THE EFFECTS OF TRIPs ON DEVELOPING COUNTRIES WITH PARTICULAR EMPHASIS ON THE PHARMACEUTICAL INDUSTRY

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CONTENTS

ABSTRACT

This dissertation explores the effects of the Trade–Related Aspects of Intellectual Property Rights Agreement ('the TRIPs Agreement') on developing countries with particular emphasis on the pharmaceutical industry. The methodology used is that of analysing secondary materials. India and South Africa are used as 'case studies' in order to assess these effects. Before TRIPs, there was widespread piracy, copying and free riding of intellectual property rights in developing countries. The producers of the pirated and copied goods were mainly from developed countries and they were losing profits by the billions. The United States decided to demand for increased international property rights under the auspices of WTO. After eight years of negotiations, the TRIPs Agreement was signed by all member countries of the WTO.

The blatant piracy of intellectual property is obviously wrong and should be prohibited. Therefore the need for increased of intellectual property protection through TRIPs is understandable. However a problem arises is in the pharmaceutical industry; due to increased patent protection, pharmaceutical products and process will become more expensive than they were in developing countries before TRIPs. The effect is that new drugs are inaccessible to the poor citizens of developing countries. This dissertation reaches a conclusion on how a balance is going to be achieved between the contrasting needs for legitimate intellectual protection and access pharmaceutical products.

India had a flourishing generic industry before TRIPs. The effect of the Agreement will be to wipe a high percentage of this industry out of business. However a research-based industry may develop due to increased patent protection.
The South African Government introduced drastic measures in 1997 in an attempt to provide cheap drugs for its dying AIDS patients. A number of international pharmaceutical manufacturing companies brought an action against South Africa claiming that this legislation, the Medicines and Related Substances Control

Amendment Act 1997, was not compatible with TRIPs. This dispute ended abruptly with the pharmaceutical companies dropping the case due to international pressure. The outcome of this dispute has encouraged other developing countries to adopt similar legislations. The South African dispute was mainly concerned with the compulsory licensing provisions in TRIPs. These provisions put developing countries in a very difficult position. The outcome of the dispute may encourage other developing countries to challenge the other provisions in TRIPs which most adversely affect them.

The conclusion reached is that developing countries will experience both negative and positive effects on the implementation of TRIPs. However, these effects cannot be assessed accurately before 2005 when the transition period for the implementation of TRIPs in developing countries expires. On the whole it seems that the negative effects will out-way any positive effects. However, if some provisions of TRIPs such as the compulsory licensing provisions are amended to better suit developing countries, TRIPs may well be beneficial to developing countries in the long run. The negative effects of TRIPs will be easier to deal with if the implementation and long-term application of the Agreement is surrounded by a climate of cooperation and understanding between developed and developing countries. It is through this cooperation that the developed and developing countries will be able to reconcile their conflicting positions under the TRIPs Agreement.

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INTRODUCTION

The provisions found in the Trade–Related Aspects of Intellectual Property Rights Agreement ('the TRIPs Agreement'), are the most detailed set of provisions, found in one document, granting international protection of intellectual property rights. They provide the widest international intellectual property protection ever and are the only single set of rules on international intellectual property to be ratified by so many countries.[1] The negotiations leading to this agreement were very heated with countries from the developing world having the completely opposite view to the one held by countries from the industrialised world. This divide came to be famously referred to as the north-south divide. The countries from the north being the developed countries while those from the south being the developing countries.

The bone of contention between the two sides is quite simple to express. The countries from the north (led by the United States) wanted greater intellectual property protection under the auspices of World Trade Organisation (WTO) with a strong enforcement mechanism, which was not found in the already existing international conventions under WIPO. The countries from the southern block such as India, Nigeria, Brazil, Argentina and Colombia did not like the idea of intellectual property being viewed as a trade issue (thus coming under the auspices of WTO) and did not want an all-encompassing agreement granting stronger international intellectual property protection. According to their view the already existing

[1] T.P Stewart, *The GATT Uruguay Round: A Negotiating History.*

international conventions were enough to protect international intellectual property rights.

Why did the countries from the North want greater intellectual property protection? The main concern was the volume of piracy, copying and free riding in violation of the intellectual property rights concerned. These intellectual property rights tended to belong to companies from the industrialised world, which were losing money by the billions. 'The United States International Trade Commission estimated that the United States corporations were victims of foreign intellectual piracy on a tremendous scale, between $40 and $60 billion per year'[2]. The developing countries did not want increased intellectual property protection because they claimed that it would mean little or no technological transfer to their countries , indigenous industries would not developed in the face of more sophisticated protected goods form western industries and the effect of TRIPs would be to keep the south dependant on the north. Developing countries are divided into two categories; the less developed countries (LDCs)[3] and the more developed countries (MDCs)[4]. Due to the fact that the MDCs are much more developed than the LDCs, TRIPs will affect the LDCs more adversely than the MDCs. Although the MDCs will also be affected by some of the effects of TRIPs highlighted, the LDCs are the main focus of this dissertation.

[2] USITC (1998), as cited in J, Boyle. . *Shamans, Software and Spleen: Law and the Construction of the Information Society.*
[3] These countries include Kenya, India, Nigeria and South Africa.
[4] The MDCs include Honk Kong, Singapore and Thailand. . See A.S. Qureshi, *International Economic Law.*

It is plain to see why the blatant copying of such commodities as compact discs and videos, the making of fake Rolex watches and low quality French perfumes is wrong, and should be stopped by the introduction of stricter international intellectual property laws. However the question is completely different when it comes to the pharmaceutical industry. The granting of patents for pharmaceutical products means that the cheap copied drugs, which, developing countries relied on, would be illegal to produce and they would have to buy expensive patented drugs. The big dilemma here is how to ensure that drugs are affordable for all people in all nations of the world and at the same time have laws, which prohibit the copying of these drugs giving pharmaceutical companies rights that will encourage them to invest in the crucial business of research for new drugs. Before the TRIPs agreement almost all the developing countries, which had any intellectual property protection, did not accord patent protection to the pharmaceutical industry. This is with the exception of South Africa which had strict intellectual property rights for almost all industries With the introduction of TRIPs these countries have no choice but to implement patent laws which protect goods produced and processes used in all industries including the pharmaceutical industry. The aim of this dissertation is to assess the effect on developing countries of the provisions in TRIPs concerning patents for pharmaceutical products and processes.

It is frequently argued by critics that TRIPs was imposed on the Third World by the United States. This criticism is well founded and is discussed in chapter one. Chapter one also discusses the important relationship between intellectual property and the pharmaceutical industry. Chapter two focuses on the various arguments which present

in a general manner the positive and negative effects of patent protection in developing countries as well as the theoretical problem of forcing western style intellectual property rights in developing countries. The topic in chapter three is the effects of the patent provisions on India. India is the perfect example of a developing country, which may be adversely affected by the patent provisions in TRIPs. Before TRIPs India had a flourishing pharmaceutical industry which relied on weak intellectual property law to produce cheap generic drugs both for export and for internal sell. India stands out as the developing country that was most vocally opposed to TRIPs. It had every reason to fear extremely negative effects on its countries pharmaceutical industry. Chapter four focuses on the recent case in South Africa in which South Africa was accused of contravening TRIPs by the introduction of its 1997 Medicines Act. The events leading to this dispute and its outcome are of great relevance to this dissertation and are a good illustration of TRIPs at work in a developing country. Finally a conclusion on all the issues raised shall be reached.

CHAPTER ONE BACKGROUND TO TRIPs

1.1 Intellectual property rights and their relation to pharmaceutical drugs.

'Without patents the AIDS drugs would not exist'

The Economist Print Edition, *A war over and patents,* March 2001

When someone invents a new method of doing something, creates a new song, writes a new book, discovers or makes a new drug or discovers or comes up with new useful information he would want legal protection for this invention or information so that he can exploit it to his benefit. This protection would be in from of a property right granted to the inventor or creator so that others may not copy, sell or reproduce it without his permission. Such a property right is referred to as an intellectual property right. These rights are typically embodied in laws regarding patents, copyrights, trademarks, trade secrets and designs. The term also refers to new forms of creativity such as computer software, integrated circuits and future technological advances.[5] Patents are the specific form of intellectual property that may provide protection where pharmaceutical drugs are concerned. 'A patent is a legally enforceable right

[5] P Stewart *The GATT Uruguay round: A Negotiating History.* P. 2246

granted by virtue of a law to a person to exclude, for a limited time, others from certain acts in relation to a described new invention'[6]

These 'certain acts ' are

'a) when the patent has been granted in respect of a product:

i) making, importing, offering for sale, selling and using , the products

ii) stoking, such product for the purposes of offering for sale, selling , or using,

b) when the patent has been granted in respect of a process.

i) applying the process

ii) doing any of the acts referred to in a) above in respect of a product obtained directly by means of the process.'[7]

Thus what is patented in a particular drug is the drug itself and the process of making the drug which a particular person has come up with after exerting himself mentally and financially. Thus the monopoly granted covers the production, distribution and utilisation of the product and process

So why have such sweeping protection for inventions? The first argument in favour of patents has been that patents are an incentive to create. Lockean theory indicates that 'property should inhere in the act of creation because that was how one would provide incentives to create. When innovators are allowed to retain rights to the output of innovative effort, they will have the incentive to devote their creative resources to developing innovations. Well-defined property rights foster productive behaviour such as investment and innovation'[8].

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[6] UN Secretariat, *The Role of Patents in the transfer of technology to Developing Countries (*United Nations Publications) sales No.65.11.B.1, New York, 1964

[7]BPRI, *Model Law for Developing Countries on Invention (*Geneva, 1965) Section 21

[8] A. Damato, *International Intellectual Property Law* p. 28

Patents are also a means for the creator to recoup the investment he has put in creating the particular drug. In the pharmaceutical industry this kind of incentive is very necessary. There is a common claim that without this incentive many drugs that are used today would not have been researched and manufactured. They would simply not exist. In addition to this there is the argument that the granting of patent rights has been due to a 'compromise deriving from the recognition that many inventions are both 'free' goods and public goods. An invention is a 'free' item in the sense that, once made, its use involves no costs other than those of communicating the knowledge and learning how to use it. Yet the invention can also be a 'public' good i.e. an item whose costs of imitation are so small in relation to the costs of invention that unless an inventor has special safeguards he will not be able to enjoy the returns from his idea. Patents try to compromise these two conflicting attributes of inventions by providing special safeguards to the inventors for a number of years and then nothing thereafter'[9]. In a nutshell the two reasons why patens are important is firstly for the inventor to recover the costs of the research and development and 'secondly the added productivity that such incentives to attain information monopoly rights will create'[10] It is obviously in the public interest that research, new products and new information are the consequences of patent protection

Firms in the pharmaceutical industry make extensive use of patent systems when available. Because pharmaceutical products are very expensive to research and

[9] W.R.Cornish, *The International Relations of Intellectual Property,* [1993] 52(1), C.L.J, p. 50
[10] Ibid, p. 46

manufacture and yet very easy to copy, patents to protect the results of pharmaceutical research and development (R&D) are very important. 'In 1990 it was estimated that it costs U.S $212 million and takes 12 years on average to develop a new pharmaceutical'[11]. R&D managers in 130 lines of business were asked to rate the effectiveness of patents, secrecy or lead-time for protecting R&D results. 'On average the pharmaceutical industry R&D project managers found patents more valuable for, protecting the results of R&D'[12]. It has been argued that the pharmaceutical industry is one of the few industries for which patents constitute the main instrument for protecting intellectual property. Most industrialised countries now provide patent protection for pharmaceuticals. 'Notably however, this is mostly a recent development with many of these industrialised nations only beginning to provide patent protection for pharmaceutical industry in the last 20 to 40 years'[13].

However one of the problems of patent protection, in relation to developing nations, is that patent licence prices are not just about recouping investment, they are about profits. 'In the USA, private enterprise is at the forefront of R&D because it has seen it as profitable and not for the good of humankind.'[14] This is the reason why patent protection is commonly associated with price increase. It is for this reason that the implementation of the TRIPs Agreement holds many disadvantages for developing countries. Before analysing the various arguments on the costs of greater patent protection in developing countries a general background to TRIPs is important.

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[11] E,Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997], 19(11) E.I.P.R, obtained form westlaw, p. 13

[12] Richard T. Rapp , Richard P. Rozer. *Benefits and Costs of Intellectual Property Protection in Developing Countries,* [1990] JWT 75 p. 87.

[13] E,Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997], 19(11) E.I.P.R, obtained from westlaw, p. 14.

[14] M, McGrath. *The patent provisions in TRIPs: Protecting Reasonable Remuneration for Services Rendered or the latest Development in Western Colonialism?* , [1996] 7 E.I.P.R. p. 399

1.2 GATT, World Trade Organisation and TRIPs

The General Agreement on Tariffs and Trade (GATT)[15] was establishment in January 1948 to regulate and, expand international trade through the reduction of tariff barriers and other measures in support of trade liberalisation. From 1948 to 1994, inter-governmental meetings under GATT's auspices to further trade liberalization took place through a series of multilateral trade negotiations known as trade rounds. It was agreed that instead of organising negotiations on single issues, there should be a package approach covering a whole series of topics. As a result these trade rounds normally took and still take several years to complete. Thus the Tokyo round of the 1970's took 6 years and the Uruguay round which begun in 1986 took 8 years .It was not resolved until April 1994 when the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade negotiations was signed in Marrakech, Morocco, by 125 governments. These are the negotiations during which the TRIPs Agreement was discussed and the WTO established.

Before the Uruguay round GATT had dealt only with merchandise goods. 'The Uruguay Round differed from previous rounds in that the agenda was extended to embrace new areas such as trade in services and intellectual property rights.

[15] GATT was meant to be a provisional arrangement that would be replaced by an International Trade Organisational (ITO). . A draft agreement for the ITO , known as the Havana Charter was agreed by more than 50 countries including all 23 founding members of GATT in March 1948. However, an insufficient number of countries ratified the Charter for it to be enforced and the ITO consequently did not come into being.

According to the WTO, the Uruguay Round was the biggest negotiation mandate on trade ever agreed and ministers gave themselves four years to complete it'[16] In the event, this four year estimation proved to be an under – estimation. . The negotiations took eight years because of the complicated and often controversial, nature of many of the areas covered. It has been claimed by various authors and participants[17] of the round that the negotiations on the TRIPs Agreement were the most controversial.

