# INTERACTION BETWEEN PATENT PROTECTION AND COMPETITION POLICY: IMPLICATIONS FOR DEVELOPING COUNTRIES

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## ABSTRACT

The relationship between patent rights and competition policy is mistakenly regarded as being inherently in conflict due to the diverse objectives of patent rights and competition policy. While Patent rights grant exclusive rights over innovations for a limited period of time which to some extent limits competition, competition policy seeks to promote fair competition and prevent anti-competitive business practices.

The interaction between patent rights and competition policy may give rise to anti-competitive effects where patent rights are exercised abusively, in a manner detrimental to fair trade and competition.

TRIPS Agreement under Article 8.2 recognises that intellectual property rights are susceptible to abuse. TRIPS also recognises that abuse of intellectual property rights may have adverse effects on trade and present a barrier to transfer and dissemination of technology to developing countries. Taking this into consideration developing countries are presented with the need to find a solution to combat adverse effects arising out of abuse of intellectual property rights.

The interaction between patent rights and competition policy is a relationship where abuse of intellectual property rights is likely to arise, resulting in anti-competitive consequences. In developing countries, the interaction is complex and multifaceted and may give rise to anti-competitive effects which have human rights, economic, cultural and social implications. This has been illustrated in South Africa following the HIV/AIDS crisis in 1998 where proceedings were instituted against pharmaceutical manufacturing companies on grounds that they were engaging in anti-competitive practices and abusing their patent rights resulting in high prices of necessary drugs, making the drugs inaccessible to a significant portion of the population suffering from HIV/AIDS and ultimately numerous deaths. Apart from pharmaceutical patents, the implications of the interaction in developing countries is also

evidenced in trade practices involving biotechnology and plant patents, transfer of technology and in other resources such as traditional knowledge which are of value and utility.

This interface between patent rights and competition policy can be seen in two instances, the first being in the determination, analysis and interpretation of the substantive standards of patentability. The non-compliance with patentability standards may result in a patent grant that affects competition from other innovators by presenting a barrier for further innovations and may also result in granting overly broad patent rights which block out competition and place the patent owner in a dominant position. The second interaction is evident where the terms and conditions of a patent licensing agreement are exclusionary such that they block out competition, and present a barrier for technology transfer.

The interaction of patent rights and competition policy is cross jurisdictional in nature and therefore warrants a cross jurisdictional approach to resolving the implications of the interaction. The appropriate approach encompasses both developed and developing countries the form of the WTO TRIPS Agreement. Implementation of TRIPS Agreement and TRIPS compliant norms by developing countries is a feasible solution to confronting the difficulties arising out of the interaction. A TRIPS Agreement solution can enable developing countries exploit the flexibilities of TRIPS, adopt favourable interpretations of the Agreement as well as advocate for review of TRIPS.

The implementation and exploitation of TRIPS Agreement will also allow developing countries set up intellectual property rights policies suited to their levels of development and aimed at promoting economic development in industries such as pharmaceutical, agriculture and biological products including seeds and plant varieties, which have implications arising from anti-competitive effects of the interaction.

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## DEDICATION

To my beloved daughter Kayla Omwomo who believes in me more than I believe in myself and my parents Mathew and Jerusha Ohanga for inspiring me and teaching me the values of focus and perseverance.

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| ARIPO | African Regional Industrial Property Organisation |
| ARV | Anti-Retroviral |
| CBD | Convention on Biological Diversity |
| CFI | Court of First Instance |
| COMESA | Common Market for Eastern and Southern Africa |
| DOJ | United States Department of Justice |
| EAC | East African Community |
| EC | European Community |
| ECJ | European Court of Justice |
| EPC | European Patent Convention |
| EPO | European Patent Office |
| EU | European Union |
| FDA | Federal Drug Agency |
| FDI | Foreign Direct Investment |
| FRAND | Fair Reasonable and Non Discriminatory Terms |
| FTC | United States Federal Trade Commission |
| GATT | General Agreement on Trade and Tariffs |
| HIV/AIDS | Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome |
| IPR | Intellectual Property Rights |
| JEDEC | Joint Electron Device Engineering Council |
| KIPI | Kenya Industrial Property Institute |
| MSF | Medicins sans Frontières |
| NGO | Non-Governmental Organisation |
| OAPI | African Intellectual Property Organisation |
| OAU | Organisation of African States |
| PBR | Plant Breeders Rights |
| PVP | Plant Variety Protection |
| SPC | Supplementary Protection Certificates |
| SSO | Standard Setting Organisation |
| EACT | Treaty Establishing the East African Community |
| TFEU | Treaty on the Functioning of the European Union |
| TRIPS | Agreement on Trade Related Aspects of Intellectual Property Rights |
| TTBER | Transfer of Technology Block Exemption Regulations |
| UN | United Nations |
| UPOV | International Union for the Protection of New Varieties of Plants |
| US | United States |
| USPTO | United States Patent Trademark Office |
| WAEMU | West African Monetary and Economic Union |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organisation |
| WTO | World Trade Organisation |

"*Appropriate measures, provided that they are consistent with the provisions of this Agreement may be needed to prevent abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.*"

*Article 8.2 TRIPS Agreement*

## INTRODUCTION

Patent rights and competition policy are essential for the economic dynamics of both developed and developing countries. In today's knowledge economy, developing countries are eager to spur economic growth and compete with each other and industrialized countries. The developing countries have therefore become conscious of the necessity to promote innovation and facilitate technology transfer in an environment of fair competition. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) in its preamble recognizes that abuses and distortions may occur in the exploitation of legitimately granted intellectual property rights. Patent rights are especially susceptible to abuse where the patentee exercises the granted patent rights beyond the legally permitted scope such that the actions of the patentee have an effect of creating trade barriers and limiting international technology transfer. Although the patent system such as the TRIPS Agreement has in place inherent flexibilities such as compulsory licensing and bolar exemption provisions intended to help limit anti-competition abuses and encourage fair competition on a level playing field. These flexibilities are not very effective in developing countries first because of lack of manufacturing capacity and infrastructure needed to utilize the flexibilities effectively, and reluctance of developing country governments to exploit TRIPS flexibilities and secondly because the flexibilities cannot be applicable in a wide range of industries. Many developing countries rely on patentees issuing of voluntary licensing. Compulsory licenses being utilized only as a last resort and usually to coerce the issuing of voluntary licenses, other flexibilities such as bolar exemptions can only be exploited by the

few countries with manufacturing capacity. Therefore in instances where patent rights are exercised in a manner detrimental to fair trade and competition as well as adversely affecting technology transfer, the legal means that can be effectively applied by developing countries to deal with and correct these abuses inherent in "patent monopolies" is competition policy.[1]

The anti-competitive abuses of patent rights may be classified in two different ways which may sometimes overlap. First, as those that originate *per se* from the patent rights such that patent rights gives rise to anti-competitive effect just by being granted the limited rights or by their mere existence. The second classification is where the anti-competitive abuses originate from effects of exploiting the patent rights themselves such as through licensing agreements. Thus the interaction between patent rights and competition policy can be viewed in the patentability standards as set out under the TRIPS Agreement and national patent legislations as well as in licensing agreements terms and conditions. The general presumption existing regarding this interaction is that patent rights and competition policy are viewed as having a complementary relationship in that they share a common objective of promoting innovation for the benefit of the consumer.

