Introduction

The health environment refers to the exposure and availability of the health care facilities and medicines across the world which is governed and affected to a large extent by the Intellectual Property Law (IPL) and International Trade Agreement (ITA). This very fact led the author of this proposal to undertake this study because there are several clashes between World Trade Organizations (WTO) members and health care activists regarding the provision of ART. These IP laws and ITA are important to manage the delivery of drugs in developing countries in an effective and lawful manner. Intellectual property "rights," in many complex ways, impede access to Anti-Retroviral (ARV) drugs in most developing countries with heavy burdens of AIDS-related mortality and morbidity. (Rovira, Juan, 2004)

This article argues that developing countries that lack the necessary pharmaceutical capacity should exploit emerging opportunities for South-South cooperation. There are some developing economies like India and Brazil which have developed the anti-retro viral drugs but still most of the developing countries not have the technological resources or they are not allowed to do produce the drugs because of the possible violation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which has been imposed by the Word Trade Organization. (Rovira, 2004)

The most recent event related to this aspect was the agreement between Uganda entered and Cipla which is an Indian manufacturer of generic anti-retro viral drugs to enable the company to open a drug manufacturing facility in Uganda. (Rosenburg, 2001) The opportunity for the cooperation shows that the developing countries can actually collaborate to fight the global AIDS diplomacy. These countries can exploit these kinds of opportunities so that they can exploit the regulations without violating the TRIPS. The only problems to this kind of arrangements can be that circumventing the obstacles which are being posed by the TRIPS

and the forces by the global pharmaceutical companies having their influence across the world.

The Problem Statement

The problem to be addressed in this study pertains to the impact of International Trade Agreement (ITA) and Intellectual Property Laws (IPL) on the availability of the anti-retro viral drugs in the developing countries. The countries which have been taken as focus of this study are African and some Asian countries which have shown to have disproportionate cases of AIDS because of which WHO (World Health Organisation) has formulated certain provisions to facilitate the fair and smooth availability of these drugs across the world especially in the developing countries against which the pharmaceutical companies are biased because of the lesser profits generated from these countries. (Rosenburg, 2001)

The Rationale for the Research

This problem is important enough to study because it has become a concerning issue for governments and pharmaceutical companies to have patents and strongest IP law for HIV related therapies, products and drug manufacturing techniques. The global pharmaceutical companies along with the World Trade Organization members, the representatives of the US and European Union trade and health-care campaigners have had an issue of contention over the logistics and availability of the anti-retroviral therapy to the AIDS affected population in the developing economies. (Africa Trade Bill)

The bone of contention has been the role and importance of patents which are required for the getting the HIV-related pharmaceutical products, engineering methods, and models of the delivery of the drug. (WHO Drug Information) These opinions have recently strengthened because of the increase pursuit by the US bilateral, regional, and multilateral trade

agreements supported by the very robust intellectual property laws. The drug manufacturing companies also support the fact that the patents are an important aspect to retain and maintain innovations across the world. There has been little proof of the current IP law creating any incentives for the innovation of new drugs. The analysis showed that the patent protection has not resulted in any kind of change in the invention and innovation of drugs. (WHO Drug Information) This challenges the fact that patent protection facilitates the development of new drugs. Moreover, the present system of patent protection does not guarantee the financial advantages for the most essential drugs.

Statement of the Research Objectives

The purpose of this study is to determine the factors affecting the availability of the anti-retro viral drugs in the developing countries and the role of the trade policies and the patent laws with respect to this issue. This study will aim to be helpful to the retailers and the healthcare professionals in understanding the factors which are responsible for the availability of the drugs for AIDS hence raising the voice against the unfair practices carried out by the pharmaceutical countries when they violate the provisions brought in place by the world health organisation. (Rosenburg, 2001) Also, this study will benefit the researchers who want to investigate the specific points related to these violations and devise solutions for the same. The future scope of the study will pertain to the research on regulatory and property law frameworks and work upon a particular drawback and loophole in these frameworks.

Hypothesis

The primary questions which need to be answered with the help of this study are related to the interrelationship of the variables which are involved in governing the impact of the trade agreements and the IP laws in determining the availability of the anti-retro viral drugs in the developing countries. The various interrelationships which can be studied are:

- If the patent laws and IP laws are stringent, it will positively impact the availability of the drugs in developing countries.

- The generic drugs are more easily available in developing countries than the branded drugs.

- The WHO and ITA have been able to solve the issue of non-availability of the AIDS medicine in African and Asian countries.

Definition of Terms

International Trade Agreement: This is an arrangement between two countries in which the two parties institute a zone of free trade in which the trading of goods and services is conducted across their mutual borders without any kind of tariff or formalities. The only restriction is on the free movement of labour and capital. The countries who are part of this arrangement impose a common external tariff to the countries who fall outside this agreement. (WTO's Agreement)

Anti-retro Viral: These are the medicines or drugs made to mitigate the symptomatic effects of the HIV infection. These hinder the growth of retrovirus which is the cause of spread of HIV. (Rosenburg, 2001)

Intellectual Property Laws: These are the regulations aimed at protecting the original creations or innovations in the field of art, literature, design, symbols, names and images used in the trade related activities. (Rovira, 2004)

The World Health Organization: is an international organisation that deals with the health and related activities across the world. The organisation is responsible for the wellbeing and public health internationally. The agency has defined its role in maintenance and development of the health care matters which are critical to the world. It is also instrumental

in engaging the partnerships where two or more entities are needed to make improvements in the field of health care facilities and innovations. Also, it shapes the research and generation of knowledge, setting of standards and monitoring of the rules and regulations which are technical, ethical as well as social in nature. (WHO Drug Information)

Summary

The Research proposal aims to study the underlying problem of the unavailability of the anti-retro viral drugs in the developing countries. This issue is addressed by working out the impact of intellectual property laws and the international trade agreements on the availability of drugs. The scope and implications of this study are to benefit the researchers who want to investigate the specific points related to these violations and devise solutions for the same. The future scope of the study will pertain to the research on regulatory and property law frameworks and work upon a particular drawback and loophole in these frameworks.