The Final Act is a voluminous document that includes the Agreement establishing the WTO and the following multilateral agreements, which are binding on all contracting parties to the Final Act and on the future members of the WTO,

- The Agreement on Trade-related Aspects of Intellectual Property Rights;
- The Multilateral Agreements on Trade in Goods; and
- The General Agreement on Trade in services

1.2.1 USA's involvement in TRIPs

> 'The TRIPs Agreement has been castigated by developing country propagandists as neo-colonialism. Its unfortunate chronological juxtaposition with section 301 of the U.S Trade Law has reinforced this view.'
>
> Michael Blakeney, *Intellectual Property and Economic Development* I.T.L.R [1998],1 p.2

In discussing the history of TRIPs there is no way to avoid a discussion on the involvement of USA in making sure that intellectual property rights were included

[16] D.Gervais, *The TRIPs Agreement: Drafting History and Analysis,* p. 12
[17] J. Watal, *The TRIPs and Developing Countries-Strong, Weak or Balanced.* (1997) 1, J.W.I.P, pp. 281-307. Jayashree Watal worked in the Government of India and was responsible for the TRIPs negotiations form May 1989 to March 1991.

under the auspices of GATT. It is not far fetched to say that without the efforts that USA made to this end there would probably be no TRIPs today, at least not under the WTO. Historically, the protection of Intellectual Property Rights had been reserved to the domain of national governments and international organisations such as World Intellectual Property Organisation (WIPO) and the United Nations Educational Scientific and Cultural Organisation (UNESCO). Established in 1976, WIPO is a specialised U.N agency whose primary mission is to administer international treaties on intellectual property. WIPO administers the Paris Convention for the protection of industrial property and the Berne Convention for the protection of literary and artistic works.

The main reason why the USA wanted increased intellectual property protection under GATT lies in the fact that 'WIPO does not have any enforcement or dispute settlement mechanisms apart from the treaties it administers. The provisions ensuring compliance in the two treaties are very weak. 'Although both conventions permit signatories to seek dispute resolution by the International Court of Justice, members are also not bound to go to the Court '[18]. GATT had an effective dispute resolution system and there was the possibility of applying trade sanctions on a non-complying member. The USA took the position that 'tying obligations to protect intellectual property rights to other trade commitments under GATT would provide the desired vehicle for pressuring recalcitrant trading partners'[19]. To illustrate just how opposed developing countries were to having increased intellectual property protection, there is evidence that before the TRIPs agreement many developing countries wanted what

[18] G.,Dutfield, *Can the TRIPs Agreement Protect Biological and cultural Diversity.* p. 4
[19] Ibid, p. 4

the industrialised countries termed as weak intellectual property rules in the Paris and Berne Conventions to be made weaker. 'Agitation by developing countries within the Berne and Paris unions to soften some of the perceived rigours of the international intellectual property regime was signally unsuccessful. The TRIPs Agreement may be regarded as the final defeat of this ameliorations campaign'[20]

The United States was compelled to demand for increased intellectual property protection due to the great losses its companies were making abroad . The relative percentage of US export with a high intellectual property content rose form 9.9% in 1947 to 27.4% in 1986[21]. This phenomenon is often attributed to two major technological revolutions in information technology (IT) i.e., the new electronic information-processing and communications technologies and the new biotechnologies. 'Both of these have multiple industrial applications, and many large powerful corporations involved in such sectors as computers, telecommunication, health, entertainment, financial services, retailing, chemicals, agriculture and food, embraced these technologies.'[22]

However these corporations are vulnerable in that the cost of researching and developing versions of software packages, CDs and drugs tend to be very high while the cost of copying them is extremely low. Thus rival producers can make multiple copies of the products very cheaply. In developing countries where laws for protection

[20] B. Sodipo, *Piracy and Counterfeiting, GATT, TRIPs, and Developing Countries,* [1998] E.I.P.R ,5, P. 197
[21] D.Gervais, (fn 16), at p. 16
[22] Ibid, p.17

of intellectual property rights were weak or non-existent, counterfeiters could quickly and inexpensively copy these products and sell them at home and abroad. In the pharmaceutical industry, drug companies which have carried out time consuming and expensive research and development to create new products had their medicines reverse engineered, manufactured and sold at lower prices by other firms. India was world renowned for this. Based on these figures, the IIPA stressed that 'the U.S government's goal must be to establish an international trading climate in which intellectual property is respected and protected'[23]. From the early and mid 80s the US government received pressure form its industries to use its domestic law as well as international law to assure protection in foreign markets. Due to the highly effective lobbying of the affected corporations[24] United States lead an effort within GATT to establish a framework to regulate trade in counterfeit goods.

The United State's position was that tying obligations to protect intellectual property rights to other trade commitments under GATT would provide the desired vehicle for pressuring non-compliant trading partners. So having recruited support from other developed nations, 1985 to 1989 saw the United States employing various methods to encourage developing countries to accept the insertion of TRIPs into GATT. These included bilateral actions using its Trade Act (1988) Super 301 measures to impose sanctions and tariffs on imported goods from countries considered to have weak IPR laws[25]. Trade sanctions by a powerful and wealthy nation such as the United States are potentially crippling for less developed countries. For example 'in 1992 the United

[23] T.P Stewart ,*The GATT Uruguay round: A Negotiating History.* p. 2254
[24] The affected United States companies allegedly determined the framework of TRIPs with Japanese and European commercial interests playing an important supporting role. See Ibid, at p.2254.
[25] In 1991 China was listed on the 'watch list' of Special 301. The USTR required, and China agreed to include pharmaceutical products (not required under TRIPs until 1999) as paternal subject-matter .

States suspended a privilege granted to India which allowed it to export certain pharmaceuticals duty free to the U.S. This sanction cost India U.S$60 million in export dollars'[26]. For many Third World nations the decision to agree to TRIPs has been a practical rather than an ideological choice.

1.2.2 1986-1994 – The TRIPs Negotiations

> From the beginning, fundamental disagreements existed between the developed and developing countries in the TRIPs negotiations.
>
> T.P Stewart, *A Negotiating History*, p. 2269.

In 1985 during the Tokyo Round at the insistence of the United States the International Anti- Counterfeiting Coalition was formed[27]. The coalition studied the counterfeiting problem and assisted the drafting of a proposed code on anti-counterfeiting. No agreement was reached before the end of the Round[28]. The effort to include counterfeiting in the GATT work program was opposed greatly by the developing countries. From their perspectives intellectual property is a public good that should be used to promote economic development. 'Brazil and India argued that GATT's jurisdiction was limited to tangible goods and therefore GATT lacked legal competence to address an issue within the intellectual property area. They contended that counterfeiting trademarked goods belonged to the exclusive jurisdiction of

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[26] E,Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997], 19(11) E.I.P.R, p. 3.

[27] The International Anti-counterfeiting coalition is an organization comprised of 100 multinational corporations . It was created to lobby national governments to strengthen protection against counterfeit trade marked goods. By the early 80's however its mandate was expanded to include strengthened protection for all forms of intellectual property.

[28] The anti-counterfeiting movement failed to draw broad support prior to the ministerial meeting of 1982. During the preparatory work for the ministerial meeting, the U.S submitted a formal proposal that articulated its position. Regarding counterfeit the United States submission advocated further negotiations and eventual adoption of the Anti –counterfeiting Code.

WIPO'[29]. This line of argument could not hold any ground after WIPO'S Director General was specifically mandated to participate in the GATT intellectual property negotiations.

In 1986 the WTO countries convened for their first session of the Uruguay Round. Although some of the delegations continued to oppose GATT's involvement in intellectual property, the GATT Council agreed to appoint an Expert group to continue the work on the area. Opposition to intellectual property rights being discussed within GATT gradually came to an end with one developing country after another backing down on is protests. According to Doane[30], once India backed down on its very vocalised protests the industrialised countries knew that there would be an agreement on intellectual property under GATT. Those countries that complied by agreeing to have the negotiations in GATT were less willing to support those countries that were opposed to it.

The United States managed to impose on the developing world its standard of intellectual property rights. The main reason for this success lies in the fact that, 'faced with a choice between a multilateral system and isolation from the global economy, most governments nowadays are predisposed ideologically to favour multinational Agreements on important trade issues'[31]. Moreover, several developing countries were increasing the information-content of their exports and starting to

[29] T.P Stewart, *The GATT Uruguay round: A Negotiating History.* p.2261
[30] Michael L Doane, *TRIPs an Intellectual Property Protection In An Age of Advancing Technology,* 9, U. J. Int'l L. & Po l'y, p. 465.
[31] G, Outfield. *Can the TRIPs Agreement Protect Biological and cultural Diversity.* p. 5

compete with developed countries in certain high-tech fields.[32] 'Inevitably some of the more technologically-advanced Third World countries corporations will also wish to protect their intellectual property at home and abroad, and consequently find the availability of intellectual property rights protection increasingly desirable.'[33]

Thus on September 2nd 1986 the ministers adopted an initial common declaration: The Ministerial Declaration on The Uruguay Round, which outlined the course of future negotiations on international trade. Under the Declaration the goal of TRIPs negotiators was to formulate a multilateral agreement on minimum levels of protection for intellectual property rights.[34] The Ministers stated the negotiating objectives for the TRIPs negotiating group. These were:

> 'In order to reduce the distortions and impediments to international trade and taking into account the need to promote effective and adequate protection to intellectual property rights, and to ensure measures and procedure to enforce intellectual property rights do not themselves become barriers to legitimate trade the negotiations shall aim to clarify GATT provisions and elaborate new rules and disciplines.'[35]

Through a series of detailed discussions and negotiations that spanned for 8 years the negotiating parties toiled over the detail that was to be the TRIPs agreement. The north-south divide was evident from a very early stage. 'In January 1988 many

[32] These are mainly the MDCs the most important example being Hong Kong.
[33] G, Dutffield. (fn 18) at p. 5
[34] See *Ministerial Declaration on the Uruguay Round,* GATT Doc. No. MIN.DEC (Sept. 20, 1986) .
[35] Ibid p.445 .

developed country governments reported to GATT that their country company operations were threatened not only by the well known practice of counterfeiting, but also from problems more generally relating to inadequate intellectual property protection. The developing countries expressed concern that they might be prevented from securing access to modern technology through the over-protection of intellectual property rights.'[36] After 8 years of discussion the TRIPs agreement was concluded and signed by 125 governments on the 1st of January 1995.

[36] *The GATT Uruguay round: A Negotiating History* p. 2269.

CHAPTER TWO THE COSTS AND BENEFITS OF INTELLECTUAL PROPERTY PROTECTION

2.1 The problem of introducing greater intellectual property protection in underdeveloped countries.

> 'Third world countries argue that TRIPs is inherently incompatible with the interests of their technologically poor countries.'
>
> Graham Dutfield, *Can the TRIPs Agreement Protect Biological and cultural Diversity* p.4.

Economic historians have concluded that there is a direct connection between the granting of intellectual property and development. The less developed a country is the less intellectual property protection it will have or desire. As it develops intellectual property protection increases. Krichanski argues that 'the level of a countries development alters the cost-benefit ratio of granting patents. As a country develops it will pass through three stages, each of which presents a different cost – benefit picture for the granting of patents.'[37]

The first stage is that of a country at a very low level of economic development. A completely under-developed country has little technological capacity and infrastructure, and will make few, if any, internationally 'patentable' inventions. Such

[37] S, Kirchanski,, *Protection of United States Patent Rights in Developing Countries: U.S Efforts to Enforce Pharmaceutical Patents InThailand,'* 16 Loy. L.A. Int'L & Comp L.J, 569. 1993 Loyola of Laos Angeles International and Comparative Law Journal. Reprinted in Damato, (fn 8) at p.445.

a country would not benefit from a patent system because 'as an under-developed county it would not be limited by a shortage of inventions but by the ability to utilise readily available technology. Whereas the economy of a developed country depends on new inventions an underdeveloped country needs to expand its economy by implementing new inventions which are already available in the public domain'[38]. The LDCs were at this stage before the TRIPs agreement.

As the country' economy develops, markets and the infra -structure necessary for innovation will also develop, and the country will reach the second stage. 'The country becomes capable of using more advanced technology and may become an intellectual property pirate'[39]. Such a country is often rapidly developing and increases its state of growth by intellectual property theft. The MDCs were well into this stage before the TRIPs Agreement. As far as the pharmaceutical industry is concerned, India was at this stage of development before 1994.

The third stage is reached when the country can create world –class inventions. At that point it becomes profitable for the country to grant patent protection so as to protect its own innovators. Profits from piracy of intellectual property are outweighed by losses to the country its inventors caused by failure to protect their own inventions. 'Because intellectual property protection is on a quid pro quo basis, the country must provide strong patent protection so that other advanced countries will reciprocate and

[38] Ibid, p. 448
[39] E,Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997] 19(11) E.I.P.R, p. 18.

respect its patents.'[40]. According to Krichanski, industrialised countries, including the United States, reached this third stage over a century ago.

The point here is that the developing countries are not ready in terms of development for increased intellectual property protection.[41] 'Attempts to force a country to adopt an intellectual property scheme will be successful only if the country is sufficiently developed to benefit form the scheme'[42]. Through TRIPs the developing countries have been denied the second stage. Somehow they hope to move on to the third stage without going through the vital second stage of diffusing technologies that already exist, a fit which the developed countries were, according to various economic writers, unable to achieve. 'Many of the problems of international intellectual property protection are caused by the failure of industrialised countries to recognise the evolutionary nature of patent protection'[43]. It is the ignorance of this evolutionary process that led to the TRIPs agreement being pushed forward by developed countries with great determination. As indicated above developed countries introduced patent protection in the pharmaceutical industry only 20-40 years ago. It is a shame that developed countires which introduced patent protection for pharmaceutical products and processes so recently, expect developing countires to introduce this protection when they are hardly as developed as the developed countires were 20-40 years ago The future for developing countries, which now have to apply intellectual property protection, which they are not ready for, looks very bleak.

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[40] A. Damato, (fn 8) , at p.451

[41] When it comes to the pharmaceutical industry a country has to be quite advanced before patent protection can be beneficial. This is evidenced by the fact that industrialised countries introduced patent protection to the pharmaceutical industry only 20 –40 yrs ago when infact most of them reached the third stage over a century ago. See E.Henderson (fn 11).

[42] E. Henderson, *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997] 19(11) E.I.P.R, p. 18

[43] A.Damato,(fn 8) at p. 450

Before, during and after the negotiations for the TRIPs Agreement industrialised countries pointed out that increased intellectual property protection would benefit developing countries in many ways. The two most significant benefits cited were:

i)Technological transfer and the attendant investment; and

ii)Incentive for domestic innovation within domestic industries.

In contrast to this the developing countries argued that the TRIPs Agreement would lead to insurmountable negative effects to their economies. One author went as far as to say that 'ultimately the only 'advantages' which developing countries can be assured of, when they implement TRIPs, will be the avoidance of the economic and trade sanctions which industrialised countries would be entitled to impose under the terms of GATT were any other course to be adopted'[44]. In order to make an assessment of the impact of increased intellectual property protection enshrined in TRIPs on the pharmaceutical products and industries in developing countries, a detailed assessment of these claims is necessary.