The study of this interaction indicates that there are socio-economic implications of the interaction between patent rights and competition on the inhabitants of developing countries. These implications affect health, food security and living standards which results in increasing poverty, hunger and disease as well as further lowering living standards of people in developing countries.



[1] A patent is by definition a property right granted by the State which gives the holder the exclusive right to exclude others from manufacture, use or sale of the invention. Under the TRIPS Agreement, patent rights exist for a minimum of 20 years from the date of application. These rights may be assigned, pledged, mortgaged, licensed, willed or donated and be subject of other agreements like any form of tangible property.

## RESEARCH QUESTION

The substantive issues addressed in this paper are centered on the implications of the interaction between patent rights and competition policy on developing countries. The implications of this interaction are interconnected requiring the study to involve patent rights in various fields of interest to developing countries from both economic and social perspectives. The fields of interest in this study include pharmaceutical patents, biotechnology patents, plant variety rights, traditional knowledge and the transfer of technology which are vital for economic development and attainment of adequate social rights such as access to basic health facilities and basic needs of food and shelter.

The thesis will address the question whether the TRIPS Agreement contains adequate provisions on competition policies related to exploitation of patent rights and whether such provisions are sufficient in addressing the implications of the interaction in developing countries.

The study while taking into consideration the circumstances of developing countries will analyze what measures the developing countries could adopt to minimize the negative implications of the interaction between patents and competition policy in the selected fields. The study will undertake a comparative examination of policies governing patent rights and competition policies in the EU and US relating to the interaction and the impact these policies have on developing countries. The thesis will also address the discussion on commodification of traditional knowledge and the question of whether traditional knowledge once commodified based on its value and utility will provide a solution through leveling the playing field in the global market place given that developing countries are rich in traditional genetic resources which are valuable and often sought after by industrialized countries.

## SIGNIFICANCE OF THE THESIS

The thesis is significant to the extent that it is a coherent analytical framework of the implications the interaction between patent rights and competition policy has on developing countries. The thesis provides a new perspective towards solving the abuses resulting from patent protection and competition policy that are currently being encountered by developing countries in the new knowledge economy.

The significance of the study is evident in that it adds value to the current discourse on intellectual property rights and competition through noting the significant role played by competition policy in the economic growth and development of developing countries and explores this role comprehensively.

The thesis is valuable to policy makers and government representatives in the related fields in both developed and developing countries as it provides a concise comparative perspective of the interaction, enabling policy makers and government representatives be informed and act accordingly with regard to enacting legislation governing areas where the patent rights and competition policies overlap such as in drafting licensing guidelines for technology transfer.

The thesis is noteworthy in that it highlights the cavity that exists in developing country legislation governing patent rights and licensing of patent rights in various fields related to food security, pharmaceuticals, transfer of technology, biotechnology and traditional knowledge; and how developing countries could benefit from clear enforceable legislation governing the fields of patent rights and competition policy.

The study is beneficial to development agencies and partners in that it provides information on how to further create a favorable atmosphere for agents of development, encourage foreign direct investment, provide sufficient food, and reduce poverty as well as combat diseases specifically through finding a balance between patent rights and competition policy in biotechnology, pharmaceuticals, plant varieties and traditional knowledge. Many developing

countries lack the requisite administrative capacity, the political will or economic leverage and practical assistance on how to implement their competition policies and enforce patent rights effectively.

The thesis is also noteworthy in that it provides a detailed analysis of how patent rights in different fields of relevance for developing countries interact with competition policy specifically as it addresses traditional knowledge and examines whether it can be commodified and exploited as a resource which like other forms of capital can be subject to competition concerns in developing countries.

Finally, the thesis proposes theories that may be utilized by the developing countries in an effort to resolve the anti-competition effects of the interaction and also provide a balance between patent rights and competition so as to encourage innovation and fair competition, which are necessary for development.

## METHODOLOGY OF RESEARCH

This thesis clearly draws from a wide range of fields, covering different disciplines including but not limited to social sciences. The main format of study is a comparative theoretical approach to evaluating the interaction between patent protection and competition policy, drawing on law and economics literature which is the dominant theory applied in assessing the functioning of intellectual property. The research relies mainly on data and opinions of recognized scholars and authoritative literature. The study also captures and analyses relevant provisions and information from appropriate international treaties and conventions governing trade, intellectual property and biological conservation. It also includes a comparative study of legislative statutes, policies and guidelines from selected jurisdictions, namely the US, EU, South Africa, Kenya and India. A case study approach is applied in an analytical context drawing from the selected legal systems and legislations in developed and developing

countries. The paper undertakes a critical analysis to intellectual property rights and specifically patent protection, with regard to its relevance and applicability to developing countries.

## SCOPE OF RESEARCH

The study examines the anti-competitive effects of the patent and competition interaction in developing countries without extending the competition analysis to other areas of anti-competition such as the treatment of cartels. Reference to developing countries in the study generally refers to and focuses on the circumstances of the selected jurisdictions of India, South Africa and Kenya. The focus of the study is on patent rights, the granting and exercise of these rights, with specific consideration given to the TRIPS Agreement provisions relating to patent abuses that result in anti-competitive effects. Reference to a patent "monopoly" basically means a legal monopoly or a grant of an exclusive right by the State and not an economic monopoly where competition is restrained in a meaningful sense. In the study, reference is made to selected cases of relevance to the patent-competition interaction and having anti-competitive consequences within the jurisdictions under examination. There may be also some reference to cases outside these jurisdictions that are applicable as persuasive precedent. For the purposes of this study the definition of biotechnology adopted covers the contemporary technologies of genetic modification that enable development of a variety of products including and not limited to agricultural, pharmaceutical and cosmetics.

