents of the TRIPS Agreement argue that patents and other intellectual property rights are essential for promoting research and development (R&D), as well as, stimulating innovation. Yet, there has been scant evidence that the introduction of TRIPS-compliant standards of IPR protection has promoted transfer of technology, R&D, or innovation in developing countries. [36]

The intensive use of the patent system by corporations is intended to protect their competitive edge and markets, by keeping out their competitors. This strategic use of the patent system has the effect of stifling R&D, preventing innovation and restricting information flows in the developing countries. Patent protection is sought to be justified on grounds that the negative effect of monopoly rights will be outweighed by the incentive for creative activity, innovation and research and development[37]. This trade-off is beginning to be questioned because the price and competition costs of strict patent

[36] TRIPS, Patents and Access to Medicines: Proposals for Clarification and Reform, Third World Network Briefing Paper, p5.www.twinside.org.sg/title./drugs
[37] ibid p 6

protection have been very high. In the health and pharmaceuticals sector, this trade-off often comes with life or death consequences.

Opponents of the implementation of the TRIPS Agreement will give rise to factors that can put access to medicines out of reach for millions of people in the developing world. The TRIPS Agreement obliges WTO Members to adopt and enforce high standards of intellectual property rights protection, which were derived from the standards used in developed countries[38]. Prior to the Uruguay Round, some 50 countries did not grant patent protection for pharmaceutical products. This number included certain developed countries such as Portugal and Spain, and many developing countries such as Brazil, India, Mexico and Egypt. Many developing countries regarded the absence of protection necessary to promote access to drugs at competitive prices.

Conforming to TRIPS - by recognizing and strengthening protection of intellectual property rights over pharmaceutical products and processes - might cause problems for developing countries. Implementation of the TRIPS Agreement may lead to high drug prices, low access to medicines and a weakening of pharmaceutical industries in the developing countries.

It is feared that patent protection for pharmaceutical products and processes will have the effect of reducing or eliminating competition from generic production of medicines.

There are about 10 industrialized countries with the pharmaceutical industry and research base, capable of developing new chemical entities or new medicines. The multinational drug companies in these countries own most of the pharmaceutical technologies and

[38] G. Boulet: Globalization and access to drugs, Perspectives on the WTO/ TRIPS Agreement, (2000)p8

products through patents.[39] The minimum term of 20-year patent protection required by TRIPS effectively allows a pharmaceutical company a monopoly over the production, marketing and pricing of patent protected medicines. It will be able to keep the price of the drug high during the protection period, free from competition. By virtue of TRIPS protection, no generic equivalent can come into the market until expiry of the 20 years, denying patients cheaper alternatives.

Domestic manufacturing of pharmaceutical products in developing countries will come to a standstill. Developing countries are able to produce new medicines by a process of reverse engineering; that is, researchers in developing countries may develop a new process different from the process invented (and protected by patent) to manufacture the new medicine or chemical entity. Reverse engineering is possible only in countries where the patent law protects processes but not products.

The TRIPS Agreement extends the scope of patent protection to both products and processes. It would therefore be possible to apply for patent rights over products for 20 years, and thereafter, further periods of 20 years each could be applied for products covered by patented processes. Some experts also caution that the 20-year protection can also be abused to extend the monopoly through process patents as well as patents on usage form, dosage form and combination form. In the US for example, patents have been taken on new combinations of drugs even when the product patent on the basic drug - the active ingredient - has long expired. Monopoly protection would be extended through minor changes to the existing medicines where the product patents have expired.

[39] K. Balasubraaamaniam, Implications of the Trips Agreement for Pharmaceuticals: Consumers Perspectives, Consumers' international (2001)p65

Developing country pharmaceutical producers will find themselves pushed out of the market, having to compete with the large Multi National Corporations MNCs. For the smaller producers in the developing world, which specialise and depend on manufacturing cheaper generic alternatives, this would no longer be possible - at least, until the expiry of the 20-year period. In some developing countries, domestic production capacity may never be developed.