2.2 Benefits : The argument in favour of TRIPs as it impacts on developing countries.

'There are substantial benefits for developing countries from protecting intellectual property. The benefits are in form of investment and technology flowing to the country, access by local firms to this technology and ultimately economic growth'

[44] Michelle,McGrath. *The patent provisions in TRIPs: Protecting Reasonable Remuneration for Services Rendered or the latest Development in Western Colonialism?* , [1996] 7 E.I.P.R. p. 401

Manish.. Saurastri *'It's time for an effective patent regime in India'* MIP 1996/97 vol 65 p. 34

Article 7 of the TRIPs Agreement proclaims that the objective of the Agreement is 'the protection and enforcement of intellectual property rights' in order to 'contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technology'. Watal[45] echoes this objective by stating that 'intellectual property protection helps countries attract technology, diffuse it through the domestic economy and, ultimately develop indigenous industries. Intellectual property protection achieves these effects by providing the incentive for innovators to devote resources to research and development'.[46]

With reference to the pharmaceutical industry it has been claimed that developing countries have a lot to gain for increasing patent protection. Before TRIPs most developing countries that had any patent provisions excluded the pharmaceutical industry from patent protection. In most cases process patents were allowed but not product patents.[47] One result of this is that patent applications for pharmaceutical goods from both foreign and local scientists are rare in these countries. As such, one disadvantage of having little or no protection for pharmaceutical goods is the fact that the scientists have no incentive to research and develop new drugs as they are weary

[45] J.Watal, (fn 17)
[46] Ibid p 290.
[47] Examples of countries that had such legislations include, India, Nigeria and Kenya

of not being rewarded adequately. 'Without patent protection, the incentive for pharmaceutical firms to devote local resources to R&D is all but eliminated.'[48]

The country, therefore, does not benefit from the advantages of having pharmaceutical research and development (R&D). The advantages of having R&D in the country are varied and include the fact that; the country will receive technological transfer, new industries will open up creating more employment, foreign investment will increase and the overall economy of the country will pick up. The best way to attract R&D is to have patent protection for both products and processes. R&D companies will feel safe enough to open industries in a country with these rights. As indicated above the R&D of a new pharmaceutical is very expensive. At the same time the reverse engineering of these drugs and their production in bulk by pirates is extremely cheap. Given this situation, the fact that the western-based pharmaceutical industry depends on patents protection is no surprising factor. 'The pharmaceutical industry has been identified as one of the few industries for which patents are actually important for encouraging technological innovation and development.'[49].

It has been claimed that 'Pharmaceutical R&D is conducted in those countries where intellectual property is protected'[50]. Statistics taken in 1990 indicate that the regions of the world where intellectual property protection was improving, received an

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[48] R. T. Rapp , R.P.Rozer *Benefits and Costs of Intellectual Property Protection in Developing Countries,* [1990] JWT 75, p. 97.
[49] G.Dutfield,(fn 18) at p. 14
[50] R T. Rapp , R. P. Rozer. Benefits and Costs of Intellectual Property Protection in Developing Countries, [1990] JWT 75, p. 89.

increasing share of R&D[51]. The statistics show an increase of 13.6% in Japan, which implemented laws protecting pharmaceutical products in 1976. 'By contrast in Latin America, where many countries have been reluctant to take steps to improve their intellectual property protection the proportion of R&D spending by U.S firms has decreased significantly from 8.4% of the total in 1977 to 2 per cent in 1987.'[52] In addition, the introduction of a more protective patent system will encourage the growth of indigenous inventions. This is because local scientists are encouraged to R&D new drugs. This is evidenced by the example of Italy and China. In 1978, when Italy introduced a strong patent system 'its turnover of indigenous pharmaceutical production increased by 64% in six years, thus making Italy the fifth largest producer of pharmaceuticals in the world. Even China, which adopted a patent system in 1993, has seen a significant growth in the turnover of its indigenous pharmaceutical industry'[53]

New uses for existing products are among the benefits of pharmaceutical research obtained when firms are encouraged by patent protection and rewarded for their innovative efforts. For example, the disease onchoecreciasis or river blindness, which is transmitted through the bite of the blackfly, is a problem unique to the developing world. 'River blindness afflicts 18 million people in Africa, Latin America and the Middle East'[54]. The infected suffer a number of uncomfortable symptoms eventually

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[51] R.T. Rapp , R. P. Rozer. *Benefits and Costs of Intellectual Property Protection in Developing Countries* [1990] JWT 75, p. 89
[52] Ibid, p. 88
[53] M. Saurastri *'It's time for an effective patent regime in India'* MIP 1996/97 vol 65 pg 34
[54] R T. Rapp, R, P. Rozer. *Benefits and Costs of Intellectual Property Protection in Developing Countries* [1990] J.W.T 75, p. 89

become completely blind. During the 1970s scientists at Merck[55] developed Mectizan (ivermetin) for the treatment of worm parasites in livestock. Mectizan was fully protected by patents in the countries it was sold. During this period, Merck scientists also discovered that the drug worked on the same worms that cause river blindness. Clinical trials were organised and by 1987, the safety and effectiveness of Mectizan for river blindness were established.[56] 'Without the exclusive right to the livestock use of Mectizan, Merck would not have had the incentive and the resources to investigate alternative uses of the product.'[57]

In discriminating against the pharmaceutical industry, and not granting patent protection to its products, developing countries ignore the fact that patent protection 'induces research on the problems that are peculiar to their populations[58]. Why would researchers embark on the expensive mission of finding cures for these diseases if they will not get any returns whatsoever from their output? Lack of patents protection means that the drugs they have researched and developed with a considerable amount of monetary investment will easily be copied by others and sold by them as if they were part of the intellect and investment that produced the particular drug.

Not only does lack of patent protection discourage foreign scientists from embarking in some life saving research, but local scientists are also discouraged. There is no denying that most developing countries have a very well educated cluster of scientists whose research and development capacities are being shelved daily due to lack of

[55] Merck is a well known international pharmaceutical Company.
[56] Merck announced a policy of providing the drug free of charge to all those who needed it.
[57] R, T. Rapp, R, P. Rozer. Benefits and Costs of Intellectual Property Protection in Developing Countries [1990] J.W.T 75, pp. 75 - 102
[58] These diseases are diseases such as Chagas' disease in South America and sleeping sickness transmitted through parasites in Africa.

patent protection. In fact most of them immigrate to other countries where their work will provide for them better incomes. It is not claimed here that lack of patent protection is to blame for this massive immigration but it may certainly have something to do with it . Under Article 27.1of the TRIPs Agreement members cannot discriminate between different fields of technology and thus developing countries will have to grant both process and product patents to pharmaceutical products[59]. From the evidence it seems that this will lead to R&D in the countries.

The governments of developing countries, having acknowledged that patents do give incentive to invention and R&D, indicate that they would rather use other means of encouraging R&D other than granting outright patents due to the costs associated with patent systems.[60] These other arrangements include an award or prize system, government conducted R&D or government supported R&D.[61] However it has been argued that these alternatives do not adequately substitute for intellectual property protection. In an award system, the first firm completing a specified project, which subsequently becomes public property, receives a monetary prize. Determining the award, however, is difficult. 'If it is announced in advance extensive knowledge of the likely benefits of the underlying innovation most be known by the awarding party. If the award is announced after the innovation, there is a tendency to exploit the fact that the costs of the innovation are sunk and thus undervalue the innovation'[62]

[59] This is in accordance with WTO's Most Favoured Nation Clause. See Web Page
[60] B.Sodipo, (fn 20).
[61] J.Tirole, *The theory of Industrial Organization.* (Cambridge :MIT Press, 1984), p. 400
[62] R .T. Rapp , R . P. Rozer. *Benefits and Costs of Intellectual Property Protection in Developing Countries,* [1990] JWT 75, p. 90.

With regard to the government actually performing R&D there is no better example than the pharmaceutical industry in the United States. For the pharmaceutical industry in the country, 'estimates of private spending for R&D equalled $7.3 billion for 1989, whereas the estimated budget for pharmaceutical research by the National Institutes of Health (NIH) in 1989 was $6.8 billion.'[63] However, even in the United States an additional amount of R&D is required beyond what the government provides to create products useful for particular diseases. Relying only on the government to provide R&D activities will result in less innovation and lost opportunities.[64] The problem in developing countries is that the governments are already struggling with an already over stretched budget with many of them having a high debt deficit. Governments of developing countries, no matter how much they would like to, will probably have very little or no money to devote to R&D. Finally, the government could negotiate contracts with a firm or firms to complete a particular project. 'The advantage of this method is that it limits the amount of duplication in R&D but the disadvantage lies in the fact that in restricting competition, it reduces the incentive to innovate.'[65] Patent protection therefore emerges as the best method of encouraging local R&D.

One of the greatest fears of developing countries is that pharmaceutical prices will increase due to increased patent protection. Rapp[66] argues that developing countries need not worry about increase in drug prices because this will most likely not happen. He indicates that the most essential drugs are way past their patent age. The current

[63] S.Patel. *The Patent system and the third world,* [1974] 2 (9), World Development . p. 13
[64] R.T,Rapp, R.P, Rozer, (fn 48) pp 75-102
[65] R, T. Rapp, R, P. Rozer. *Benefits and Costs of Intellectual Property Protection in Developing Countries* [1990] JWT 75, p. 90.
[66] Ibid, pp. 75 – 102

Essential Drugs List[67] published by the World Health Organisation (WHO) contains over 250 chemicals entries. Of the drugs on the list, over 90 percent are not protected by patents. These drugs would be subject to competition from generic drugs produced by companies in every part of the world. 'The only possible effect (on the price of these essential drugs) that strengthening patent protection for new drugs could have is to drive their prices down. Patent protection for new drugs fosters the creation of substitute drugs. As the number of drugs that serve a similar purpose increases, the pressure for price reduction also increases.' [68]

In addition to this a patent grants exclusive rights for a limited amount of time for a product or process narrowly defined by the claims of the patent . 'This narrowly defined right to exclusivity must not be confused with monopoly power. Economists define monopoly as a situation where one firm is the only supplier of a product or service for which there are no close substitutes. In the pharmaceutical industry there are dynamic competitive forces at work which serve to keep the prices of drugs low'[69]. Competition among pharmaceutical products for similar purposes is common. For example, 'Inrton-A (schering-plogh) and Roferon (Roche) are interferon products that compete with one another, although each drug has its own biomedical properties. Tagament (cimetidine) and Zantac (ranitidine) compete in the anti-ulcer category.'[70] The protection provided by intellectual property protection does not prevent other products, for similar or almost similar functions from entering the market. 'This is

[67] The essential drugs list published by the WHO contains those drugs selected as truly needed by the majority of people. These are normally almost the same as the essential lists made by various countries.
[68] R, T. Rapp , R, P. Rozer. *Benefits and Costs of Intellectual Property Protection in Developing Countries,* [1990] JWT 75, p. 90.
[69] Ibid, p.92
[70] Ibid, p 90

clearly evident in the treatment of hypertension, where 19 new pharmaceutical products or improvements of existing products entered the market between 1980 and 1990.'[71]

Cornish[72] supports Rapp by stating that 'a patent confers on the right holder the power to restrict production and maintain prices so as to maximise profitability in the *absence* of direct competition and in the case of a *true break-through*'[73]. Thus in the presence of competition and unless the product is an important new discovery, the patent holder will not be able to charge any price he pleases as market forces will force him to maintain a reasonable price otherwise his product will not sell. Therefore patents do not necessarily mean that prices will go up. The problem here is that developing countries are in desperate need of break-through drugs for diseases such as AIDS and cancer which have no substitutes and which are therefore extremely expensive. A recent dispute in South Africa, which shall be discussed in chapter four, arose out of measures taken by the South African Government to avail cheaper drugs to its dying AIDS victims.

The other side of the coin presents us with arguments that suggest that the granting of patents does not necessarily lead to investment, technological transfer, development of the local industry or R&D . There are also strong suggestions that Rapp and those who think like him are wrong about pharmaceutical prices not increasing in developing countries due to the implementation of TRIPs.

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[71] Ibid , p 93
[72] W.R.Cornish, (fn 9) pp 46-68
[73] Ibid , p. 49.

2.3 Costs: The argument against TRIPs as it impacts on developing countries

'Are I.P laws to the general benefit of the public? Do they encourage creativity? Do they create general wealth? Do they result in investment and technology transfer? In the developing world the answer is probably 'no'. The prevailing perception is that these laws merely protect ephemeral property rights if foreigners.'

L.T.C Harms Offering Cake for the south E.I.P.R 2000 ,10, p. 451

Penrose[74] indicates that 'foreigners seeking patents in less developed countries normally do so primarily to enhance the monopoly position of their product in the local market and thus the granting of patents does not assist in industrialisation nor benefit local industry either through foreign investment, research or manufacture by local businessmen.'[75]. Any investment that foreigners holding patents may put into the country granting the patent will inevitably go out of the country and into the country of the patentee as profits. 'When we talk about patents in developing countries we really mean foreign patent holdings.'[76]. Developing countries do not have inventions that they can patent in industrialised countries and thus they cannot gain benefits that reciprocate those gained by foreigners holding patents in their countries.

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[74] E.Penrose, *International Patenting and the Less Developed Countries,* [1973] Sept E.C.S, pp.768-785.
[75] E.Penrose, *International Patenting and the Less Developed Countries,* [1973] Sept E.C.S, p.783.
[76] C. Vaitsos, '*Patents revisited: Their function in developing countries*' Journal of Development Studies Vol9 (October 1972). P 451

Vaitsos[77] sees in patents a 'defensive strategy' by foreign companies ' ....to preserve markets that were once captured through exports and are subsequently threatened by competitors within or without the country and/or by the import –substituting strategies of the host countries. The evidence leaves open the possibility that, once the investment decision is made, the existence of a patenting option may serve to increase the firm's chances for collecting monopoly rent on its activities. Put another way, the prior existence of patent protection may reduce the country's bargaining scope concerning the terms and conditions under which the investment can take place'[78] In this context patents far from providing a stimulus to foreign investment, appear to be a critical factor in blocking investments. 'Even recent studies in Australia and Canada of the economics of patent protection have been unable to point to a decisive economic justification for this form of intellectual property protection. Those reports recommended the retention of the patent system largely because it already existed.'[79] If this argument is true, it looks like the only thing TRIPs will do is to give manufactures a 20 year monopoly .

A few LDCs had patent protection, even in the pharmaceutical industry, prior to TRIPs. Examples are Kenya, Botswana and South Africa. However in these countries there was little technological transfer due to the fact that the patents were not worked in the countries. Company heads from industrialised countries indicate that their patents remained un-worked owing to the inadequate level of economic and

[77] Ibid, p 449-531
[78] P. Obrien, *Developing Countries and the Patent System: An Economic Appraisal,*[1974] 2(9), p. 33
[79] M Blakeney, *Intellectual Property and Economic Development,* Int. T.L.R [1998]1 pg 1

technological development of the patent-granting country.[80] This means that the patents were used exclusively to protect imports. Statistics show that 'At least 95 per cent of patents in developing countries are never used in domestic production i.e. there is no technological innovation and investment on the basis of these patents. It could be that the remaining 5% are the most valuable. However, the costs associated with the other 95% of patents in use thought the developing countries make it unlikely that the patent-granting country receives any net benefits.'[81] There is no reason why this phenomenon will change after the implementation of TRIPs given the fact that Article 27 of the Agreement comes close to encouraging the non- working of a patent in the country granting the patent. This article indicates that there should be no discrimination in granting of patents between import goods produced locally[82]. The TRIPs agreement may therefore lead to little technological transfer. This is a direct contradiction of its main objective of technological transfer, as declared in Article 7.