## LITERATURE REVIEW

In the new global economy, patent rights have become a powerful tool for economic development. Economic progress in developing countries is dependent on their ability to compete effectively in the global market relating to both products and technologies. It is undisputed that innovation in developing countries is rated to be at a very low level, with most of the innovation and inventions being patented, originating from developed countries. The challenge for developing countries is to stimulate development and economic growth so as to meet their basic needs with regard to food production and access to affordable health care, through encouraging innovation while simultaneously ensuring fair competition.[2]

In this regard patent rights play a crucial role. The focus on patents and not all other intellectual property rights stems from the characteristic of patents being intellectual property rights vulnerable to abuses which give rise to anti competition effects.[3]

Intellectual property rights are today an important resource in generating wealth not only for individuals but for countries as well. The owner of patent rights once legally granted has immense control over exploitation of the rights and resulting profits. This has been illustrated by the pharmaceutical industry and seed industry where the intellectual property rights holders exercise immense control and procure huge profits. Developing countries recognize the wealth generation possibilities in owning and exercising intellectual property rights. Following this recognition the developing countries have therefore under the encouragement of the WTO and WIPO entered into a number of intellectual property rights agreements the



[2] *See* U.S. FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003) [hereinafter FTC REPORT], *available at* www.ftc.gov/os/2003/10/innovationrpt.pdf.

[3] *See* A SULLIVAN & WARREN S. GRIMES, THE LAW OF ANTITRUST: AN INTEGRATED HANDBOOK 874 (2d ed. 2006) (discussing that most intellectual property cases giving rise to antitrust violations under Sherman Act section 2 have been patent cases); *see also* Thomas K. Cheng, *Striking a Balance between Competition Law Enforcement and Patent Policy: A Developing Country's Perspective*, *in* THE EFFECTS OF ANTI-COMPETITIVE BUSINESS PRACTICES ON DEVELOPING COUNTRIES AND THEIR DEVELOPMENT PROSPECTS 633-659 (Hassan Qaqaya et al. eds., UNCTAD 2008) *available at* http://ssrn.com/abstract=1303345

most important of which is the TRIPS Agreement.[4] Developing countries have also entered into other intellectual property agreements both bilateral and regional with the aim of promoting the global protection of intellectual property rights and consequently encouraging innovation as a means of achieving development.

In developing countries, the campaign to promote intellectual property rights and specifically patent rights focused on convincing the governments that more inventions are needed which would be unavailable without the patent system. Second, proposing to developing countries that patent rights and enforcement of the rights is the most efficient way to increase innovation and third, persuading the countries that patent rights being granted on inventions leads to development.

Believing that the patent system was crucial for development, developing countries adopted recommended intellectual property systems under their legislations making them enforceable at national level in the courts. The enactment of national intellectual property legislation fulfilling the requirements set out under the TRIPS Agreement by the WTO Member States resulted in strengthening of intellectual property protection globally.[5] During this period of adopting the TRIPS Agreement, there were concerns that the intellectual property system strengthening nationally through legislation and globally through international agreements may not have been in the best interest of developing countries from an economic perspective.[6] The view was that developing countries were adopting legislation not suited to their stage of development. This is because unlike industrialized countries, the developing countries are not in need of additional new inventions as in developed country standards but rather "[T]hey are in need of basic capability that will enable the country assimilate even the state of the art into



[4] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. l5, 1994, Marrakech Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULT OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

[5] *See* PUBLIC POLICY AND GLOBAL TECHNOLOGICAL INTEGRATION 25 (Frederick M. Abbott et al. eds., 1997).

[6] *See* John H. Barton, *Antitrust Patents and Developing Countries* (Stanford Law & Econ. Olin. Working Paper No. 371), *available at* http://ssrn.com/abstract=1405350.

their industrial base."[7] Having developed such an industrial base, developing countries will be able to accommodate and utilize new inventions lacking such an industrial base, intellectual property rights hinder technological progress and development as opposed to encouraging such development.

The view regarding the negative economic implications of intellectual property rights for developing countries is strongly supported by commentators against patent protection in developing countries who assert that the rationale for granting of patent rights is not applicable to developing countries. The rationale for providing patent rights is basically to provide an incentive for innovation through ensuring that inventors recoup on their research and development investment. Given that innovation is low in developing countries and most patents issued protect inventions from developed countries, the patent system is viewed by these commentators as contrary to developmental objectives of developing countries.

Patent rights to be efficiently exploited need an environment of fair competition with effective competition policies in place. There are no international agreements relating to competition policies in place to date. Countries rely on national legislation to govern competition issues. It has been established that new competition legislations have been enacted in countries around the world in the last 20 years, in Europe with the end of socialism followed by joining the EU. In the developing world, the focus on economic growth may have spurred the increase in competition legislation. The effect of the different new legislation has increased the variance of competition laws worldwide, both in terms of applicability and enforcement.[8] The national nature of competition law has a setback in that competition law remains national, while the market on the other hand is global in nature. In addition to this the objectives of protecting



[7] *See* FRITZ MACHLUP, AN ECONOMIC REVIEW OF THE PATENT SYSTEM, S. DOC. NO. 85-15 (2d Sess. 1958) (adopting an anti-patent stance and noting that if no patent system existed it would be a mistake to establish one, however since one is in place it may well be maintained); *see also* EDITH PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM 110-117 (1951) (where the findings are highly critical of the patent system in developing countries after a study is conducted on the economic justification for developing countries to participate in the international patent system.); *see also* Samuel Oddi, *The International Patent System and Third World Countries: Reality or Myth?*, 54 DUKE L.J. 831 (1987).

[8] *See* Michael D. Hausfeld, *Global Enforcement of Anticompetitive Conduct*, 10 SEDONA CONF. J. 9 (2009).

consumer welfare, encouraging innovation and trade are today global, reflecting the global market and are not limited to the domestic borders. This means competition issues although requiring a cross jurisdictional approach, are limited to national or regional jurisdictions. Another possible reason for the divergence in competition policies internationally requiring that they be governed by national legislation is that, countries have different economic levels of development and economic goals relying on different economic strategies to drive their economies, therefore the competition policy in place must be one that is custom-made to the specific needs of the country.

The interaction between patent protection and competition policy is of importance to developing countries because globalization although beneficial in many respects especially trade and commerce, resulted in some problems for developing countries. The resulting liberalization of economies and relinquishing of State control in key sectors of the economy had implications for developing country industries and technology acquisition capabilities. This is because liberalization did away with the protectionist measures previously applied by developing country governments in key sectors of the economy such as health and agriculture. These sectors were exposed to volatile market forces and anti-competitive practices in an international playing field. The effects of market forces had implications for developing country industries to an unexpected extent. The anti-competitive effects of trade can have widespread effects especially in developing countries having weak economies, even where the actions are undertaken in a different region or country. According to Hausfeld, "[I]t is now widely recognized that anti-competitive conduct can have a negative effect on a wide range of countries or regions even if the conduct is targeted to only one or a handful of countries."[9]

The adoption of standardized intellectual property rights has had a profound effect on developing countries because the globalization and uniform applicability of intellectual property rights resulted in mandatory patenting of products and processes previously not

[9] *Id.*

patented, making them inaccessible. In addition to this standardized patent protection, was the infiltration of foreign patented products into the domestic market coupled with the prohibition of imitation and high licensing fees. The end result was that essential products and processes under patent became too expensive for the domestic markets of developing countries. The consumers in developing countries were left with the option of using imitated low quality products which tended to be obsolete unsuitable to their needs and ineffective. It is partly due to the high costs of relevant technology and quality products that competition law and policy has been touted as being important to counter the anti-competitive effects of the abusive exercise of patent rights in those industries providing basic needs for the population in developing countries.