TRIPS proponents and the pharmaceutical industry argue that patent protection is essential to ensure R&D for new drugs, but there has been little evidence to demonstrate that the patent system will ensure investment in R&D for diseases of the poor. Of the 1,223 new chemical entities developed in the 21-year period between 1975-1996, only 11 were for the treatment of tropical diseases.[40] The last major new tuberculosis drug was developed 30 years ago, but tuberculosis remains a major cause of death in many developing countries. Furthermore, there is concern that R&D in the pharmaceutical sector is concentrated on products intended for the lucrative developed country markets. Hence, the increased investments for R&D on drugs for impotence, obesity and baldness, instead of R&D on new and more effective drugs for life-threatening or poverty-related "Third World diseases", include malaria and tuberculosis.

Civil society groups and NGOs have called for amendment of the TRIPS Agreement so as to ensure a proper balance between the protection of private rights and corporate interests, and the promotion of public interests in socio-economic, technological development of member countries, including that of public health. Public criticism is mounting, as are questions about the legitimacy of patents on life saving drugs and the

global monopolies provided to pharmaceutical companies by such patents. There is increasing public opinion that the present model for intellectual property rights protection advocated by TRIPS is too heavily tilted in favor of private right holders and against the public interest. The public outrage over HIV/AIDS medicines has added fuel to the negative public perception about the IPR system and about the role of TRIPS.

All this is leading to a crisis of legitimacy for TRIPS. In the 6 years since its coming into force, there has been increasing evidence of many social and economic problems caused by the introduction of stricter intellectual property rights, as a result of the implementation of the TRIPS obligations[41].

Further to their arguments, the proponents of the TRIPS Agreement state the following facts as regards the actual situation of patented Drugs in developing countries:

1. 95 % of the medicines listed on the WHO „essential drugs list"are not, or no longer, patented. However, the populations in many developing countries still have no or insufficient access to these medicines.

2. In those countries which are hardest hit by AIDS, malaria or tuberculosis, there is no patent protection for many of the medicines used against these diseases for two reasons: Either the respective country is not obliged to guarantee patent protection, or, the owner of the protective right waived the right to pursue patent protection in that country.

3. The TRIPS Agreement includes a general transition period during which the least developed countries (30 WTO Member Countries) can meet their obligations

[40] The World Bank,2000 World Development Indicators p45

under the agreement by 2006. Until that date, these countries do not need to guarantee patent protection.

4. The TRIPS Agreement includes a grace period for developing countries which do not have any patent protection for medicines when the TRIPS Agreement comes into force. They have until 2005 to introduce such legislation. For example, India, which has a large generic medicines industry, has been granted this grace period.

5. The patent protection rate (the ratio of patented medicines to the number of countries) is no more than 18 % of the total 53 African countries in the case of 16 of the particularly effective anti-retroviral medicines used against AIDS.

6. In the case of other serious illnesses with high rates of recovery, the importance of patented medicines is even lower: for example, only 1 of 13 malaria medicines is patent-protected in any African country; the degree of patent protection for this one medicine is in total 5 %. In the case of tuberculosis, the patent protection is even less: 1 %. And in the case of the insidious sleeping sickness, it is 0 %.

The proportion of patent-protected medicines against epidemic illnesses such as AIDS, malaria, tuberculosis and others of similar proportions in developing countries is, in fact, very small. In addition, the TRIPS Agreement, which sets the minimal standards of protection for all intellectual property rights (patents, trademarks, designs, and Copyrights), grants all WTO Member States a high level of flexibility during the establishment of an efficient public health program.

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[41] Felix Ador: Access to Medicines in Developing Countries Patent Protection( ) p7

1. The TRIPS Agreement includes generous transitional and grace periods. It also has provisions for least-developed countries to extend the transitional period upon request. All of the countries benefiting from this transitional period are not required to guarantee patent protection for medicines.