It has also been claimed that even if no production takes place in the country granting the patent, the fact of the grant may encourage investment[83]. However according to Obrien some statistics show a different story. 'Various summaries of questioners enquiries indicate that patents have little influence on the investment decision' [84]. It has also been argued that un-worked patents provide a social benefit to developing countries because the countries benefit through having information contained in the

[80]P, Obrien. (fn 78) at pp. 27-36
[81] Ibid p. 36
[82] This is in accordance with Article 111 of GATT on National Treatment to all products whether imported or domestic
[83] See W.R Cornish, (fn 9)
[84]P.Obrien, (fn 78) at p.33.

patent documents[85]. As such industrialised countries claim that Article 7 is fulfilled in developing countries simply by having the information in the documents. However the true nature of inventions is often not identified in patent documents. Inventors tend to cover up the true genius of the inventions in technical language. The TRIPs Agreement requires disclosure in the patent documents to a level that reasonably skilled worker can understand. However, 'the knowledge disclosed may bear scant resemblance to the skill levels in developing countries i.e. the patent information is useless without the corresponding know-how'[86]. A library is of no use if one cannot understand the language in the books. In addition to this, the technological know how which may be found in the patent documents could be obtained very cheaply through other channels. 'Since all foreign patents have previously been filed elsewhere, subscription to such publications as the *Gazette* of the United States patent office would suffice to keep up to date whilst avoiding the administration costs entailed in repeating the registration process at home. '[87].

One Canadian study shows no relationship necessarily between patents and investment in R&D. 'The replies to a questionnaire prepared by the Canadian Economic Council indicated that for 40 per cent of the companies concerned, the exits of patent protecting was of little or no significance in deciding to embark upon production in Canada; However 45 per cent replied that it was of 'fair significance'.[88] Leser indicates that 'overall there is no direct statistical association between the existence of patents and private R&D investment. Stronger patent laws are associated

[85] W.R. Cornish, (fn 9) 56.
[86] L.T.C,Harms. *Offering Cake for the south,* [2000] 10 E.I.P.R. p. 451.
[87] P, Obrien. (fn 78) at p.33
[88] Economic Council of Canada, *Report on Intellectual and industrial property* (Ottawa, January 1971) p.75

with more patent applications, but whether those inventions would be forthcoming even in the absence of intellectual property protection is not known with certainty'[89]

Thus on the issue of how far and to what extent patents provide an incentive for local R&D, no clear and unambiguous answer can be given. Though several studies show a close relationship between patent and R&D and technology transfer several others fail to reveal any. Penrose concludes that 'the presumption is strong that that the less-developed countries gain little or nothing and may even lose from granting patents on inventions developed published and primarily worked abroad. This presumption is strong but not conclusive. The less-developed countries want to develop their own industry. To this end, they need to absorb foreign technology from the industrialised world.[90]' Dr Sodipo agrees with Penrose and points out that a problem with the premise of technological transfer is that 'the evidence is equivocal, inconclusive or not cannot be generalised from one country to others'[91]

As indicated above Rapp argues that due to competition in the pharmaceutical industry increased patented protection does not necessary lead to increased pharmaceutical drug prices. However, the problem for developing countries lies in the fact that the level of income is very low and unemployment levels astronomical. As Dr Sodipo argues, despite competition in the pharmaceutical industry, western pharmaceutical companies are not able to sell drugs at prices that are low enough for

[89] Leser 1991:33,35-36. B, Dasgupta. *Patent Lies and Latent Danger,* http://www.epw.org.in/34-1617/sa3.htm. p. 3
[90] E. Penrose. *International Patenting and the Less Developed Countries,* [1973] Sept E.C.S, p.9
[91] B. Sodipo (fn 20) at p 60.

the citizens of developing countries to afford them and yet high enough for the companies to make a profit. Thus, notwithstanding the fact that a drug has other substitutes, the citizens of the developing countries will simply not be able to afford the newer and better versions of the drugs despite the competition. If TRIPs was not in place the generic producers of these substitutes would supply developing countries with much cheaper and affordable drugs. For example Bayer's Ciprobay is an antibiotic used to treat many infectious diseases. This antibiotic obviously has many substitutes. It is listed as an essential drug in South Africa as well as the Essential Drugs Model List of the WHO. In South Africa 'the state tender price per 250mg Ciprobay tablet (an anti-retroviral drug), is R2.93. The marked up retail price 250mg Ciprobay in India is R0.65 i.e. 4.5 times cheaper.'[92] Perhaps it is from these considerations that most authors in the anti-TRIPs camp conclude that on the implementation of TRIPs, drug prices in developing countries will inevitably increase.

Subramanain[93] investigated annual price welfare and profit effects consequent upon the TRIPs Agreement for some developing countries. 'Welfare and price effects were found to be negative although given the transitional period provided by the agreement and the extensive time required for the approval of a medicine, the effects would be felt 20yrs hence. Annual welfare losses for India ranged between $162 and $1,261 million and annual profit transfer to foreign firms was estimated between $101 and $839 million .'[94] The United Nations Conference on Trade and Development carried

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[92] Affidavit of Carmen Perez-Casas in *The Pharmaceutical Manufacturer's Association of South Africa and Others* V *The President of the Republic of South Africa.* *www.tac.org.za/drugcampaign/case/cn:4183/98* p. 5.

[93] Subramanian A. (1991) '*The international economics of intellectual property right protection: a welfare theoretic trade policy analysis*' World Development Vol 19 No 8. (August) pp. 945-956.

[94] UNCTAD Secretariat. *The TRIPs Agreement and Developing Countries,* UNCTAD/ITE/I. p. 62

out an investigation in1996 into the possible effect on prices for pharmaceuticals in developing countries on the implementation of TRIPs. ' Price effects were calculated for four different scenarios, taking into account the initial competitive duopolistic market structure and different price legalities and assertions with regard to the share of patented drugs in the total market of each country. Price increases estimated for patented drugs ranged from 5 per cent to 67 per cent.'[95].

What Rapp disregards is the fact that even if there are market forces at work in the pharmaceutical market, the effect of these forces in bringing prices down can be very strong in developed countries where the level of income is high but these forces will be negligible in developing countries. The citizens of developing countries are very poor as such they cannot afford drugs at prices, which are meant to recoup investment in research and development no matter how many substitutes there may be. The WTO has indicated that the solution to this price problem does not lie in doing away with patents in the pharmaceutical industry but in differential pricing. Differential pricing is when a drug is charged at different prices in different places according to the level of income. The WTO came to this conclusion after a meeting that took place between the 8th and 11th of April 2001, in Hosbjor, Norway. The meeting was attended by WTO and WHO representatives form both developing and developed countries . They agreed that differential pricing was not contrary to the provisions in TRIPs and was one way of ensuring that essential drugs could be afforded in developing countries.

[95] Ibid, p. 67

As indicated above, the greatest problem for developing countries is found where there are no substitutes for an essential drug, meaning that there is no competition and the prices are simply too high for them to be purchased in developing countries. There are some pharmaceuticals which have no close substitutes . This is the case with Retrovir (zidovudine), popularly known as AZT. AZT is used to treat patients with AIDS . It is in the case of such rare drugs where the patent holder can charge exorbitant prices which are unchecked by competition. Rapp suggests that 'any –anti competitive effect should be balanced against the therapeutic gain that results when a revolutionary new product appears'. The question here is how is this balance to occur if the millions in developing countries who have AIDS cannot afford the drugs and their therapeutic gains?[96]

In developing countries it is virtually impossible for AIDS patients to afford the anti-retroviral drugs. 'It has been estimated that the most effective combination of medicines to fight AIDS costs individuals in the United States $10,000 a year. However the average income in South Africa is less than $1000 a year'[97]. Without the TRIPs Agreement the South Africa government would be able to afford these drugs at a much cheaper rate from Brazil. ' The South African trade price per 100mg capsule of Glaxo SmithKline's Retrovir (Zidovudine) is R3.23. . The Brazilian trade price is R2.91 (1,46 times cheaper).'[98] However, under article 31 of the TRIPs agreement compulsory licensing of intellectual property rights in certain circumstances is possible. Compulsory licensing is when a government allows

[96] Harms equates Rapp's suggestion to that of Queen Marie Antoinette of France who asked her people to eat cake as they could not afford bread. See L.T.C Harms (fn 83)
[97] F. Wooldbridge, *Analysis: Affordable Medicines-TRIPs and United States Policies,*[2000]1, I.P.Q , as Obtained from westlaw , p.1
[98] Affidavit of Carmen Perez-Casas, (fn 92), p.7.

someone else to produce the patented product or process without the consent of the patent owner. South Africa is making preparations to implement the Medicines and Related Substances Control Amendment Act 1997. Article 10 of this Act allows for compulsory licensing of drugs in certain circumstances for the benefit of the public health. The details of this legislation and the dispute surrounding it shall be discussed in chapter four.

In the past the research that has produced the cure to killer diseases such as polio and malaria was done merely as a response to an urgent need of the human race. Scientists are currently searching for other compounds to alleviate the symptoms of AIDS. Although it has been claimed that 'substantial amounts of research for new produces that represent improved forms of therapy for AIDS would not be conducted without the incentive provided by the intellectual property protection system.'[99], it is not far fetched to say that this research would be taking place, albeit on a smaller scale, to alleviate the human suffering and death caused by AIDS. Patents are not the only incentive that scientist have to create new drugs.

Thus will greater patent protection mean pharmaceutical product prices will increase in developing countries.? Most likely yes. Do patents granted on foreign inventions to foreign patentees facilitate the transfer of technology, foreign skills and foreign capital? This is a simple question, but it has no conclusive answer. 'Most of the evidence indicates that patents are of little importance, but it is *possible* that in some

[99] UNCTAD Secretariat. *The TRIPs Agreement and Developing Countries,* UNCTAD/ITE/I. p. 51

industries and in some circumstances foreign patenting will promote technological transfer and its implantation in the local economy.'[100] Therefore the often quoted rationale for the implementation of the TRIPs Agreement that it would encourage technological transfer is only but a presumption with most evidence showing that it is not true. However as Penrose indicates some industries may just need patent protection in order to develop. As patents are very important in the pharmaceutical industry, the provision of stronger pharmaceutical protection in developing countries through TRIPs may indeed be a means of the development of this industry, the transfer of technology and its attendant investments. Whether or not this speculation is true will only be evident some years after 2005 when TRIPs becomes fully operation in developing countries. A closer look at the impact of TRIPs on the pharmaceutical industries of India and South Africa may provide us with a clue.

[100] E,Penrose. *International Patenting and the Less Developed Countries,* [1973] Sept E.C.S, p.9

CHAPTER THREE TRIPs and INDIA

3.1 India's patent law before TRIPs

> 'India is the best place in the world to manufacture pharmaceuticals; manufacturing costs are two-thirds of rich-country levels. It has good research staff, low wages rates and a potentially sizeable local market '
>
> Brian Tempest, president of Ranbaxy Laboratories ,India's largest drug maker.

The availability and price of pharmaceutical products is of particular importance in India. Sickness and disease are widespread and there is a great deal of poverty and unemployment. While it was a British colony India had a strong patent law, which was mainly put, in place to benefit the interests of British patent holders. As such 'Indian drug prices were among the highest in the world, partly due to the fact that 90% of the pharmaceutical market was controlled by foreign owned companies and India was completely dependant on Imports'[101]

After independence in 1945 India conducted two reviews of its patent system through two committees; the Tek Chand Committee and The Ayyangar Committee[102]. The Tek Chand Committee made several unsuccessful attempts to enact a Patents Act. The issues that dominated the debates were whether patents should be available for food, medicine and chemicals and if so whether product and process patents should be available. What was most evident in the parliamentary debates was the long-standing

[101] E,Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997], 19(11) E.I.P.R, p. 15

[102] Dhavan, Harris and Jain, ' Whose interest? Independent India's Patent Law and Policy', (1990) 32 JILI 429 p. 430

opposition of India to patents in the pharmaceutical industry. These issues also centred upon the work of the Ayyangar Committee. Its efforts were successful and it's work was rewarded by the passing of the Patents Act 1970.

The Indian Government was aware of the importance of having patent protection generally but also wanted to ensure that drugs were affordable. This act reflects the compromise that the government was prepared to reach. 'The government did not choose to discard patent protection but did choose to severely limit the availability of patent protection, particularly for inventions relating to food, medicine and chemicals.'[103] As shall be discussed below, the overall effect of the Patents Act 1970 was to allow almost no patent protection in the pharmaceutical industry. The same effect applied to the chemical and food industries. Due to very weak patent protection for pharmaceutical products, a very lucrative generic drug industry came up in India . Generic drugs are drugs which are about to reach the end of their patent life and which are manufactured by other companies without the specify permission or license from the patent holder. The provisions, which facilitated the growth of this industry, are relatively easy to pick out from the Act.

One of the most important provisions in the Act was sec 48(2). This Section made a distinction between.

process patents--a patent for a method or process of manufacturing an article or substance whereby the patentee gains the "exclusive right ... to use or exercise the

[103]E,Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997], 19(11) E.I.P.R, Obtained form westlaw p. 11.

method or process in India" and

product patents--a patent for an article or substance whereby the patentee gains the "exclusive right ... to make, use, exercise, sell or distribute such articles or substance in India".

Article 5 of the 1970 Act allowed for process patents but not for product patents for food, medicine and agro-chemicals.

Thus a person could gain a patent for pharmaceutical process but not for a pharmaceutical product. The 'process patent' for a particular medicine would be the actual physical process of making it and the combination of all the ingredients that the medicine is comprised of in specific propositions. These include for example medicinal plants, herbs, chemicals and other biological products as well as the technique of combining them in order to come up with the desired medicine. 'It was therefore, possible for an India pharmaceutical company to buy a 'process' of making a particular medicine by using cheap, local material. This way life saving drugs could be sold in India at a price that is one – twentieth of the price in the developed countries'[104]

The patent term for most inventions under the Act is fourteen years, which contrasts with the twenty-year term found in most western country jurisdictions. To make matters better for the India pharmaceutical industry, the patent term for pharmaceutical process is only seven years from the date of application or five years

[104] B,Dasgupta. *Patent Lies and Latent Danger,* http://www.epw.org.in/34-1617/sa3.htm. p. 8

from the date of sealing whichever is shorter. This is again much shorter than what the laws of most industrialised countries permit. In practical terms this seven or five year protection period for process patents amounted to no protection at all. This is because, 'on average pharmaceutical drug manufacturing processes take eight years to come into the market by which time , the patent protection in India would have expired'[105] . As such in some cases the India pharmaceutical companies did not even get a licence for the process from a foreign company as they could lawfully obtain it from any source once it was available in the market without permission from the right holder. This, combined with a notoriously slow court system means that, 'in effect almost no patent protection is available for pharmaceuticals in India '[106].