It has been established that both patent law and competition policy play an important role in regulating trade and encouraging innovation making competition policy undoubtedly necessary in today's global economy. As Hanns Ullrich observes, having in place a functioning intellectual property law that is enforceable, coupled with competition law is necessary for the promotion of innovation and thus overall economic advancement.[10] The dynamic and intangible nature of intellectual property rights and vulnerability to free riders requires a functioning and efficient competition law to prevent free appropriation of rights and encourage further investment.[11] This susceptibility to free riding makes patent rights vulnerable and likely to be abused by patent owners anxious to recoup on their investment and make a profit from their invention. Competition law is therefore crucial to prevent the abuse of patent rights beyond the parameters specified by legislation.[12]

A large and growing body of literature has investigated the interaction between patent rights and competition policies from different perspectives. The most common being where patent

[10] *See generally* Dan L. Burk, *Trans border Intellectual Property Issues in the Electronic Frontier*, 6 STAN. L. & POL'Y. REV. 9 (1994).
[11] *Id.*
[12] *See* Hanns Ullrich, *Expansionist Intellectual Property Protection and Reductionist Competition Rules: A TRIPS Perspective*, 7 J. INT'L. ECON. L. 401, 402 (2004).

rights legally granted result in *per se* anti-competitive effects. It has however been found that a very limited number of patents have the ability to exercise such monopolistic control in the market. The pharmaceutical industry is one such limited circumstance where *per se* anti-competitive effects may result from patent rights where pharmaceutical patents allow pharmaceutical companies to set high prices beyond that necessary to recoup their research and development costs as well as receive a reasonable profit.[13]

Traditionally the view on patents was that it amounted to granting of monopoly rights and was regarded as a legal monopoly exempt from antitrust and competition regulation.[14] As early as 1906, patent rights have been abused in an effort to influence competition through companies engaging in patent abuses namely buying up patents from competitors and then suppressing those patents so as to eliminate the competition. These activities prompted legislators in industrialized countries such as the US to address the shortcomings of the patent system and attempt to correct these shortcomings.[15]

The characterization of patents as monopolies can thus be traced back not only to their historic origin as in the "abuse of monopoly" in British patent law but also as evidenced by the US Supreme Courts view of patent rights during a period where the court referred to patent rights as "patent monopoly".[16] On the international sphere, this characterization is evidenced in Article 5A (2) of the Paris Convention where anti-competitive patent monopoly is a ground for issuing a compulsory license.



[13] *See* ALAN S. GUTTERMAN, INNOVATION AND COMPETITION POLICY: A COMPARATIVE STUDY OF THE REGULATION OF PATENT LICENSING AND COLLABORATIVE RESEARCH AND DEVELOPMENT IN THE UNITED STATES AND THE EUROPEAN UNION 430 (1997) (explaining that while in theory patent holders may have the opportunity to extract monopolistic prices from the consumer for a limited period of time, patents do not appear to create that opportunity in general).

[14] *See* A.D. NEALE & D.G. GOYDER, THE ANTITRUST LAWS OF THE UNITED STATES OF AMERICA: A STUDY OF COMPETITION ENFORCED BY LAW 288 (1981) (stating that every patent is a grant of monopoly power by the State).

[15] *See* REVISION OF THE PATENT LAWS, H. R. DOC. NO. 62-1161 (2d Sess. 1912).

[16] *See* Graham v. John Deere Co., 383 U.S. 1, 11 (1966) (stating that Congress may not enlarge the patent monopoly without regard to the innovation advancement and social benefit gained thereby).

The more recent perception of the relationship between patent rights and competition policy is that where the interaction gives rise to some anti-competitive effects, there is a need to resolve the effects by finding a balance between patent rights and competition policy, which will allow the unfettered exercise of patent rights without affecting competition. This issue has been highlighted and discussed by the US Federal Trade Commission (FTC) in their report when the Commission stated that,

> Competition and patent policy are bound together by the economics of innovation and an intricate web of legal rules that seek to balance the scope and effect of each policy. Errors or systematic biases in the interpretation or application of one policy's rules can harm the other policy's effectiveness. For example, patent law precludes the patenting of an "obvious" invention. If, however, patent law sets the bar for "obviousness" too low, and erroneously allows patents on "obvious" inventions, then patent law can thwart competition that otherwise might have developed based on the obvious technology. Conversely, competition policy as implemented through antitrust law prohibits only anticompetitive business conduct. If antitrust enforcement erroneously condemns efficient, welfare enhancing conduct with respect to a valid patent, then antitrust enforcement can undermine the incentives the patent system creates to encourage innovation. A challenge for both policies is to find the proper balance of competition and patent protection.[17]

The general literature on the interaction between these two legal regimes shows that they share common goals although significant tension exists. The commentators holding this view consider it politically incorrect today to make assertions and state outright that there exists a conflict between the exercise of patent rights and competition policies. A proponent of this school is Ward Bowman, who although observing that patent rights and antitrust law are conflicting in their respective goals, finds that the two legal regimes share a common economic goal, "to maximize wealth by producing what consumers want at the lowest cost."[18] Attempts at reconciling patent rights and competition have been addressed by both legal scholars and in the courts of law. With some scholars concluding that the goal of promoting progress can be best achieved by giving priority to competition in the patent regime when

[17] *See* FTC REPORT ch.2.
[18] *See* WARD. S. BOWMAN, JR, PATENTS AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL 1(1973).

resolving questions of patent policy.[19] There are divergent approaches that have been applied in the analysis of the relationship between patent rights and competition policy. Under the first approach the view adopted in analyzing the interaction concludes on the basis of being either pro patent or pro competition. Under the second approach to resolving the interaction between patent rights and competition policy an analysis is undertaken to assess the effects of the interaction on consumer welfare and not to analyze the conflicting objectives of the two legal regimes.[20] The second allows consumer welfare to take priority over a debate as to which legal regime has priority over the other.