2. The TRIPS Agreement has provisions for a Member State to grant a compulsory license when the owner of a patent refuses to put a medicine on the national market or does so only at overly expensive rates. In case of a national emergency, such as, for example, the AIDS epidemic in certain developing countries, a country can even grant a compulsory license without contacting the patent owner.

3. The TRIPS Agreement does not prohibit any country from allowing parallel importation of patented medicines. Parallel imports involve the import and resale in a country, without the consent of the patent holder, of a patented product that was put on the market of the exporting country by the patent holder[42]. The underlying concept for parallel imports is based on the principle of exhaustion of rights. This principle is premised on the fact that the patent holder has been rewarded through the first sale or distribution of the product; he/she no longer has the right to control the use or resale of the product.

However, despite the clear need for developing countries to exercise their rights for compulsory licensing to enable their people to have access to affordable medicines, a major and perhaps the most disturbing aspect of the crisis of patents and drugs is that obstacles have been, and are being put, in the way of developing countries seeking to

[42] TRIPS and the Primary of Public Health p 7. http//www.iips.org/Doc1

make use of TRIPS provisions on compulsory licensing and parallel importing in order to buy or produce drugs at more affordable prices.

It is vital that the right of governments to use compulsory licences and parallel importation measures are upheld and respected.

In summary these TRIPS provisions are coupled with numerous conditions, making them difficult to operationalise effectively and speedily. More significantly, although the TRIPS Agreement allows for these measures to be undertaken for the protection of public health, some developed countries have sought to give a narrow interpretation of the provisions relating to compulsory licences and parallel imports, with the purpose of restricting of scope of such measures. This situation has led to the perception that there is a lack of legal clarity or common understanding of the TRIPS provisions. As the Africa Group had stated " ... *recent legal challenges by the pharmaceutical industry and some members in national law and the WTO/DSU have highlighted the lack of legal clarity on the interpretation and/or application of the relevant provisions of the TRIPS Agreement*"

This was a reference to cases of Brazil and South Africa. In the WTO, Brazil has been taken by US to the WTO dispute settlement system for enacting legislation (which has yet to be enforced) allowing for compulsory licensing in cases of non-local working; that is, where the patent is not exploited locally. In 1997, South Africa, introduced the medicines and related substances control amendment Act number 90. This was intended to provide a framework for its nation drugs policy. The Act allowed the government to override patent rights in the pharmaceutical sector on public health grounds.

It appeared that this would allow the health minister to permit the use of parallel importing and compulsory licensing. This legislation led to the US to place South Africa on its 301 watch list and filled a complaint against the South African government by some 40 drug companies, which argued that the new law conflicted with South Africa's Constitution and contravened WTO patent rules.

The case aroused considerable public and media interest. In December 1999, the United States stopped its action stating that it was committed to helping developing countries gain access to essential medicines.

In April 2001, the drug companies withdrew their case when the South African government reaffirmed its commitment to honour TRIPS and the parties agreed to work together to implement legislation.

This situation has led to some unease and uncertainty on the part of developing country Members, who are now hesitant, or feel circumscribed in their ability, to undertake such measures in their national legislation, because while the outcome of the dispute between South Africa and the United States has been portrayed as a moral victory for South Africa and for HIV/ AIDS campaigners, it is by no means clear that the South Africa government ever intended to use the proposed new law to provide anti-HIV drugs . The South African health Minister made the following comment:

"that South Africa could not afford to use the drugs even if they were available free of charge, due to the high cost of distributing, administering and monitoring their use.

Equally disturbing is the fact that some developed countries, in conjunction with their corporations and industry lobbies have been exerting political pressure on developing

countries to prevent them from exercising their rights under TRIPS, and from enacting policies and laws on compulsory licensing and parallel imports for HIV/AIDS drugs and other drugs. Articulating the same concerns in the TRIPS Council, the Africa Group reports on "... *attempts ... by some developed countries through bilateral and regional arrangements to get developing countries to apply TRIPS-plus measures, or to forego their rights*".

Examples of such pressures include the bilateral pressure applied on the South African government by the US Administration, which was subsequently eased when AIDS activists caused significant embarrassment and damage to Al Gore's presidential campaign.