I. Research's method

The method and the research procedures include all efforts used to guarantee high quality health care services and to improve population health. The present paper gives an overview of the following research directions:

- The feasibility of ART in resource-poor settings,
- The distinct approaches being adopted to delivery of ART,
- The problems to be considered in scaling up ART provision.

1. Method of research

The method of research is based on case studies from several regions around the world with the use of cross-sectional survey questionnaire. Guidelines have to be developed

based on these studies in wealthy industrialized countries, which rely heavily on laboratory tests which are most of the times unavailable in the developing countries, may not be feasible or appropriate for resource-limited settings. In general, the delivery of antiretroviral therapy in the developing world needs guidelines for the appropriate monitoring of therapy, including monitoring for treatment effectiveness and treatment failure, drug toxicities, adherence to therapy, and the emergence of resistant organisms.

2. Participants

The participants in our study are samples taken from the health care centers since they are receiving many patients from various entry points, including:

- Prevention of mother-to child transmission (PMTCT),
- Maternal and child health (MCH)
- TB (Tuberculosis) programs,
- VCT (Voluntary counseling and testing) centers,
- Other hospitals and pediatric clinics.

3. Research design

Cross-sectional survey questionnaire is to be adopted to collect data and to conduct the study. Strategies and approaches have to be developed to support health institutions to deliver ART support, and these strategies should be based on lessons learned and previous experiences. While there has been enormous evolution in the prevention, treatment of disease and diagnosis and several argue that many regions remain largely excluded from such scientific advance. The debate is in relation with the value and the role of patents published for drug manufacturing techniques, medicines and forms of drug delivery. In practice, it is the question of whether the developing countries should have the possibility to produce patented drugs so as to give their citizens with drug that may otherwise be too expensive for the majority of the world's poor that is the problem at the centre of this international debate. Governments could potentially produce generic (non-

branded) drugs/medicines and make them available at a fraction of the price of the branded equivalents. Branded medicines are marketed and made by the international pharmaceutical enterprises that hold the patents on the medicines.

4. Methods, Instrumentation and Data Collection Plans

Participants had to complete a questionnaire during a dedicated meeting. The questionnaire was made up of following sections: (1) Participants' ratings of the importance of chosen criterias about ART; (2) Participants' selection of 10 criteras from a list of 20 essential and non-essential ones, given a limited budget; (3) Participants' knowledge and understanding of terminology used in clinical trials and economic analyses.

II. Data analysis

1. Analysis's variables

The intervening parts have to analyze the input variables and to establish priorities for the given technical support and work on the basis of the following 5 strategic acts, each act shows a critical field where the health sector must invest if important progress is to be made towards reaching universal access.

1. Enabling any person anywhere to know their HIV status.

2. Growing the health sector's contribution to HIV prevention.

3. Accelerating the scale-up of HIV and AIDS care and treatment.

4. Expanding and strengthening health systems.

5. Directing the investments in strategic information to guide a more effective response.

The ART treatment can be both complicated and very expensive to be able to take it. In practice, treatment costs can be minimized by adopting generic rather than brand

name medicines. The United Nations organizations, several foundations, bilateral donors and private voluntary organizations are assisting low- and middle income countries to help them to have access to ART. It should be noticed that once ART is started, it must be continued for life since it minimizes the effects of the Human Immunodeficiency.

2. Relationship between variables

Health entities have to work together in order to be able to coordinate a wide range of ARV providers in emerging national programmes. Many providers in several settings are working under a variety of financing, management, clinical practices and logistic arrangements. The rapid growth of these different approaches and methods to ARV provision makes it hard for planners and policy makers to make the coverage evaluation, equity impact and quality of services.

3. Decision making criteria

Participants rated the following criteria as always important: quality of life, potential for the ART to be used, patient compliance, severity of the clinical indication, burden of disease and whether the ART treatment provided symptomatic relief or cured the condition. When asked to choose the criteria given a limited budget there was a trend towards choosing drugs to treat chronic conditions (HIV, hypertension, diabetes, etc.) and infectious diseases (antibiotics and anti-TB drugs). In conclusion, participants can rate their understanding of clinical and economic terms as high.

4. Used computer software

Such study has to be developed and evaluated using computer software programs which are delivered in conjunction with clinical care in increasing and supporting antiretroviral therapy

adherence in HIV-infected individuals to be able to measure the effectiveness of an individualized and interactive research work.

5. Validity of the measurement

The present study provides evidence of the validity of the measurement tools. The health-related quality of life helps in examine the convergent validity of the measurement. Most poor persons pay for drugs out of pocket, so even slight cost rises mean that life-saving drugs are really unaffordable. In order to address this concern and to face this problem, the poor regions around the world must be permitted to access to certain patents and must be able to produce generic versions of essential and vital medicines, for example those destined to treat HIV/AIDS. Generic medicines can be given at a fraction of the price of their branded equivalents.

6. Reliability of the variables

The answered the knowledge questions by the participants can only be considered only if they are correctly answered. It is necessary to consider a range of other variables in addition to the selected criterias. It should bear in mind that we have to consider cost-effectiveness and efficacy as priority issues in drug selection.

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