The discussion on the interaction between competition policy and patent protection can be seen to have gone through a paradigm shift, with two schools of thought emerging. The old school of thought governing this interaction is of the belief that patent rights confer monopoly and are in themselves monopolistic in nature, has been discussed above. This school of thought considers the granting of patent rights to amount to the conferring of monopoly rights. The attempts to characterize patents as monopolistic have been rejected by some commentators on various grounds firstly the nature of patent right is that unlike tangible property it is exclusive for a specified limited period of time with a minimum of 20 years. This requirement that patent rights expire after a specified period does not allow patent rights to amount to a monopoly. Another opinion is that patents constitute a resource among other resources that when availed can be used to gain competitive advantage therefore patents cannot be characterized as being monopolistic in themselves. Kitch in support of this states that, "A patent can have value like any input that gives a firm a comparative advantage over its competitors, but that does not mean that the owner of the patent owns a "monopoly"."[21]



[19] *See* Rudolf J. R. Peritz, *Patents and Competition: Toward a Knowledge Theory of Progress*, *in* INTELLECTUAL PROPERTY AND MARKET POWER. ATRIP PAPERS 2006-2007 (Gustavo Ghidini et al. eds., 2008).
[20] *See* BOWMAN, *supra* note 18.
[21] *See* Edmund W. Kitch, *Patents, Monopolies or Property Rights?*, 8 RES. L. & ECON. 31, 38 (1986) (explaining that patents are not the only tools used in competition to gain a competitive advantage, many firms will rely more on trade secrets rather than patents).

This old school of thought has been superseded by the new school of thought that refutes the notion of patents being monopolistic in nature and in fact states that patents encourage competition as opposed to imposing a barrier to competition. This paradigm shift is illustrated by the changes in the treatment of the relationship between patents and competition policy in the US by the courts and antitrust agencies. In the US the patent rights and competition relationship has gone through a cycle of changes with patent rights sometimes being upheld in resolution of conflict between patent rights and competition polices and at other times competition policies being upheld. During the 1980's there was pro patent wave as illustrated by the negation of the Nine No No's, followed by the release of the Enforcement Guidelines for International Operations. These Guidelines sought to regulate the relationship between patent rights and competition by providing guidelines with requirements to be taken into consideration in analyzing whether licensing terms were anti-competitive.[22]

During the depression period, the approach to patent rights that the rights were regarded as monopolies as characterized by the court decisions which were anti patent in nature and patent licensing practices were generally subject to antitrust scrutiny. This anti patent era in the US continued through the period of Nine No No's regulating patent licensing during the early 1970's. The Regan period saw the removal of the Nine No No's which were subjected to criticism and the view on the patent antitrust interaction underwent a change. Patent rights were no longer regarded as monopolistic; rather antitrust enforcement agencies realized the value of the patent and its exclusive rights for technological change.[23] Another reason for this was the focus the US had taken on international trade and the realization that intellectual property rights were crucial in increasing international trade and revenues to the US as well as protecting US interests outside its borders. The period thereafter saw the enactment of



[22] *See* John DeQ. Briggs, *Intellectual Property and Antitrust: Two Scorpions in a Bottle*, 10 SEDONA CONF. J. 65 (2009) (since this time, there have been guidelines, reports and conferences dealing with the patent- antitrust interaction such as the FTC REPORT, *supra* note 2).
[23] *Id.*

guidelines, and publishing of reports analyzing the relationship between patents and competition policy in an effort to exploit the benefits of the interaction with regard to fostering innovation, encouraging fair competition and meeting social objectives of consumer welfare.

The 1995 Guidelines for the Licensing of Intellectual Property further reinforced the view that intellectual property rights and antitrust law are not in conflict due to differing objectives and functioning but rather intellectual property rights and antitrust have a common dual purpose which is to promote innovation and enhance consumer welfare.[24]

Three basic principles regulating the relationship between patents and competition protection were illustrated under the 1995 Guidelines which are internationally accepted today and are considered basic principles for understanding and analyzing the interaction between patent rights and competition policy. These principles are; First, intellectual property is similar to other forms of property. Second is the presumption that intellectual property does not amount to or generate market power. Third, licensing is pro-competitive so far as it allows the combining of complementary factors of production in an efficient manner.

It is a basic principle that patents do not result in market power since there are other substitutes available in the market. However there may be circumstances that arise where there are no substitutes or the patent system allows imposition of limits on competition. Under these circumstances, patents may result in market power.

The current thinking on the interaction between patent rights and competition policy therefore tends to place emphasis on the need to find a balance between these two legal regimes so as to encourage innovation, which is crucial for development in developing countries.

This study differs from the literature on the patent rights and competition policy interaction in that it deals with the implications of the interaction in developing countries. Another aspect

[24] *See* U.S. DEP'T OF JUSTICE, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (1995) [Hereinafter DOJ Antitrust Guidelines 1995] *available at* http://www.justice.gov/atr/public/guidelines/0558.htm

from which the study differs from the previous literature on the interaction is that it analyses the implications of the interaction in specific fields of relevance to development and economic growth in developing countries.

The previous literature discussing the interaction between patents and competition policy rarely focuses on developing countries. Where the literature on the patent rights and competition policy interaction makes reference to developing countries, it has failed to carry out an in depth analysis of the interaction because competition law and policies were for a long period of time regarded as irrelevant to the poor nations. Previous studies mainly dwelt on the barrier to competition caused by oligopolies based in developed countries through raising costs of products and technologies for developing countries.

The angle taken in this study emphasizes on the interaction between patent protection and competition policy in specific fields of relevance to developing countries and attempts to outline anti-competitive effects that may arise as a result of this interaction. The ultimate objective is to suggest feasible solutions to counter the anti-competitive effects. The particular fields of relevance under analysis here are the pharmaceutical industry, transfer of technology, plant variety rights, plant breeders' rights, biotechnology and traditional knowledge. All these fields are interlinked and cannot be strictly separated during the analysis of the patent rights and competition policy interaction.

## CHAPTER SUMMARY

The first chapter provides a theoretical background of the development and regulation of patent rights and competition policy, outlining the rationale and economic justifications of both patent rights and competition policy. The chapter summarizes the historical development of patent rights in the international arena and the resulting differences in wealth and development between industrialized and developing countries. It addresses developments in the interaction between patent rights and competition policy, laying the foundation from which the study proceeds. The chapter examines circumstances under which the patent rights and competition policy interaction is likely to give rise to anti-competitive effects. The section concludes by outlining the possible theories that may be applied in resolving the anti-competitive effects of the interaction between patent rights and competition policy.