South Africa was also the target of the now-dropped legal challenge by 39 pharmaceutical companies, which sought a court declaration that the South African legislation on compulsory licensing was illegal. Thailand has also been the target of similar US pressures. In Thailand, US pressure was brought to bear on the Thai government to ban parallel imports, and to restrict the use of compulsory licences, under threat of high tariffs on Thai exports.

It is therefore, necessary for the WTO Members to clarify and come to a common and agreed understanding of the TRIPS provisions. Compulsory licensing and parallel imports are clearly allowed within the TRIPS framework. Therefore, developing countries should be allowed the maximum flexibility in interpreting and implementing the TRIPS Agreement provisions, and should be allowed to do so, without fear of litigation or other pressures.

It is vital that interpretations allow full flexibility for developing countries to exercise their rights to provide affordable medicines to their people, rather than interpretations that may restrict the scope and ability of developing country members to adopt measures to ensure access to medicines.

Even though proponents of the Trips Agreement argue that patent protection is not the problem but the solution, here are some disturbing examples of the effects of patents on the price of drugs[43]:

Prices of branded or patented products are often far higher than prices of similar medicines produced by alternative or generic sources:

For example, a comparison of prices for HIV/AIDS medicines illustrates the fact that the drugs Multi National Corporations MNCs sell their medicines at much higher prices than those of generic producers. For instance, the US price of *3TC* (Lamivudine) marketed by Glaxo is USD3, 271 (per patient per year) whilst Indian generic manufacturers, Cipla Ltd. and Hetero Drugs Limited, offer their generic versions for USD190 and USD98, respectively. In the case of *Zerit* (Stavudine), the US price offered by Bristol-Myers Squibb is USD3, 589 (per patient per year) as compared to USD70 and USD47 for the generic versions by Cipla and Hetero, respectively. As for *Viramune* (Nevirapine) marketed by Boehringer Ingelheim, the US price is USD3, 508, compared to the Cipla and Hetero prices of USD340 and USD202 .

[43] TRIPS, Patents and Access to Medicines: Proposals for Clarification and Reform, Third World Network Briefing Paper, p18. www.Twnside.Org.sg/title/drugs

This point is further illustrated by Cipla's recent offer of USD350-600 for a year's supply of a combination of these three anti-AIDS medicines, as compared to the price of USD10, 000-15,000 for the branded medicines.

Another study by Health Action International shows that retail prices of 10 out of 13 commonly used drugs, are higher in Tanzania (annual per capita GNP of US$120) than in Canada (per capita GNP of US$19,380). The average retail price of 20 commonly used drugs in 10 developing countries of Central and South America are all higher than the average retail prices of the same drugs in 12 in developing countries.

The above discussion suggests that the pharmaceutical industry fixes the prices for medicines by setting the limits according to what the market can bear Profit maximisation, through the elimination of competition and the maintenance of market monopoly, is the main objective. Patent protection is the most effective tool for drug MNCs to keep out competition from generic producers and thus, maintain a monopoly control on the production, marketing and pricing of medicines.

The pharmaceutical industry and its government supporters justify patents on medicines and high prices on the ground that R&D of pharmaceutical drugs is extremely expensive. Thus far, there is little convincing evidence to support this claim. Research indicate that industry estimates for R&D on each new drug ranges from US$350-500 million, while independent estimates range from US$30-160 million. Using either estimate, revenues from many life-saving drugs very easily exceed their R&D costs. For example, in 1999,

the sales of Bayer's *ciproflaxin* totaled US$1.63 billion and Pfizer's sale of *fluconazale* totaled US$1 billion. [44]

It is also debatable for drug MNCs to claim that their huge investments in R&D warrant the high prices for their products. A number of the patented drugs were not discovered by the MNCs. Public-funded institutions and universities were largely responsible for the initial R&D of several medicines. For instance, the National Institutes of Health (NIH) in the US was instrumental in the discovery of a number of the AIDS medicines. In fact, the NIH estimated that in 1995, its contribution to the overall US health R&D accounted for 30% of the total, whilst that of private industry amounted to 52%. And yet, it is the pharmaceutical industry that reaps most of the profits from the production and sale of medicines. [45]