In addition to this sections 84-90 the Patent Act 1970 had very wide provisions on compulsory licensing.. Any person could apply for a compulsory licence where:

> 'the reasonable requirements of the public with respect to the patent invention have not been satisfied or where the patented invention is not available to the public at a reasonable price'[107].

India attempted to gain benefits from having patent protection by making it conditional on local working of the patent. If the patent holder did not comply with this requirement he would be required to licence the patent rights to local industries in return for compensation failure to which the government would grant the license. This licensing was an important measure that further weakened patent laws in India

[105] E,Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997], 19(11) E.I.P.R, p. 11.
[106] Ibid, p. 11
[107] Section 84 of India's Patent Act 1970.

'the Government took an interventionist approach in terms and conditions of the licensing Agreement and controlled royalty payments.'[108]

The overall result of the Act was a 'rapid decline in new applications from non-nationals and an even greater decline in domestic and foreign pharmaceutical patents applications The lack of patents protection, combined both high tariffs on bulk drugs and intermediates, were additional benefits for domestic drug companies. These measures resulted in foreign companies losing interest in India such that the India industry came to dominate the local market.'[109]. Thus the pharmaceutical industry in India flourished considerably depending solely on the weak patent rights for pharmaceutical goods and producing generic drugs for home use and export. . In 1997 it was concluded that India had 'the largest number of operating unites in the world.'[110] Further it was considered to be the world's fourth largest industry [111]. Its total value was estimated as $2000 million and was made up of both inland and foreign companies. . Chiefly the companies relied on the generic drug market and were very competitive in this market at an international level. The India drug industry had an international reputation as a reliable manufacturer of bulk drugs. . The most important result of the 1970 Act was that the cost of drugs in India were among the lowest in the world. Because these drugs were produced in India at a fraction of the cost of production in the developed countries, India became the source of cheap drugs for the developing world.

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[108] E,Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997], 19(11) E.I.P.R, p. Obtained form Westlaw p. 13.
[109] Ibid, p. 15.
[110] Ibid, p. 18.
[111] Ibid p. 15.

3.2 The negative effects of TRIPs on India.

The Indian pharmaceutical industry became profitable in the latter half of this century largely because of government controls, price ceilings, tariffs and lack of product patent protection as well as favourable treatment for India companies. The provisions of TRIPs and the measures brought about by GATT will see an end to most of these features.

E,Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India*

Before and during the Uruguay Round, the Indian population and the Indian pharmaceutical industry had different fears. The population, made up of a majority of very poor people, feared that the implementation of TRIPs would make drugs in India very expensive. The pharmaceutical industry feared that it would be displaced by multinational corporations which would gain a monopoly in India due to having a bulk, if not all, of the share of patented drug manufacturing .

Prior to TRIPs the industrialised countries were very unhappy with the patent law in India. The United States' pharmaceutical companies made great losses due to the cheap drugs sold worldwide by the India companies which they could not compete with. A report cited by the president of the Pharmaceutical Manufacturers Association, Gerald J. Mossinghoff claimed that in 'India alone, United States companies had lost two million dollars to the pirating of patents between 1980 and

1994?.[112] The multinational companies whose drugs were being copied and manufactured in India claimed that the reverse engineering and bulk production of their products amounted to theft.[113] The United States was determined to stop this theft in India.

The monopoly granted by western nations had enabled western pharmaceutical companies to make high profits. However the western market was increasingly becoming saturated. Developing countries such as India became potentially ideal markets for pharmaceutical products. A high rate of sickness combined with huge population, which were and are still rapidly increasing, resulted in high demand. In India 'the growth of population per year at present surpasses the entire population of a whole nation when countries in Europe or Africa are being considered. Just 10% of such a population represents a large market for goods and processes protected by patents even if the disparity of income remains great.'[114] However the lack of patent protection in India and indeed in many developing countries, meant that the pharmaceutical industries of the developed world lost out to the cheaper generic copies. It is hardly surprising; therefore that the Indian companies claim that one of the aims of the advocators of TRIPs was to make sure that the multinational pharmaceutical companies of developed countries had a significant if not total share in the markets of developing countries[115]. However those who pushed forward the TRIPs Agreement simply point out that they were forced to do so in order to protect

[112] E,Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997], 19(11) E.I.P.R, Obtained form Westlaw p. 15.
[113] Ibid, pp 1-22.
[114] M. Saurastri *'It's time for an effective patent regime in India'* MIP 1996/97 vol 65 pg 34
[115] B, Dasgupta, (fn 104) pp. 1-11.

their suffering industries[116]. Whatever the truth is, TRIPs contains provisions which may harm India considerably.

The lack of product patents for foods, medicines and agro-chemicals in Indian Law caused the most controversy in the international community. Under Article 27 of the TRIPs Agreement the distinction between 'process' and 'product' patents has been abolished. It is the product that is patented. The process is also implicitly patented at the same time. After 2005, if India decides to avoid trade sanctions by amending the 1970 Patens Act to comply with the provisions of TRIPs, pharmaceutical products will be protected by patents [117]. Thus before a twenty year period is over for each new pharmaceutical product, the products will have to be purchased from foreign companies. This situation has two possible consequences. Firstly drug prices will increase considerably and the local generic industry will go out of business, as it will be illegal to reverse engineer and produce patented pharmaceutical products. It is because of the possibility of these two serious consequences that India was up in arms against the TRIPs Agreement.

Under the 1970 Patent Act the average citizens in India could afford most drugs and Indian drugs were said to be five to thirty percent lower in price than they were in countries that allow product patent for pharmaceuticals.[118] From an analysis of detailed market data on patentable drugs in the pre-product stage in India, it is clear

[116] *The GATT Uruguay Round: A Negotiating History.*
[117] India has not as yet amended this law and is most reluctant to do so.
[118] For more on specific prices of pharmaceutical products in India after the TRIPs Agreement see. Mesevage (1991) ' *The carrot and the stick'- protecting U.S intellectual property in developing countries* ' 17 (2) Rutgers Computer and Technology LJ 421 at 422.

that 'a move to monopoly position, through TRIPs would entail welfare losses in the order of $33 million and an average increase in price in drugs of about 52 per cent'[119]. Under Section 84 of the Patents Act 1970 the India Government could grant compulsory licences if a drug was too dear for the average citizens to afford it. Compulsory licensing normally happens if a government deems an essential drug too costly or too short in supply. The government licenses local generic manufacturers to make it more cheaply. Section 84 states that if a 'patented invention is not available to the public at a reasonable price' anyone can apply for a compulsory licence. This will not be possible under the TRIPs Agreement. The Agreement does not provide for compulsory licences where products are expensive. It is inevitable that the TRIPs Agreement will result in a sharp increase in drug prices. This will impact heavily on India. As indicated in Chapter one, competition within the pharmaceutical industry may not serve to reduce prices in India.

Besides not providing for compulsory licensing where drugs are expensive, Article 31 of TRIPs lists a series of detailed provisions, which must be respected in regulating any use of the patent without the patent owner's authorisation. These provisions will severely limit the power of the Indian Government, to grant compulsory licenses. Among a host of other conditions, the patent not meeting 'the reasonable requirements of the public'[120] will not be enough to merit the granting of compulsory licences. Compulsory licences will only be granted if the person seeking the license has attempted to obtain a licence from the patentee unless it is in the case of national

[119] J.Watal, (fn 17), pg 300.
[120] India's 1970 Patent Act ,section 84.

emergency, extreme urgency or for public non-commercial use.[121]In other words the government is entitled to grant automatic compulsory licences only under these three circumstances. In addition, the licence can only be of a limited duration and scope.

According to the 1970 Act, the patent did not meet the 'reasonable requirements of the public' if it was not worked in the country. Therefore the Indian Government granted compulsory licences where a patent was not worked in India. This is no longer possible under the TRIPs agreement. Nowhere in the TRIPs Agreement is non-working of a patent in the country granting the patent a reason for granting compulsory licenses. In addition to this, as indicated in chapter two, a close reading of Article 27 shows an implication that local working of a patent is not necessary. Article 27 indicates that there should be no discrimination in granting of patents between import goods produced locally. 'The combined effect of Articles 27 and 31 is that local working of the patent by the owner is not required so long as importation of patented products 'is sufficient to meet local needs'[122] is provided. The Indian Government will have very little room to deal with un-worked patents in its territory. TRIPs will take away from India the advantages of having patents worked locally. These include employment and a certain level of profit brought about due to local production. Most importantly, Article 27 does not seem to lend much support to Article 7 which indicates that the main objective of TRIPs is technological transfer. This is a serious and most unfortunate contradiction. Technological transfer is not likely to take place if patents are not worked in the developing countries.

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[121] TRIPs Article 31 (b).

[122] M, McGrath. *The patent provisions in TRIPs: Protecting Reasonable Remuneration for Services Rendered or the latest Development in Western Colonialism?* , [1996] 7 E.I.P.R. p. 402

The Indian generic industry strongly relied on lack of patent protection while the western pharmaceutical industry strongly relies on patent protection. 'As a result of TRIPs the Indian industry will be required to compete on western industry terms and in legal environment to which it is a newcomer.'[123] An Indian committee working on patents laws estimates that most of the 10,000 local manufactures which now produce 70% of the county's drugs, would eventually go out of business once TRIPs is implemented. 'Local firms would be in danger of going out of business as better medicines monopolised by their inventors replace the drugs prescribed today .'[124] Their very existence and ability to make profits depends on weak patent laws. Once these are replaced by the provisions in TRIPs, a high percentage of the generic industry shall certainly be wiped out of the picture.

At present the generic pharmaceutical industry in India is run by foreigners .The presence of these foreign pharmaceutical companies run by foreigners promotes the transfer of technology and information to the scientific communities in India. This technology and information benefits the local companies greatly. However the implementation of the TRIPs Agreement will remove all these benefits. 'When TRIPs comes into force in India, it has been predicated that the local producers of products which can be patented will gradually find themselves cornered out of the market, and any hopes of fostering indigenous R&D will be smothered'[125]. In other words TRIPs will achieve the exact opposite of what it promised. Technological transfer will be

[123] E.Henderson,. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997], 19(11) E.I.P.R, p. 16

[124] The Economist, *'intellectual property. is theft'* 22nd January 1994 p. 63

[125] M, McGrath. *The patent provisions in TRIPs: Protecting Reasonable Remuneration for Services Rendered or the latest Development in Western Colonialism?* , [1996] 7 E.I.P.R. p. 400

reduced if not completely done away with. In fact, 'TRIPs will be the vehicle for frustrating development efforts in India and probably increasing the country's dependence on and indebtness to the industrialised countries.'[126]

Another controversial provision of TRIPs, as far as India is concerned, is Article 34. The Article reverses the burden of proof in patent cases: it is for the defendant to prove that an identical pharmaceutical product has been produced by a process other that the patented one. The defendant is presumed guilty until he proves himself innocent. Article 29 of TRIPs indicates that the appropriate description must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the relevant art. However as indicated above, a person skilled in the relevant art in an industrialised country may be much more skilled than 'a skilled person' in a country still developing its industrial base. For this reason section 10(4) of India's 1970 Act indicates that the description, in the patent documents must be sufficient to enable a person in India 'possessing average skill in, and average knowledge of, the art to which the invention relates to work the invention'. This provision will obviously have to disappear in compliance with Article 29 of TRIPs by the year 2005 meaning that India will have a great deal of information from patented medicines which she has no skill to work. It is important to remember here that most Indian scientists in India who may be 'skilled in the art' are working in foreign countries[127].

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[126] ibid p. 400.

[127] Prof Sachs indicates that many of the scientific and technological breakthroughs are made by poor-country scientists working in rich-country laboratories. Indians accounts for a great number of these scientists. See J.Sachs, *Helping the World's Poorest,* The Economist August 14th 1999 pp 15-20

Reverse engineering has effectively been denied to the pharmaceutical industry in India TRIPs . 'In the case of Japan and other east Asian countries 'reverse engineering' was nearly always the first step towards technological self-sufficiency, a path that India can no longer take.'[128] As indicated in chapter one every developed country has gone through a three stage development process with the second stage being the stage where the economic development of the country is fuelled by the pirating of intellectual property . Some established companies such as Microsoft even went through this important second stage. It is common knowledge that the first windows program was designed after some information had been 'stolen' from another company called Apple. Prior to TRIPS India had not yet reached the third stage where patent protection is important to its development as it could not yet produce its own world class inventions. 'If the country has not reached this point, the cost of intellectual property protection will outweigh its benefit and the protection scheme, if adopted, will be enforced only sporadically'[129]. India, like many developing countries, has been denied an important stage of development and only time will tell if it will be able to develop without going through this important stage.

In India a patent was protected as long as they were worked in the country for a considerable period. If it was not worked then the compulsory licensing measures would be taken and the right holder would be compensated. 'Before TRIPs, Indian

[128] B,Dasgupta. *Patent Lies and Latent Danger,* http://www.epw.org.in/34-1617/sa3.htm. p. 7
[129] Kirchanski: *Protection of United States Patent Rights in Developing Countries; United States Efforts to Enforce Pharmaceutical Patents in Thailand.* [1994] 16 Loyola LA International and Comparative Law Journal. P. 589

law on intellectual property strikes one as having already found a reasonable balance between fair remuneration and promoting the national interest in development. The 1970 Act focused on the public interest rather than on the protection of private property interests'[130]. Its underlying philosophy is expressed in section 83, which states:

' ... patents are granted to encourage inventions and to ensure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay

... they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. '

'The rationale underpinning Indian patent law is that the government grants exclusive rights to exploit an invention on a quid pro quo basis. In return for exclusive rights the patent owner works the invention in India leading to the establishment of a new industry, increased employment and capital. Patent law centers around this bargain--exclusive rights in exchange for knowledge and input into the local economy.'[131] This bargain has now been replaced by an Agreement, which on the face of it seems to be leaning very much on the side of the industrialized countries and which may have adverse negative effects on India.

Article 65 sets down transition periods for the implementation of substantive changes to domestic law, which are required by TRIPs. India had ten years to implement the substantive TRIPs provisions into domestic law. This means that it will be able to

[130] M. McGrath, (fn 122), 402
[131] Elizabeth,Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997], 19(11) E.I.P.R, obtained from westlaw, p. 14

prohibit pharmaceutical product patents until January 2005. 'However India had to comply with some minor TRIPs provisions before then, including the requirement that it had to accept patent applications by January 1 1995'[132]. This is yet another disadvantage to India as it has to suddenly apply intellectual property law, which it is not economically, socially or intellectually ready for.