The second chapter outlines the regulatory frameworks governing patent rights and competition. It analyses the relevant provisions under the TRIPS Agreement addressing prohibition of anti-competitive abuses of patent rights. The chapter examines patent and competition law, policies and guidelines in the jurisdictions of the US, EU, South Africa, Kenya and India. A brief scrutiny of the judicial approach to anti-competitive abuses resulting from the patent and competition policy interaction in the relevant jurisdictions is also undertaken. Chapter two also outlines those internal mechanisms provided for under intellectual property legislations such as compulsory licensing aimed at resolving the anti-competitive abuses of patent rights.

The third chapter is an in depth analysis of the circumstances under which the interaction between patent rights and competition policy can be viewed. The chapter addresses patentability standards of non-obviousness and disclosure requirements that affect patent scope and breadth and the implications these standards have on competition. An evaluation of the courts approach in the US and EU through analyzing case law involving the anti-

competition effects of patent rights where the standards of patentability are not adhered to are carried out. The chapter in the analysis of substantive and procedural standards of patentability deals with the issue of claim interpretation in the US and EU and its effect on patent scope. The interaction between patent rights and competition policy that occurs in licensing agreements is examined in the chapter. The licensing agreement terms analyzed include; terms affecting price restrictions, tying arrangements, royalty arrangements, territorial restrictions, refusals to deal, patent pools and cross licenses. The chapter also examines the principle of exhaustion, parallel trade and the position of the TRIPS Agreement and developing countries with regard to these issues.

The fourth chapter examines the relationship between pharmaceutical patents and competition policy, with the objective of outlining the implications the interaction has on developing countries. A comparative analysis of legislation and policies relating to generic medicines in the US, EU and developing countries is carried out. The chapter carries out an examination of compulsory licensing of pharmaceutical patents in these jurisdictions and analyses the provisions of the TRIPS Agreement dealing with compulsory licensing as well as the changes brought about by the Doha Declaration on public health of 2001 and the Implementation Decision of 2003 which was aimed at making access to affordable medicines easier for those developing countries lacking manufacturing capacity. The implications of the Doha Declaration for Public Health and the WTO Implementation Decision on developing countries are illustrated through a case study of the NGO *Medicins sans Frontiėres* attempts to procure cheaply HIV/AIDS medicines from Canada under the Implementation Decision regime of 2003.

The fifth chapter addresses the interrelated fields of plant patents and plant variety rights, biotechnology and traditional knowledge. The chapter begins by undertaking an examination of the international, regional and national frameworks governing the respective fields. In so

doing, an analysis of the UPOV Conventions, CBD and the TRIPS Agreement is carried out from a comparative perspective, before addressing the anti-competitive practices in the interaction between patent rights and competition policy in these fields. Under the section addressing traditional knowledge, the chapter examines certain suggested models for structuring rights in traditional knowledge based on their value and utility and implications of its commodification for developing countries.

The sixth chapter deals with the implications of the interaction between patents and competition policy in technology transfer. The chapter makes reference to licensing of patent rights and addresses the obligations developed countries have towards developing countries with regard to technology transfer under the TRIPS Agreement and CBD. The chapter focuses primarily on developing countries and the licensing of technology barriers faced by developing countries. The chapter also outlines some of the anti-competitive practices the technology owner may resort to in technology transfer through licensing of technology.

The seventh chapter contains recommendations that can be undertaken so as to limit the negative implications the interaction between patent protection and competition policy may have on developing countries. The recommendations and proposals focus on the application and reviewing of the TRIPS Agreement as well as recommendations and proposals related to competition policies. These proposals are addressed to both developing countries and developed countries.

## 1: DEVELOPMENT OF PATENT RIGHTS AND COMPETITION POLICY

### *1.1 Justification and Economic Significance of Patent Rights*

Patent rights play a significant economic role in the development of a country. The patent system was basically conceived as a tool to stimulate indigenous technological development, promote domestic inventiveness and enhance the exploitation of patented inventions in a country.[25] The granting of patent rights had the initial objective of protecting proprietary rights of the owner of the invention, in so doing allowing the patentee to profit from his ingenuity and providing an incentive for the patentee to place the invention in the public sphere for the benefit of the general populace.[26]

The economic rights to intellectual property in general have been recognized since medieval time. The justification of intellectual property rights stretches as far back as John Locke.[27] John Locke contended that effort deserves reward as in previously common land being awarded to the most diligent and hardworking cultivator.[28] The philosophy of western countries coupled with the enlightenment placed emphasis on the issue of individual property rights and flowing from this, the patent system. In discussions about property, philosophers such as Georg Wilhelm Friedrich Hegel and Locke, as well as Mills to name a few may have laid the foundation on these modern property theories.[29] It follows logically from Locke's discussion on property, that intellectual property is also the fruit of one's labor. This is because mental labor like physical labor is an extension of the person and belongs to the



[25] *See* Edgar Tabaro, Patent *Law Reform in Uganda: Addressing Priorities and Strategies*, 12 J. WORLD. INTELL. PROP. 575 (2009).
[26] *Id.*
[27] *See* JOHN LOCKE, *The Second Treatise of Government* in TWO TREATISES OF GOVERNMENT, 303-320 (P. Lasslet ed., 1970).
[28] *Id.*
[29] *See*, J. Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287-366 (1998); *see also* H. M. Spector, An *Outline of a Theory Justifying Intellectual and Industrial Property Rights*, 8 EUR. INTELL. PROP. RTS. 270-273 (1998); *see generally* W. J. Gordon, *A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property*, 102 YALE L.J.1533 (1993).

person. Hegel on the other hand makes a brief observation on property and products of the mind. Hegel is of the opinion that property is an expression of personality.[30] This Hegelian theory of property provides that property is a unique or especially suitable mechanism for self-actualization for personal expression and dignity and recognition as an individual.[31]

In defining what amounts to property rights, Landes and Posner have defined property as any "[L]egally enforceable power to exclude others from using a resource without the need to contract with them."[32]

The philosophical justification of intellectual property rights lies not only in the economic concept in that the goal of intellectual property rights is to promote economic growth but also in the need for individuals to own the products of their efforts and to express their self-identity. The product of inventors mental work results in property due to the notion of property rights being granted as a protection to guarantee lack of interference from others or the State as originally set out by Hegel in the 19th Century.[33]

Another justification of intellectual property rights is closely related to capitalism and focuses on the argument that intellectual property creates a scarcity and market which further promotes efficiency and use. Patents therefore have a standard economic rationale which is to protect the inventors from imitation, simulate innovation by offering an incentive to promote more research and developments through enabling the inventor recover the cost of the invention.