It is not sufficient reason for pharmaceutical companies to justify high drug prices in developing countries as an incentive for research and development on new drugs. 80% of the projected worldwide drug market is in North America, Europe, Japan and Australasia. All of Africa accounts for only 1.3% of the world market in pharmaceuticals. In fact, Africa and Asia with 67% of the world's population account only for 8% of the world market. The small markets in developing countries will not significantly affect the research and development costs. The profits of the pharmaceutical industry will also not be affected by weaker patent protection in developing countries, which would enable the latter to manufacture and market medicines at lower prices.

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[44] C. Correa: Intellectual Property Rights, The WTO and Developing Countries(2000) p10
[45] ibid p11

Various countries in developing countries have cried out to the relevant authorities to look into their plight. The following statement was made by one of countries in the developing world:

"(A) all this has further aroused public interest and led to the conclusion, in some quarters, that patents have enabled drug companies to raise prices of their products far above the levels that can be afforded by a great number of people. Further it is argued that contrary to the principles and objectives of the TRIPS Agreement, the present model of intellectual property rights protection is too heavily tilted in favor of rights holders and against public interest. ... In the same manner, patent protection is seen, whether rightly or wrongly, as shielding drug firms from competition from other firms and other products" [46]

The case of access to affordable medicines has illustrated a disturbing aspect of TRIPS: that this Agreement has facilitated, and is continuing to facilitate, anti-competitive behavior and the flow of trade in products at prices that are influenced or determined by monopolistic elements, which hinder trade at free-market prices.

CHAPTER FOUR:

CONCLUSION:

Every problem needs a solution and it has been said that we fail more often because we solve the wrong problem than we get the wrong solution to the right problem.[47]

Intellectual property law is a branch of law that protects some of the finer manifestations of human achievements. The main characteristic of intellectual property law is that it defines conduct that may be pursued in relation to the products of the mind expressed and manifested in some material form with the consent of the right owner. This form of protection applies to ideas and information that are of commercial value.

This paper centred a lot on patents and how the affect access to pharmaceutical drugs and access to health especially in developing countries.

It is generally accepted that Pharmaceutical products can not be regarded as ordinary commodities. In the first judge the usefulness, prices and quality of drugs, secondly, this is because drugs play a significant social role in that they are an integral part of the realisation of a fundamental human right- the right to health. This is why they are classified as essential goods, to emphasize that they have to be accessible.

The concept of accessibility is very important. It means that the policies pursued must aim to make drugs available for all who need them, and at affordable prices.

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[46] Health Action International. NO.100, April 1999 p

[47] Russell L. Ackoff, Redesigning the Future: A System Approach to Social Problems 1974 p10

It has been noted that there is a gap between developing countries and developed countries in terms of accessing drugs, it seems developed countries easily access drugs despite the patents and that the reason why developing countries have problems in accessing them is because of other factors such as poverty and not just patents because the look at patent protection not to be the problem but rather that patents are part of the solution because it is an incentive for the research and development of new, more effective medicines.

Certainly, to develop new drugs is costly, thus patents are not only an insurance to drug companies that they will recoup their investment for the research and development (R&D) without being undercut by copycats. It also follows that the expenditure on R&D would be passed through the cost of the price of patented medicine.

As critics argue, the problem is that the huge prices commanded by branded drugs are because of the patents which give the company exclusive rights for 20 years. Nevertheless, to blame patent protection for the inaccessibility of essential drugs is a feeble argument. Merely opposing patents and patent legislation is counterproductive, as true innovation deserves to be recognized and protected.

It is clear that acknowledgement that a flexible interpretation of the TRIPS Agreement could be part of the solution and not part of the problem.