3.3 The positive impacts of TRIPs on India.

> India should realise the great potential it has. The country posses the third largest number of scientific personnel in the world and could become a strong force in the world market for drugs and medicines. But the present inhibitions and shortcomings in the Patents Act 1970 only help in making *Bonsois,* i.e. rather decorative white elephants, of its vast scientific community
>
> Manish Saurastri *'It's time for an effective patent regime in India'* MIP 1996/97 vol 65 pg 34

Just as there are bound to be disagreements between Third World countries over the appropriate stance that should be taken in trade negotiations, countries may be divided internally as well. Although farmers in India are usually assumed to be vehemently opposed to TRIPs, Bhat[133] reports that one farmers' group in that country supported TRIPs in hope of better trade prices for certain commodities whose prices were kept low by government interventions such as monopoly purchase programmes and import substitution'[134] Despite all the negative effects of the TRIPs Agreement to the generic

[132] ibid p. 4
[133] Bhat,1996 as cited in G. Dutfield, (fn 18), p. 4
[134] Ibid, p. 5

industry and community at large, within India there is some support for the TRIPs Agreement.

Surprisingly this support is coming from the pharmaceutical industry itself. Many local pharmaceutical firms 'support extending process patents protection from the current seven years to twenty years as the TRIPs Agreement stipulates, since their own processes are being stolen by other local firms'[135]. There are firms in India which need protection for their own inventions. The 1970 Act caused a decline in both local and foreign pharmaceutical companies seeking patents in India. The guarantee of protection of rights in TRIPs may encourage India scientists to invent new drugs. 'India has a highly educated labour force. Our R&D and technological capabilities in select fields are not inconsiderable and the scientific and technical manpower in India is the third largest in the world. The talents and creativity of the components of this manpower cannot bloom in an intellectual wasteland devoid of incentives and protection....It is for this reason above all other that we need a strong sand effective patent regime, free from the obstacles that dog it at present'[136]

One of the possible things that may happen in the Indian pharmaceutical industry is that the India pharmaceutical industry may develop from a generic production industry to a research and manufacturing industry. As Abuja[137] claims 'once the various controls on the drug industry are removed and the Patent Law amended, the big Indian drug companies expect to grow tenfold in the coming decade. All the top

[135] The Economist, *Brand X is Better* , (1 July 1989), p. 58
[136] M. Saurastri *'It's time for an effective patent regime in India'* M.I.P [1996/97] 65, p. 33
[137] N. Abuja, *GATT and TRIPs – the impact on the Indian pharmaceutical industry.*

50 Indian drug companies have plans to upgrade their R&D facilities to accommodate new products and process. Most Indian companies are actively seeking joint ventures with British, Israeli, South African and American companies to manufacture and market new as well as generic products '[138]

In any case one of the arguments that the Unites States had, at the advent of TRIPs, was that India could support a number of large research based pharmaceutical companies. It has the expertise and the infrastructure to do that. The same plants where bulk generic goods were produced can be used to produce drugs researched by the many India scientists who work abroad and at home. Creation of such companies will create jobs to the many unemployed people in India and develop a profitable export market. 'It may also lead to increased research and development in India. If patent protection were to foster a strong research based industry then this would be of considerable benefit to local skilled workers. Stronger protection may give incentive to local scientists to invent rather than copy. Manish points out that 'a nation is not healthy if its creativity was not fully taken care. The 1970 Act inhibits, a good many number of worthy inventions from seeing the light of day'[139]. From the evidence it seems that 'the day' for these inventions has now arrived with the introduction of TRIPs.

[138] Ibid p. 32
[139] M. Saurastri, *'It's time for an effective patent regime in India'* MIP [1996/97] 65 p. 33

This challenge of transforming Indian drug firms from copycats to innovators is already being carried out by a number of India drug companies. From a recent article in the economist[140] it is reported that one Dr Anji Reddy's Hyderid based company has already come up with inventions of its own 'It has licensed two diabetics drugs to a Danish firm, which is testing them on human subjects '[141]. Another firm called Ranbaxy has turned from straight copying to finding other ways of delivering generics. Ranbaxy is 'targeting difficult-to-make products; and it is innovating, specialising in new ways to control the release of a drug into a patient's system and thus reduce the number of times he must take it.'[142] This evidence seems to verify the claim that 'protecting intellectual property provides the incentive to search for new, improved products or new uses for old products.'[143] If other companies follow the footsteps of these two pioneers then India will benefit as a whole. The other group of people who will benefit are the research scientists who will now be much needed at home and thus will not have to immigrate to work in the cutting edge pharmaceutical industry. 'Once India develops a viable and competitive world class pharmaceutical industry, then there will be more winners that losers '[144].

Indian scientists have argued that the Indian Government should subsidise any losers as 'this would be a small cost in comparison with the benefits which will result from

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[140] The Economist print edition, 20th September 2000, *Generic Genius*, obtained from www.theeconomist.com pp. 1-3
[141] Ibid p.2.
[142] Ibid p.3.
[143] R. T. Rapp , Richard P. Rozer. *Benefits and Costs of Intellectual Property Protection in Developing Countries,* [1990] JWT 75, p. 95.
[144] E, Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997], 19(11) E.I.P.R, p. 18

TRIPs'[145]. If the Indian government can afford to do this then this would indeed be an amicable solution. However the chances are slim given that India is a developing country. There is no doubt that the government would rather spend its limited resources on other ventures rather than on subsidizing manufactures of generic drugs whose companies are suffering due to the introduction of the TRIPs agreement.

There is even a flicker of hope as far as drug prices are concerned. Taking into account the transactional period of the TRIPs agreement there will be absolutely no impact on the price of new patented drugs on the India market until 2005 'not more that 15 percent by value of the India market will be covered by the new patents sometime after 2005 and the remaining 85 per cent of the market will continue to be exposed to the full impact of generic competition'[146] Most of the essential drugs made by India companies at low prices will have been in the world for well over 40 years. These range from essential and well-known drugs like panadol, anadin, cough syrups to life saving drugs such as malaria tablets. Thus India drugs companies *will still be in business* if they choose to continue producing these drugs. Drugs are not 'non-perishable' goods which need to be changed every 7 years or so. The cheap prices of the drugs produced in India will be no match for the expensive prices in industrialised countries and as such will still be an important export for India to other developing countries.

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[145] Elizabeth,Henderson. *TRIPs and the Third World: The Example of pharmaceutical patents in India,* [1997], 19(11) E.I.P.R, p. 18

[146] M. Saurastri, (fn 139), p 34.

Despite a number of Bills being put before parliament since 1994 to amend the Patents Act 1970 no amendments have yet been passed. The Indian government has stated, however that when passed, the amendments will take effect retroactively from January 1995[147]. Despite the fact that India is a signatory to TRIPs, there has been widespread political resistance in India to any attempts to implement TRIPs in domestic law. In August 1996 The Hindu reported that the government was to take a 'go slow' approach. 'In the meantime the United States has been placing considerable pressure on India to comply with its obligations'[148]. The United States has brought a complaint against India before the WTO for failing to amend its patent laws and in 1996 it placed India on a priority watch list under special 301. India has until 2005 to implement the agreement or face serious trade sanctions. India will eventually have to implement TRIPs. This implementation will have both positive and negative effects in India. It remains to be seen which of the two will be the overall effect.

[147] The Hindu January 1995 as cited in E. Henderson, (fn 11) p.8
[148] Ibid, p. 4

CHAPTER FOUR : TRIPs and SOUTH AFRICA

4.1 Too much protection – drugs too expensive

> 'Protecting human life must take precedence over protecting intellectual property'
>
> Carmen Perez-Casas, Coordinator for access to Patented Medicines in the organisation Doctors without Borders (Medecins Sans Frontieres-International) .

AIDS was discovered twenty-one years ago and has now become the world's greatest pandemic. An estimated 36 million people are infected with HIV and another 22 million have died form AIDS so far. An estimated 16,000 new infections occur everyday worldwide. Based on current trends AIDS death will exceed those associated with the Black Plague of the 14th century by the year 2004 [149]. When AIDS was first discovered there was no treatment for it. Through a lot of tireless research scientists made a great breakthrough in the mid 1990s when they developed a highly active anti-retroviral therapy (HAART), a treatment cocktail of anti-retroviral drugs. 'Since the advent of HAART the disease has been transformed into a treatable and chronic condition for a significant proportion of those with access to this treatment'[150].

Since HAART was such a new and extremely important discovery it was patented immediately and is sold at exorbitant prices with no chance of the prices going down

[149] Harvard University. *Consensus statement on Antiretroviral Treatment for AIDS in poor countries.* http//www.Harvard.edu
[150] Ibid, p.3

in the short run as it has no competing drug. Those who can afford it are mainly found in wealthy countries which have governments whose budgets are able to subsidize prices for those there, who cannot afford them .As such in wealthy countries, there has been dramatic success in the fight against HIV/AIDS largely through the use of antiretroviral therapy. Those with access to this therapy have a better quality of life and a longer survival span. Yet despite this success, anti-retroviral therapy remains largely inaccessible to the 95 percent of those suffering form AIDS who live in low-income countries. In the poorer countries of sub-Saharan Africa and other affected parts of the world, HAART remains almost completely unavailable. It is estimated that only around 10,000 of Africa's 25 million HIV-positive can afford HAART.[151] There are soaring death rates from HIV/AIDS in these countries. South Africa is no exception.

It is estimated that 4m citizens of in South Africa are infected with AIDS (out of a population of 43million). It is true to say that the higher the percentage of people with AIDS the higher the percentage of uninfected people who may get infected in the future. In South Africa the number of HIV infected people who die every year has been estimated to be 400,000[152]. If these focuses are correct the disease will send 4million South Africans to an early grave in the next ten years. 'If the pessimists are right, it will have killed as many as 6million by 2010 when the epidemic is expected to reach its peak. That would mean that AIDS would have claimed as many as Hitler's Holocaust, in South Africa alone'[153]. This high death rate has been attributed to the

[151] UNAID as citied in Harvard article (fn 149) p.2
[152] Ibid, p. 2
[153] John Grimond, *Africa's great black hope,* The Economist print edition February 22nd 2001, obtained from www.theeconomist.com

fact that most of these people cannot afford the expensive medicines that are available which could be able save their lives or give them a longer and better quality of life.

South Africa being a member of the WTO is a signatory of the TRIPs Agreement. As such, South Africa has to protect the patents found in the HAART therapy. It has been pointed out that 'if the patents owned by American and other multinational pharmaceutical companies are strictly enforced, AIDS patients in South Africa will not receive treatment and will continue to die. Without such patent protection the relevant drugs could be profitably produced in South Africa at a cost of $200 per patient per year'[154]. It currently costs $10,000. This is an outrageous price given that the average income in South Africa is less than $1000 per year[155]. Patients are dying miserable deaths when anti-retroviral drugs are available in chemists and hospitals across the country. The only way patients can get drugs is if they participate in drug trials. At presentations to the South African Parliamentary Committee on Health on the 13th of May 2001, one HIV patient woman, Fagmida Miller, explained that she was on clinical trial. Her viral load was undetectable and her health was good. This was *the only way* that she could get treated for HIV.[156]

TRIPs has a number of rules which limit the rights of patent holders in certain circumstances. As we have already seen, some of them are found in Article 31, which allows for other uses of a patented invention without the authorisation of the patentee where the law of the relevant member state so permits if a number of conditions are

[154] Frank, Wooldbridge. *Analysis: Affordable Medicines-TRIPs and United States Policies,*[2000]1, I.P.Q p. 2.
[155] Ibid, p. 1
[156] Zackie Achmat, *Hearings on HIV/AIDS Treatment Access at the South African Parliament 9 and 10,* http://www.tac.org.za/parlhear.txt

complied with. These 'other uses' include compulsory licences which can be taken advantage of 'in the case of a national emergency or other circumstances for extreme urgency or in cases of public non-commercial use'[157]. Another rule is found in Article 6 which permits parallel importing. Parallel importing is when a country imports a patented drug from another country where it is sold for less than the price found in the importing country.

In an attempt to find a cheaper means of obtaining drugs South Africa took advantage of these two provisions the South African government made legislative changes to its patent laws. In 1997 it amended section 15c of the South African Medicines and Related Substances Control Act 1965. The amended section allowed compulsory licensing and parallel trading and is embodied in Article 10 of the South African Medicines and Related Substances Control Amendment Act 1997. When the proposals to pass this Act were made public, the United States government, The Pharmaceutical Manufactures Association and 40 pharmaceutical companies including Glaxo – Welcome and Smithe Kline Beecham (the plaintiffs), brought an action against South Africa. The case was titled *The Pharmaceutical Manufacturer's Association of South Africa and Others* V *The President of the Republic of South Africa*[158] and was lodged in South African courts. The plaintiff's claim was that the provisions in article 10 of the 1997 act were unconstitutional and violated certain provisions of the TRIPs agreement. More specifically the plaintiffs argued that sec 15c 'violates article 27 and 28 of TRIPs and does not seem to have paid sufficient

[157] Article 31(b) of TRIPs
[158] The High Court of South Africa (Transvaal Provincial Division), Case number 4183/98

attention to article 6 and 31 thereof.'[159]. The case 'provoked hysterical claims on both sides with drug companies accusing the government of patent piracy and AIDS activists accusing the drug firms of genocide'[160]

After many deliberations and a three-year case, the multinational companies dropped the case in April 2001. It is clear that massive pressure from an outraged international public was the reason why the case was dropped.[161] As such compulsory licensing and parallel importing of essential unaffordable drugs is permitted under South African law. The outcome of this dispute has great implications but before we go into that it is important for us to look into some of the arguments put forward by both sides. This dispute is a good illustration of TRIPs at work. It presents us with a good opportunity to examine the various provisions in TRIPs, which allow restrictions on intellectual property rights. These provisions are of particular importance to developing countries.

[159] Frank, Wooldbridge. *Analysis: Affordable Medicines-TRIPs and United States Policies,*[2000]1, I.P.Q, p6
[160] The economist print edition, *A war over drugs and patents),* March 8th 2001, obtained form www.theeconomist.com. p.2
[161] There were numerous letters and editorials written across the glob condemning the plaintiff's . John Grimond, condemned the plaintiff's actions and termed them as modern barbarism. See John Grimond, *Africa's great black hope,* The Economist print edition *Africa's great black hope,* The Economist print edition

4.2 The 1997 Act and its criticisms

> 'If drug companies call compulsory licensing theft, then we will call AIDS profiteering murder'
>
> Zackie Achmat, *Hearings on HIV/AIDS Treatment Access at the South African Parliament 9 and 10*, http://www.tac.org.za/parlhear.txt.

What is interesting about South Africa is that although it is a developing country, it had strong patent laws even before TRIPs. These laws were put in place during the apartheid era and were meant to protect inventions made by the white minority. As indicated above the amended section is section 15 c of the Medicines and Related Substances Control Act 1965.

The Section is sub headed "measures to ensure supply of more affordable medicines" and provides that;

"The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may--

(a) not withstanding anything to the contrary contained in the Patents Act 1978 (Act No. 57 of 1978) determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend in relation to acts in respect of such medicine which has been put on the market by the owner of the medicine or with his or her consent;

(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but

which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported

(c) prescribe the registration procedure for, as well as the use of the medicine referred to in paragraph (b)."