There is little evidence that patent rights have resulted in a similar effect in developing countries. Developing countries may not easily apply the philosophical justification of intellectual property rights following the Lockean and Hegelian models. The philosophical justifications were applicable in so called "viable societies" which at that time had in place

[30] *See* G.W.F. HEGEL, PHILOSOPHY OF RIGHT 68 (T.M. Knox trans., Clarendon Press Oxford 1967) (1952).
[31] *Id.*
[32] *See* William Landes & Richard Posner, *The Economics of Trademark Law*, 78 Trade Mark L. 267 (1988) *quoted in* RICHARD A. SPINELLO & MARIA BOTTIS, A DEFENSE OF INTELLECTUAL PROPERTY RIGHTS 149 (2009).
[33] *See* HEGEL, *supra* note 30.

certain rules forming them into organized societies. These rules included rules restricting use of violence, minimum rules governing the institution of property, dynamic rules allowing the setting of obligations making promises and commitments through some form of contractual relationship and the presence of sanctions in event of derogation from specified rules.[34] Taking into consideration the colonial history of many developing countries, coupled with social and cultural differences, they cannot be categorized to have fit into these viable societies. Today many developing countries are striving to achieve industrialized status and have weak legal enforcement systems.

The justification of patent rights in developing countries is characterised by the belief that intellectual property rights are subordinate to other social rights.[35] This is evidenced by the lack of or weak intellectual property protection offered prior to the TRIPS Agreement and weak enforcement of intellectual property rights to date. The developing countries also give little support to the theory that with strong intellectual property protection in place, the technological developments will eventually be transferred down to them "trickle-down theory"[36]

The utilitarian arguments of justifying intellectual property rights are most applicable to developing countries since they are applicable to all levels of development. The utilitarian theory states that intellectual property rights are needed to ensure that maximum net social welfare is obtained from an invention or idea, in so doing intellectual property rights protect the incentive to create and invent, encouraging the production of quality goods. However, these utilitarian arguments justifying intellectual property protection are held by some opponents of patent rights for developing countries to be unsuitable developing countries due to the heavy cost of intellectual property protection as opposed to the benefits they stand to



[34] *See* DAVID LEA, PROPERTY RIGHTS, INDIGENOUS PEOPLE AND THE DEVELOPING WORLD; ISSUES FROM ABORIGINAL ENTITLEMENT TO INTELLECTUAL OWNERSHIP RIGHTS 216 (2008).
[35] *See* RICHARD A. SPINELLO & MARIA BOTTIS, A DEFENSE OF INTELLECTUAL PROPERTY RIGHTS 138 (2009).
[36] *Id*.

gain. If anything the problem of exploitation of developing countries intellectual property rights is now seen to be connected with this utilitarian theory and the perceived tendency to commodify what was previously accessible to all in nature.[37]

Ideally, patent protection is justified on ground that the negative effect of granting exclusive rights for a limited period of time will be compensated by the incentive for increased creativity, investments in research and development as well as increased innovation. This view is beginning to be doubtful due to the cost of implementing and enforcing strict patent protection for developing countries.[38]

### *1.2 Developments in Patent and Competition policy: Socio Economic Evolution*

The patent system has evolved over history from a system of awards, privileges and monopolies to the current system of modern individual property rights that are legally enforceable. The system of awards is one of the oldest and can be traced back to ancient times.[39]

In medieval England, the government at that time used privileges to induce the creation or the importation of technology.[40] Privileges and monopolies were granted generally, through letters that the king or the lord of the land would address to the introducers of new techniques. These letters were made open, public or patent, so that third parties were made aware of the right being granted, hence the royal favors being called patents. Flowing from this, the Statute of Monopolies of 1623 was enacted in England. The Statute protected only monopolies made by an inventor whose inventions met the specification of being true and first and whose invention was a method of manufacture. The reason being to encourage inventions aimed at



[37] *Id*. at 139.
[38] *See* T. G. Palmer, *Are Patents and Copyrights Morally Justified? The Philosophy of Property Rights and Ideal Objects*, 13 HARV. J.L. & PUB. POL'Y. 817 (1990).
[39] *See* NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 9 (2d ed., 2005) (description of patent law being traced from ancient Egypt).
[40] *Id.* at 10.

carrying out efficient production of goods.[41] In many commonwealth countries the meaning of "invention" derives expressly from the Statute of Monopolies and many countries rely on this jurisprudence of the Statue in their patent legislation.[42]

In France the rights of the inventors were recognized in 1791, thereafter patent law spread throughout Europe. In the colonies the law adopted was generally similar to that of the colonial master.[43]

In the US, the beginnings of patent law can be traced as far as the constitutional convention where a proposal for the US Patent Clause,[44] written by James Madison was presented. Madison in his proposal for a patent clause in the US Constitution sought to "encourage by premiums and provisions, the advance of useful knowledge and discoveries."[45] This is one of the few clauses at the constitutional convention that was passed without debate. James Madison in the Federalist No. 43 also wrote on the importance of intellectual property rights and the necessity of granting intellectual property rights, that "[T]he utility of [Article 1, Section 8, clause 8] will scarcely be questioned."[46]

Economists such as Adam Smith and John Stuart Mill considered the granting of exclusive patent rights in this period to be "the best and most efficient form of promotion of invention by the state"[47] because it does not imply any cost to the state and the rewards of the inventor depend on private initiative and market factors. In more recent times the State is known in some industries to engage in research and development through providing private firms with



[41] *See* PETER DRAHOS, A PHILOSOPHY OF INTELLECTUAL PROPERTY 13-39 (1996)
[42] New Zealand and Australia are among the countries still relying on the meaning of invention set out in the Statute of Monopolies.
[43] *See* F. Machlup & E. Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1, 3 (1950).
[44] U.S. CONST. art I, § 8, cl. 8.
[45] *See* John Boyle, *Patents or Premiums*, 26 J. PAT. OFF. SOC. 446, 450 (1944).
[46] *See* THE FEDERALIST, NO. 43 (James Madison) *quoted in* SHELDON W. HALPERN ET AL., FUNDAMENTALS OF UNITED STATES INTELLECTUAL PROPERTY LAW: COPYRIGHT, PATENT, TRADEMARK 195 (2d ed. 2007).
[47] *See* DRAHOS, *supra* note 41

funding for research and development with the aim of ensuring the consumer can access the end product at reasonable prices as well as with the aim of encouraging innovation.[48]

The enactment of national intellectual property regimes began later in the 19th Century. The history of patent law emphasizes the various changes undertaken by developed countries and the administration and enforcement of patents. The developing countries having a brief history of patents are at a disadvantage with respect to administration and enforcement of patents. In many developed country jurisdictions during industrialization and the period after, patents in some industries were outlawed so as to enable certain industries develop. This to a large extent has not taken place in developing countries. The inability to imitate inventions without sanctions or repercussions due to having in place enforceable patent protection has had the effect of slowing development by raising costs of production sometimes to levels unaffordable by majority of the population in these countries.