Some argue that the real barrier to procurement of medicine for poor countries has nothing to do with patent protection but finance, or rather, lack of. It is self-evident that insufficient funding, both public and private, exacerbates the situation and poverty reduction would be a primary objective of all developing countries.

Lack of funds is certainly a contributory factor but should be of a wider discussion on development economics rather than on this issue of access. Other barriers to access is the level of development of a developing country; such as the state infrastructure, health facilities, staff and equipment, education, access to information, distribution channels and so on. In addition, certain drugs do not even have patents including those for infectious diseases such as malaria and tuberculosis, as well as 95% of the medicines considered by the World Health Organisation (WHO) as "Essential Drugs"

However many people in developing countries insist that the reason for the pandemic scale of diseases is the lack of medicines- either because they are not available or far too expensive.

Developing countries claim that their suffering is because of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) of which they have said that TRIPS has given rise to factors that have put access to medicines out of reach for millions of people in the developing world. The TRIPS Agreement obliges WTO members to adopt and enforce high standards of intellectual property rights protection, which have been derived from standards used in developing countries.

In developing countries, the TRIPS Agreement has exacerbated conflicts between private corporate interests, and the public interest including public health. The controversy over access to medicines has highlighted just one aspect of the imbalances within the TRIPS Agreement, which is heavily tilted in favour of private right holders and against the public interest. There is growing evidence of social and economic problems caused by the

introduction and enforcement of stricter intellectual property rights, which developing countries are obliged to implement as part of their obligation under TRIPS.

This has resulted in calls for a re-assessment of the Agreement itself

The agreement should take into consideration that access to essential and vitally needed medicines is a fundamental human right.

Poor people have the right to good health, and therefore to medicines for the treatment of poverty-related diseases. Protecting people's health and saving their lives must take precedence over the strict protection of intellectual property and the very high profits which drug companies derive from this.

All in all, it would be false to reduce the entire problem of access to medicines to patent protection and the TRIPS Agreement, and would detract from a constructive and long-term solution.

The insufficient access to medicines in developing countries is due to complex and multifaceted problems which the community of countries affected must address with concentrated action and financial support.

It is said looking at the TRIPS Agreement is like looking at a young footballer trying to make a career in a promising team. Young football stars have innate qualities to become celebrities.

Such an ambition is much more difficult in a first-rate team than in a team threatened by relegation in the national league, as the requirements are higher than elsewhere. For those young footballers, hard work and special training is paramount.

The TRIPS Agreement is, in many ways like a promising young star amongst the WTO Agreements-a young Agreement, which has already achieved a lot.

A balance has to be struck between providing health care and drugs to the sick in developing countries and protecting the inventor's rights because access to drugs is not a luxury reserved for the rich but is a human right for all.

RECOMMENDATIONS:

For developing countries, providing affordable access to drugs will require the following changes:

-Rather than focusing on the Pharmaceutical industry and the TRIPS Agreement as inhibiting people in developing countries from accessing health care, Governments in these countries should attempt to classify the underlying causes of access problems as due to physical, informational, social, or ethnic barriers. The underlying causes of access problems in particular countries may differ. Physical barriers may be primary cause in one case, whereas informational barriers may exist elsewhere. Therefore various stake holders in the relevant authorities should identify the set of causes for access problems and then formulate country-specific reform plans to improve access.

-Governments also need to invest in the basic health care infrastructure to distribute, store and dispense drugs and to monitor patients. They need to provide certain minimum standards of health care.

-Public health concerns should be considered when implementing the TRIPS Agreement.

- Governments should be encouraged to implement measures such as Differential Pricing which is where pharmaceutical companies make and sell the same drug at different prices in different markets hence getting cheaper drugs in developing countries.

-The issue of Compulsory Licences and parallel importing should be addressed. They should be addressed in a manner that allows developing countries the maximum flexibility to exercise their rights. It is vital that the right of government to use Compulsory Licences and Parallel importation measures are upheld and respected.

It is imperative that developing country members are able to make policies with a reasonable amount of assurance that they will be able to exercise their rights in the TRIPS Agreement without fear of being taken to court.

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