The plaintiffs claimed that the provision gave broad unspecified powers to the South African Minister of Health. A closer look at the wording in the first sentence of the provision shows the origin of this claim, which may be true. However the claim that the health minister 'would be able to grab patented ideas without proper legal authority', seems to be rather far fetched as the 1997 Act would be a legal document passed under the proper law of an independent state.

A much more credible argument was that the patent holders rights would be taken away from them without adequate compensation. The 1997 Act does not cover compulsory licensing to the detailed extent required by Article 31 of TRIPs. The article prescribes certain strict conditions which the statute of a member states permitting compulsory licensing. One of the conditions is that 'the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization'[162] The South African Act does not seem to give the right holder any compensation and the plaintiffs were perturbed about this.

[162] Article 31 (h) of TRIPs

South Africa defended itself on this point on by indicating that 'the requirement of just and equitable compensation is derived form Article 25 of the South African Constitution, which guarantees property rights'[163]. As such any right holders whose products were compulsorily licensed would be compensated by decree of the South African Constitution.

Article 31 also indicates that the statute of a member state shall also have regard to the fact that any use shall be non-exclusive, non-assignable and 'shall be liable to be terminated if and when the circumstances which led to it cease to exist'[164]. An examination of the amended section does not reveal any attempt to prohibit compulsory licensing that does not comply with these three conditions. This caused further consternation to the plaintiffs. A further bone of contention originated from Article 32 of the TRIPs Agreement, which states that there shall be a judicial review facility available, i.e. an appeal, for any decision to revoke or forfeit a patent. The amended Act provides no legal basis for a judicial review.

So South Africa was criticised for directly contradicting its duties under TRIPs by not complying with Article 31 and 32. It was also attacked because of parallel licensing. The plaintiffs argued that although parallel importation of copyrighted goods is lawful under most countries legislations including the United States, it was 'inappropriate to apply the doctrine of exhaustion to patents'[165]. In some jurisdictions, once a right

[163] Frank, Wooldbridge. *Analysis: Affordable Medicines-TRIPs and United States Policies,*[2000]1,I.P.Q, pg 103-111
[164] Dr Peter, L. Kolker. *TRIPs Agreement Patent Protection,* Pg 30
[165] Frank, Wooldbridge. *Analysis: Affordable Medicines-TRIPs and United States Policies,*[2000]1,I.P.Q, p 6

holder sells or exposes his goods to a market he is said to have exhausted his intellectual property rights and his goods can be exported to other countries without his permission and sold at a cheaper prices. This is termed as the doctrine of exhaustion of patents.

The issue of parallel importing was one of the most contentious issues in the TRIPs Agreement. This is because the economies of developing countries such as Hong Kong and Singapore depend to a great extend on parallel exporting. For parallel trading to occur the Intellectual Property rights have to be exhaustible. Exhaustion of rights would mean that once a product is out on the market in one WTO member, the owner of the intellectual property right on this same product in another WTO member, would not be able to prevent the importation of that product into that other member and subsequent marketing there. 'From the right holder's point of view, this doctrine would be a severe, almost devastating problem. It would undermine the interests of the holder of the intellectual property right who sought to market his product internationally'[166]. It is for these reasons that the developed countries whose citizens would be the holders of most intellectual property rights did not want the introduction of parallel trading and international exhaustion of rights.

As this issue was so hotly contested in the negotiations leading to TRIPs, it is no surprise that there are divergent views as to whether or not TRIPs prohibits parallel importation or international exhaustion of intellectual property rights. Article 6 of

[166] Dr Peter, L. Kolker. *TRIPs Agreement Patent Protection,* P. 31

TRIPs does not prohibit members from following their national laws on the question of parallel imports or exhaustion of intellectual property rights as long as national treatment and most-favoured nation (MFN) treatment are accorded. The article goes on to say that 'nothing in this Agreement shall be used to address the subject of exhaustion of intellectual property rights'[167]. Some authors, such as Weismann, argue that a simple reading of Article 6 indicates that member countries are not prohibited from practising parallel trading and exhaustion of rights.

On the other hand others[168] argue that Article 6 removes the subject of parallel importing from the jurisdiction of the dispute settlement process. This argument goes on to say that TRIPs has different provisions on parallel importing for different intellectual property rights and does not commit itself to either condemning or permitting parallel importing as a whole. In the case of patents, it has been argued that 'notwithstanding the footnote to Article 28, the substantive provision, allowing the right to exclude third parties from the right of importation, along with that prohibiting any discrimination on grounds of whether the product is imported or domestically produced, sets out an obligation prohibiting parallel imports.'[169] Therefore it is arguable whether parallel trading and international exhaustion of intellectual property rights is compatible with TRIPs. This uncertainty as to whether or not TRIPs prohibits parallel trading has been identified, by Weismann,[170] as one of the loopholes in TRIPs which developing countries can take advantage of. Given this situation, the parallel

[167] TRIPs article 6
[168] Strauss, *TRIPs and Patent Law,* in Beier and Schriker (eds.) , *From GATT to TRIPS – The Agreement on Trade Related Aspects of Intellectual Property rights.*
[169] J. Watal, *The TRIPs Agreement and Developing Countries,* p. 283
[170] R, Weismann, *A Long Strange Trips: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules and the Remaining WTO Legal Alternatives Available to Third-World Countries,* University of Pennsylvania Journal of International Economic Law, Winter 1996, Vol. 17, pp. 1069-1125, Weismann has a particularly radical view on the loopholes in the provisions on patents in TRIPs .

importing provisions in the Medicines and Related Substances Control Amendment Act 1997 may or may not be compatible with the TRIPs agreement and only a detailed interpretation of Article 6 and Article 28 will be able to settle the matter.

The plaintiffs in the South African dispute feared that if the drugs were compulsorily licensed in South Africa they would be exported to developed countries and to the more lucrative private market in South Africa at very cheap prices.. In an indirect support to of the plaintiffs point, 'the view is adopted in paragraph 71 of the Report of the House of Commons Trade and Industry Committee "Trade Marks, Fakes and Consumers", H.C. 380, that the nature of the pharmaceutical market means that any move towards international exhaustion of intellectual property rights would have severe consequences. It would prevent pharmaceutical companies from selling products at low prices to third world countries for fear of their re-importation into developed countries where prices were higher'[171]. Frank[172] suggests a solution to this problem by suggesting that 'if AIDS medicines are compulsorily licensed in South Africa (or in any of the developing countries for that matter) there is some ground for thinking that the exportation of such medicines ought to be prohibited'[173]. The other way of thinking about this 'problem' is for the plaintiffs to realise that the rich minority in South Africa or any other country that is developing is purely a minority and if this minority does have access to the cheaper drugs the profits that the companies may have made from selling the drugs at their high market prices is really negligible.

[171]Frank, Wooldbridge. *Analysis: Affordable Medicines-TRIPs and United States Policies,*[2000]1, I.P.Q p. 6
[172] Frank, Wooldbridge *Analysis: Affordable. Medicines-TRIPs and United States Policies,*[2000]1, I.P.Q , 103-111.
[173]Ibid, p. 7

Had this case come to full trial South Africa may have been forced to change some of the most important provisions in the Medicines and Related Substances Control Amendment Act 1997. Although South Africa claims that the Act is compatible with TRIPs there are a few areas where this seems to be a falsity. However, as the case ended prematurely South Africa has been given the go ahead by the international community to implement a law that may not be compatible with TRIPs. The outcome of the dispute has many important implications.

4.3 The consequences of the outcome of the dispute

> Parallel importing will allow South Africa to import desperately needed medicines from countries where they were available for far less-than a drug company would charge in South Africa. Compulsory licensing will reduce the price of drugs by as much as 90 percent'
>
> L.J.Davis, *A Deadly Dearth of Drugs*, Mother Jones, January 2000

The first and direct impact of the passing of the Medicines and Related Substances Control Amendment Act 1997 will be that cheap drugs will be available for South Africa patients who previously could not afford them. These are not necessarily only AIDS drugs but also any drugs which are needed in 'certain circumstances so as to

protect the health of the public'[174]. This will include drugs for serious conditions such as cancer or even malaria. . An important example is Ceftriaxone. This drug is needed for the treatment of severe infections such as pneumonia or septicaemia. 'The South Africa trade price per 1mg vial of Roche's Rocephin (cefttriaxone) is R136.18 while the Rocephin trade price in Spain is R85.24 (1.6 times cheaper).[175]

Harvey Bale the head of the International Federation of Pharmaceutical Manufacturer's Associations was worried about the precedent that a defeat for the drug companies in a South Africa court would set[176]. His fears that other countries which may have profitable markets among their rich minority will follow the lead and alter their patent legislation has come true with a number of developing countries following South Africa's lead and amending their laws to allow for compulsory licensing and parallel importing of drugs which their citizens need and cannot afford.

In the case of Brazil, Harvey Bale's fears had become a reality long before he made them public. Brazil had actually amended Article 68 of its Patents Act 1968 in 1999.This amendment was almost identical to the South African Amendment. Article 68 allows the Brazilian government to grant compulsory licences in matters of national emergency and other special circumstances waiving the patents rights in order to get . The United States lodged a trade dispute with the WTO in Geneva in June 2000 claming that Article 68 of Brazil's patent law breached the rules in the TRIPs Agreement. 'The dispute had become a symbol of perceived intimidation by

[174] Medicines and Related Substances Control Amendment Act 1997 sc 15c
[175] Affidavit of Carmen Perez-Casas ,(fn 92), p.7
[176] The Economist print edition, (fn 160) p.4

the US and Pharmaceutical multinationals against developing countries that sought to obtain cheaper and wider access to essential medicines'[177]. On the 25th of June, 2001 the United States withdraw this dispute while Brazil pledged to consult with American companies before it applied compulsory licenses against them. The withdrawal of this dispute by the United States is most probably a direct consequence of its 'defeat' by South Africa just a month before. Public outrage surrounding the dispute with Brazil is also a reason for the withdrawal.

Malawi is making plans to adopt new patent laws permitting compulsory licensing and parallel importing. In Malawi 'only 30 persons out of 800,000 HIV –positive individuals currently receive anti-retroviral drugs'[178] .It may be predicted that almost all developing countries will soon introduce Acts which are identical to the South African and Brazilian ones in the next few months. Most people in these countries simply cannot afford the drugs they need to survive. 'The crisis of disease facing developing countries is dire. Every year malaria, tuberculosis and AIDS kill around 6 million people, almost all of them from developing world'[179]. Africa makes up 75% of what is termed as the developing countries. The continent accounts for around 80 percent of all HIV-infections in low income or high prevalence[180] countries. At the end of 1999, The United Nations Agency on AIDS (UNAIDS) estimated that 24.5 million of Sub – Saharan Africans were living with AIDS. There are roughly 5 million more HIV-positive individuals in other developing countries, outside of

[177] Peter Capella , *Brazil wins HIV drug concession from US* , The Guardian Tuesday June 26th 2001, http://www.guardian.co.uk/aids/story/o,7369,512651,00.html
[178] Harvard University, (fn 149), pg 7
[179] M.Moore, *Countries must feel secure that they can use TRIPs' flexibility,* www.wto.wrg/english/new-e/news01-eldg-trips-medicines-o18620.e.htm, p.1
[180] See the United Nations Agency for AIDS report 1999 .Low-income countries are countries with an income of <$755 per year while high prevalence countries are countries with > 2% of adults infected. ,

Africa.[181] 'In addition to tremendous human suffering the pandemic has become a major cause of social, political and economic instability.'[182] Africa will not pay for the expensive drugs that are available and will simply implement laws that allow compulsory licensing and parallel trading

Kenya introduced just such an Act in June 2001. The Industrial Property Act 2001 is the Act in question and was implemented in Kenya mainly to comply with the requirements of the TRIPs Agreement. Having granted patent rights to an invention which is 'new, involves an inventive step and is industrially applicable'[183], the Act allows for parallel trading and international exhaustion in section 58 (2) which reads; 'the rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya by the owner of the patent or with his express consent'. Section 58 (5) of the act allows for compulsory licensing by indicating that 'the rights under the Act shall be limited by the provisions on compulsory licences for reasons of public interest'. The reasons for introducing these provisions were identical to the ones in South Africa; 'to allow for cheaper medicines which are required for human life, especially on the HIV/AIDS and the ones the doctors call opportunistic diseases, as well as malaria.'[184]. 2.2 million Kenyans are afflicted with AIDS. The disease was declared to be a national emergency in 1999.

[181] These include 4.7 million in India, South and Southeast Asia (of which 3.7 million are in India) and around 350,000 in the western Hemisphere (mainly Haiti and the Dominican Republic
[182] Harvard University, (fn149) p. 1
[183] The Industrial Property Act Sec 22
[184] Mr Biwott, Hansard, Parliamentary Debates On the Industrial Property Bill, June 12th, 2001 p.1040

In much the same way as the South Africa Act the Kenyan Act does not mention remuneration of the affected right holder, it is not clear whether the compulsory licences will be non-exclusive and non-assignable and there is no sign of a provision for allowing judicial review if a patent is compulsory licensed. There seems therefore, to be evidence that The Industrial Property Bill 2001 does not comply with the provisions in TRIPs. However the affected pharmaceutical companies have said nothing and will probably not say anything. The effect of the South Africa dispute was literally to silence them. The fact that these parliamentary Acts of South African and Kenya are not TRIPs compliant does not seem to be bothering the WTO either. The Director –General of WTO welcomed the end of the South African dispute by sating that, the dispute clearly shows TRIPs should be as a means rather than a hindrance of ensuring that cheap drugs find their way to the developing countries. Perhaps he should at the same time heed the demands currently being made by developing countries to make the compulsory licensing provisions in TRIPs less strict and converge a group of negotiators for this very purpose.

The compulsory licensing provisions in TRIPs are considered by developing countries to be too strict. They are certainly stricter than they are under the Paris convention.[185] It is has been claimed by some writers that the one set of provisions which USA was relentless about was the compulsory licensing provisions. Penrose indicates that 'Article 31 was practically written by the United States International Trade Commission'[186] and that they were put in place predominantly to stop what the developed countries considered to be abuses of compulsory licences by developing

[185] J. Watal, (fn 17) p.288.
[186] Edith,Penrose. *International Patenting and the Less Developed Countries,* [1973] Sept E.C.S, pp. 768-785.

countries. Cornish[187] indicates that compulsory licensing was an obsession of developing countries particularly when patented technology was not being used in domestic production. The USA was determined to put a stop to this obsession by introducing very strict conditions to compulsory licensing despite the fact that it had relied on compulsory licences in its second stage of development.[188]

Developing countries have asked for the relaxation of the compulsory licensing conditions found in Article 31[189]. The particularly contested one is section 31(h) on remuneration. It is difficult to see where developing countries are going to get money from their over stretched budgets to pay for remuneration in order, in most cases, to give their citizens a chance to live. The entire situation looks unfair and unbalanced. Perhaps in cases of national emergency, such as the AIDS catastrophe, this remuneration should be waived. The same should apply to the requirement of judicial review [190]. Dr Peter L Kolker insists on the importance of judicial review where a compulsory license measure has been put in place by stating that ' a patent is a piece of property and any taking away of that property should be subject to a proper appeal procedure.'[191]. This is fair enough but this appeal procedure could be time consuming and in emergency situations the saving of time is crucial. The other recommendation is that parallel importing provisions should be made clear with parallel trading and international exhaustion of rights being encouraged where and when it is necessary.

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[187] W.R. Cornish (fn 9) pp. 46-63.
[188] Kirchanski: *Protection of United States Patent Rights in Developing Countries; United States Efforts to Enforce Pharmaceutical Patents in Thailand.* [1994] 16 Loyola LA International and Comparative Law Journal. pp. 536-591.
[189] www.wto.org/eng/tratop-e/trips-e/factsheet. P.6
[190] Article 32 of TRIPs
[191] Dr Peter, L. Kolker. *TRIPs Agreement Patent Protection,* Pg 30

The case of *The Pharmaceutical Manufacturer's Association of South Africa and Others* V *The President of the Republic of South Africa*[192] is really a conflict between a developing country and the industrialized countries over the compulsory licensing provisions in TRIPs. 'Although article 31 is the main issue in the case, the dispute 'is an early warning shot in a much larger struggle over access to the fruits of knowledge'[193]. It is suggested here that, the greatest effect of the outcome of this dispute will be to encourage developing countries to introduce legislations, which are contrary to TRIPs in other areas of intellectual property in an effort to acquire information, science and technology. These three components are indispensable for a country which wishes to develop. If trade sanctions are threatened on the implementation of these legislations, public outrage may win the day as happened in South Africa. In this way the provisions in TRIPs which most adversely affect developing countries will slowly but surely become overlooked and eventually hopefully amended.

[192] The High Court of South Africa (Transvaal Provincial Division), Case number 4183/98
[193] J.Sachs, (fn 127) pp 16-19

CONCLUSION

> The current order continues to accentuate poverty in the developing countries…. Developed Countries are continually manipulating international systems to their benefit yet purporting to be democratic
>
> Robert Mugabe, President of Zimbabwe, Speaking at a meeting of the non-aligned nations in Caracas 27 November 1991.[194]

The TRIPs Agreement is one of the most controversial agreements of our time with the developed countries and developing countries wanting completely opposite outcomes. In the first place developing countries did not want the Agreement to be passed. It was their conviction that the already existing Paris and Berne Conventions provided adequate international intellectual property protection. On the other hand the industrialized countries led by the United States, were determined to ratify the TRIPs Agreement in order to protect some of their industries which were suffering great losses due to the widespread piracy, copying and free riding taking place mainly in developing countries. 'The US took an unrelenting position in TRIPs negotiations – the rest of the world would have to adopt U.S style intellectual property protection. U.S style patent protection means a strict patent regime with a long patent term for process and product patents and no compulsory licensing'[195]

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[194] Cited in Deepa Ollapally. *' The South Looks North: The Third World on the New World order'*, April 1993 Current History 175.
[195] E. Henderson, (fn11), p.2

Having TRIPs under the auspices of GATT would mean that there would be an effective enforcement mechanism which did not exist under WIPO. However Dr Sodipo[196] warns against having too high an expectation on the efficacy of the enforcement of rights in those countries where an intellectual property tradition is yet to develop. When a country has not reached Krishanki's[197] third stage of development, introducing greater protection of intellectual property rights will be more disadvantageous than advantageous. The pharmaceutical industry is of particular importance as far as international intellectual property is concerned. Developed countries are determined to have patents in order to benefit their pharmaceutical industries while developing countries want to have as little protection as possible so as to provide their citizens with life saving drugs and to maintain public health.

The full and true impact of the TRIPs agreement on the pharmaceutical industry will be felt in most developing countries only after 2005 when the transitional periods allowed for them to implement the agreement under Part VI of TRIPs expires.[198] There is great uncertainty (and anxiety) as to the actual impact of TRIPs on developing countries. There are a number of possible scenarios for the future. Despite the presence of competition in the pharmaceutical industry the effect of TRIPs will be that prices for pharmaceutical products will increase in developing countries. No matter how much the pharmaceutical companies claim that they take into

[196] B. Sodipo, (fn 20).
[197] A. Damato, (fn 8)
[198] The effects of the Agreement will not be very different from one LDC to another. However there may be variations as far as the extent of the effects is concerned between MDCs and LDCs.
This is because these two categories of the developing countries are in different stages of development . As already illustrated, a country's level of development has an impact on the effect of increased intellectual property protection.

consideration the low levels of income in developing countries or offer to bring down the prices, the patented drug prices will never be as cheap as they would have been had the drugs been reverse engineered and produced locally or imported from generic drug companies such as the Indian ones. It is true that the high drug prices should not be seen as a disadvantage when balanced with the benefit that the people of the world will receive by having more new pharmaceuticals than they would otherwise have, due to the increased research that patent protection encourages. However this argument ignores the fact that new pharmaceuticals are of no use to the poor people of developing countries if they cannot afford them.

Article 27 of TRIPs encourages the non-working of patented products locally. This means that there will be little or no technological transfer not only in the pharmaceutical industries, but across the board in all industries where patents are required for protection. This seems to contradict Article 7 where technologic transfer is cited as one of the objective of TRIPs. However, despite non- encouragement of local working of patents, the pharmaceutical industry may be one of the industries which will attract, technological transfer, local R&D and its attendant investment, in the long run. This is evidenced by the studies of countries such as China which experienced increased R&D once patents were introduced in the pharmaceutical industry. Developing countries have indicated that they would rather bring about R&D through other means such as Government funding and awards. These other means are not as effective as the granting of patent. If R&D is the actual outcome of implementing TRIPs then developing countries will benefit immensely not only from the transfer of technology and investment but also from the employment opportunities

in the new R&D companies. In addition to this, drugs for diseases which are akin to the developing countries will be developed.

Due to competition in the pharmaceutical industry, it may be that patents will not necessarily make drugs more expensive. However, the drugs may still be expensive despite the competition because of the low level of income in developing countries. The solution here lies in differential pricing which the WTO[199] indicates is compatible with TRIPs. On the other hand, if a drug is completely new with no close substitutes, it will be extremely expensive and differential pricing may not even be able to bring the price down low enough for people in developing countries to afford it. . In such a case the solution may be found in compulsory licensing. However TRIPs does not allow for compulsory licensing where a drug is too expensive. Developing countries want Article 31 of TRIPs to be amended such that compulsory licensing of pharmaceutical products is not prohibited when a drug is simply too expensive for their citizens to afford.

Over and above all this, it is hoped that manufacturing companies will be reasonable in setting prices and helping in R&D in developing countries. As we have seen, increased intellectual property rights through TRIPs are important and may even benefit developing countries in the long run. This is particularly so in that it stops outright piracy and may bring about technological transfer. Thus the solution to the

[199] The uncertainty of this must again be stressed. The true effects of TRIPs in developing countries will only be known some years after 2005.

difficulties of developing countries in getting cheap drugs is not to decrease intellectual property rights or patents altogether. The solution lies in sensitising intellectual property right holders in the pharmaceutical industry towards the problem of access to drugs in developing countries. It is hoped that this will encourage them not to demand for the enforcement of increased intellectual property protection in developing countries .We live in a civilised world where human suffering cannot be ignored while profits of big pharmaceutical companies are protected. .

In India in addition to an increase in pharmaceutical prices, the local generic industry may will not be as lucrative as it has been in the past. 'As the pharmaceutical industry in India increasingly becomes patent based as opposed to generic based, foreign corporations will gain an immediate edge because they own the majority of pharmaceutical patents'[200]. All the provisions in the Patent Act 1970 which allowed the Indian generic industry to thrive will be replaced by the provisions in the TRIPs Agreement, which will lead to the inevitable collapse of a huge part of the industry. Product patents will be available for all industries without discrimination. Both product and process patents will have a twenty year term as opposed to the previous fourteen and seven year terms respectively. The discretion of the Indian Government to grant compulsory licenses will be drastically limited. However the generic industry may still be able to operate in limited manner. This is because it will be legal to generically produce the many drugs that had outlived a 20-year patent period before 1994.

[200] E.Henderson. (fn 11) p.17

There is the possibility that the generic industry in India will develop into a research-based industry. Local scientists will be encouraged to invent and they may be persuaded into staying in the country rather than immigrating abroad in search of more promising environments of work. Thus, India will be able to make use of its wealth of well-trained scientists to research and manufacture its own drugs instead of copying the work of others. The new research oriented industry will be a good source of cheaper drugs for its own people. India has all the resources and infrastructure required for such an industry. There is already evidence of the presence of such an industry with the innovative work being done by Dr Anji Reddy's company.

The outcome of the dispute in South Africa has a number of important implications. Firstly, it may encourage developing countries to introduce legislations challenging the particular provisions in TRIPs which are most disadvantageous to their countries. This may eventually lead to the revision of this provisions as may happen with the compulsory licensing provisions which were at the center of the South African dispute. Secondly, there is every reason to believe that other developing countries will imitate South Africa in enforcing legislations which allow for compulsory licensing under conditions that are more relaxed than those found in Article 31 of TRIPs. These legislations will also permit parallel importation and international exhaustion of rights under certain circumstances. Brazil implemented such legislation long before the South African dispute came to an end. Kenya and Malawi have followed swiftly.

Thirdly, the dispute in South Africa illustrates that the compulsory licensing provisions in TRIPs are too strict for developing countries to use effectively under emergency conditions. There is an urgent need for a revision of the compulsory licensing provisions in TRIPs and a clear statement as to the legality of parallel importing[201]. It is advocated here that parallel importing and international exhaustion of rights should be encouraged in emergency situations. Developing countries can only get cheap drugs for its dying people only through bold legislations where the countries expose themselves to bilateral actions from the countries such as the USA [202]. Brazil and South Africa succeed in providing their citizens with more affordable drugs only by putting their countries' economies at risk. The very daring legislations and national policies that they wished to implement may have earned them trade sanctions had the international community remained silent, as it has sometimes done.

The amending of Article 31 making it less strict, at least as far as pharmaceutical drugs are concerned, would send a clear message to developed countries that in some cases, they have to share their intellectual property with the developing countries without making profits purely for humanitarian concerns. Time and time again the WTO secretarial has argued that 'TRIPS strikes a carefully negotiated balance between providing intellectual property protection and allowing countries the flexibility to ensure that treatments reach the world's poorest and most vulnerable

[201] Medecins Sans Frontiers (MSF) asked the European Commission to allow for and advocate a wide scope of interpretation of Article 31 and support fast track administrative compulsory licensing procedures. See, Campaign for Access to Essential Medicines, *Recommendations to the European for discussions at the June 2001 TRIPs Council on Health and Access to Medicines Commission,* http//195.114.67.76/msf/accessmed/acc.../4DTSR2.

[202] The USA succeeded in making Thailand abandoned its attempts to implement laws allowing for cheaper drugs. See McGrath (fn 122).

people'[203] This assertion will be much more evident if the compulsory licensing provisions are made less strict. It is suggested here that in particular the conditions of judicial review and remuneration should be ignored in emergency cases. Parallel importing and exhaustion of rights should be automatic where drugs are required and cannot be afforded .If these recommendations are put in place, developing countries do not have to go through a long, arduous and expensive court case before the implementation of such important legislations, such as the Medicines and Related Substances Control Amendment Act 1997.

The case of India is a perfect example of a developing country which had very weak intellectual property protection laws and now due to TRIPs will be forced to change these laws. South Africa contracts to India because before TRIPs it had laws granting very strong intellectual property rights and now after TRIPs it has implemented a legislation going directly against the provisions in TRIPs and granting less intellectual property rights than before. India is most reluctant to change its old weak patent laws evidenced by the fact that even now, six years after the signing of TRIPs, it has not yet implemented TRIPs. Even when it does so it may very well apply a less stricter version of the compulsory licensing laws in TRIPs (just as South Africa has done) in an effort to find AIDS drugs for its 4.7 million AIDS patients[204]. South Africa has moved into a form of weak patent law and India may well follow suit. This is a phenomenon that will certainly be repeated in most developing countries showing clearly that developing countries do not want and will not have strict patent laws practically in the pharmaceutical industry.

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[203] M.Moore, (fn 179) p. 1
[204] UNAID, (fn 180)

It is appreciated that developed countries have to protect their interests by strengthening intellectual property rights. However this strengthening of rights may lead to considerable disadvantages in developing countries. 'The current task is to reach beyond national boundaries, as technology has done, and attempt to create relationships which acknowledge both the property rights of owners as well as the legitimate need of developing economies to access information and maintain low drug prices. It is hoped that these relations will help developing countries to join the global economy'[205]. These relations may emerge if developed countries take up the call of the UN to assist developing countries in matters of international intellectual property [206]. The UN suggests that it will be in the interests of developed countries to help developing countries in the implementation of TRIPs 'through technical and financial support as stipulated in the Agreement'. The UN provides what it terms as an 'non-exhaustive' list of what the developed countries can do to help in the implementation of TRIPs. These include:

'• Assisting countries to understand the options, costs, opportunities and challenges arising from the TRIPs Agreement

• Preparing them for the various stages of implementation of the Agreement, including the provision of training

• Collaborating in the dissemination of information on laws and regulations concerning transfer if technology

[205] Damato, (fn 8) p. 446.
[206] UNAID, (fn180)

Over and above this help from developed countries, developing countries need to realise that they have to look within themselves for ways and means of achieving development, such that an Agreement like TRIPs does not cause such major problems. There is a great deal of corruption in developing countries and it is the main reason for their under-development. These countries need to work on their internal systems instead of always waiting upon aid from developed countries in order to develop. The meeting held in Abuja, Nigeria by leaders of 44 African Countries [207]to discuss the ways and means African countries could help each other find cheap pharmaceutical products is a welcome move. If such cooperation continues and the rest of the world assists in any way it can, the TRIPs Agreement may well turn out to be a means of development for developing countries as opposed to a hindrance to development.

A climate of cooperation and understanding between developed and developing countries is crucial in the long-term implementation and application of TRIPs. Developing countries need to understand that increased patent protection is necessary to protect the industries of developed countries and may benefit them in the long run. Developed countries have to be made aware of the adverse problems that TRIPs may create in developing countries. These countries have to be sensitised enough to do whatever is in their power to alleviate any problems developing countries may suffer over the implementation of the Agreement even if

[207] The meting was held on the 26th and 27th of April . The leaders showed their determination to face the fight against AIDS and other infections by declaring to raise substantially the health budgets in their respective countries among other decisions. See Eugene. Agboifo, *Africa needs other changes*, Aceprensa 65-01, 9th May 2001

it means a relaxation of intellectual property protection. An atmosphere of compromise is necessary. In this way the 'north – south divide' will hopefully become the 'north-south cooperation' with the TRIPs Agreement being a means for all countries of the WTO to gain technological transfer and advance economically.

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