The extent and scope of geographical protection of patent rights was important in international development of patent rights. A principle of patents that has been in existence from the middle age privileges to modern patents is the principle of territoriality. The territoriality principle links state sovereignty, property rights and territoriality.[49] This principle became unfavorable to inventors since rights were limited to territories leaving the inventions vulnerable to copying and imitation outside the home territory.[50] These agreements resulted in the recognition of the need for an international framework for regulating intellectual property. The acceptance and implementation of the Paris Convention of 1883 in response to this need provided a solution.[51]



[48] *See* WORLD INTELLECTUAL PROPERTY ORGANIZATION, INTRODUCTION TO INTELLECTUAL PROPERTY: THEORY AND PRACTICE 54 (1997).

[49] The principle states that intellectual property rights do not extend beyond the territory of the sovereign which has granted the rights in the first place.

[50] *See* S. RICKETSON, THE BERNE CONVENTION FOR THE PROTECTION OF LITERARY AND ARTISTIC WORKS: 1886-1986 25-28 (1987).

[51] Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as revised at Stockholm on July, 1967, 828 U.N.T.S. 305.

The Paris Convention centered on the principle of national treatment, and was followed by other multilateral treaties dealing with international co-operation in intellectual property. These multilateral treaties paved the way for the internationalization and globalization of intellectual property laws. The TRIPS Agreement annexed to the Marrakech Agreement establishing the WTO resulted in construction of a strong international regime governing intellectual property. The TRIPS Agreement has been described as an agreement which in addition to comprehensively providing intellectual property protection,

> [TRIPS Agreement] effectively globalizes the set of intellectual property principles it contains because most states of the world are members of, or are seeking membership of, the WTO. It also has a crucial harmonizing impact on intellectual property regulation because it sets, in some cases, quite detailed standards of intellectual property law.[52]

TRIPS Agreement has a forceful and compelling nature because it links intellectual property rights to the WTO dispute settlement mechanism, such that in event of disputes resulting from issues under TRIPS the parties have recourse to the WTO dispute settlement mechanism whose decisions are respected and must be complied with. Once the least developed countries adopt TRIPS Agreement, following ending of the transition period, the final result would be a standardized form of intellectual property protection with minimum requirements set out under the Agreement.

The TRIPS Agreement in setting minimum requirements for intellectual property protection presents a problem for developing countries because it applies uniformly to all countries, irrespective of the level of development. Uniform applicability of the TRIPS Agreement however has not precluded many developed countries from seeking to impose more stringent measures related to the protection and enforcement of intellectual property rights in developing countries. This has been done through encouraging the enactment of TRIPS plus



[52] *See* PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY? 11 (2002).

provisions in national legislations as well as having in place bilateral agreements with TRIPS plus terms and obligations for developing countries.

The socio-economic evolution of patent rights can be drawn from the evolution of intellectual property rights. Previously, patent rights were protected basically as an incentive to the inventor, encourage innovation and benefit the society at large. The primary rationale for protection although remaining the same has somewhat undergone a paradigm shift following developments of international frameworks governing intellectual property and discarding of the territoriality principle. This is because the primary rationale for providing patent protection being to provide incentives for inventors to innovate and recoup on their research and development costs in some industries seems to have been overtaken by the second objective of patent protection which is to ensure that the society benefits from the invention through full disclosure of the invention. This consumer welfare objective today seems to outweigh other objectives since it has been determined that inventors will continue to invent so long as there is a need for an invention and a ready market for that invention. An example of an industry where the incentive to innovate objective has weakened is in the software and computer technology industry where new programs and technology are invented due to the need for these programs. On the other hand the pharmaceutical industry is dependent on patent protection to provide incentives for investment in research and development. Where patent protection is not given, then the pharmaceutical industry is reluctant to invest in research and development.

Despite this shift with regard to the rationale for patent protection, the plight of developing countries remains the same. The situation remains that inventors from developed countries have strong intellectual property protection which has economic value to them and their countries. The inventors however make the same inventions inaccessible to the developing countries since the costs of the inventions are beyond the means of many consumers. The

social impact of inaccessibility of these inventions is that, developing countries continue to lack technology and skills therefore enabling the persisting low development and living standards as well as increasing poverty.

### *1.3 Relationship between Patent Rights and Competition Policy*

Traditionally lawmakers attempted to balance the interests of patent protection with anti-competition concerns. Today patent rights are viewed as complementary and do not confer monopolies in exercising the exclusive nature of the rights for the limited time period the patent rights have been granted. In addition to this, the patent system under the TRIPS Agreement incorporates flexibilities and provisions which countries may employ in efforts to limit patent rights where they exceed the allocated parameters.[53]

An issue of interest is whether the TRIPS Agreement adequately provides competition rules that cover dynamic technologies given the advancing nature of these technologies. For example where there is the use of an intellectual property as an essential facility.[54]

Competition law and policy has the objective of limiting anti-competitive practices with the goal being to protect competition and not to protect competitors.[55] Competition is a primary characteristic of a free market. Adam Smith in *The Wealth of Nations* observed that when individuals or companies are forced to compete, they work harder in pursuit of their own self interests.[56] Following this process, there is elimination of weak firms and the stronger firms produce better quality goods at cheap prices.[57] In enforcing competition law and policy the state should ensure that competition laws are not used to undermine intellectual property

[53] *See* Aashit Shah, *The Abuse of Dominant Position Under Article 82 of the Treaty of the European Community: Impact on Licensing of Intellectual Property Rights,* 3 CHI.-KENT J. INTELL. PROP. 41 (2003).
[54] *See* Ullrich, *supra* note 12, at 403.
[55] *See* Gerald F Masoudi, *Promoting Economic Development Through Sound Competition Policy: The Role of Competition Law and Policy in the Socio-Economic Development in* TAIWAN 2006 INTERNATIONAL CONFERENCE ON COMPETITION POLICIES AND LAWS 19 (Tzong-Leh-Hwang ed., 2006).
[56] *Id.*
[57] *Id.*

rights, this is because intellectual property rights promote innovation which drives economic growth. It follows therefore from this that competition laws implemented and enforced in a manner that respects intellectual property rights, in essence promotes innovation.[58]

The objectives of competition policy and intellectual property, specifically patent rights, can have underlying tensions, which are intensified by intellectual property rights being exploited on the international level beyond the domestic borders.[59] The international exploitation of intellectual property is evident in the many firms and organizations entering into alliances and other collaborative arrangements, such as licensing agreements and mergers, while competition policy still remains on the national level. As a result of this, competition policy is extremely limited in its applicability, with the exception of regional regulations of the EU and some extra-territorial effects of the US antitrust laws. However keeping in conformity with the new school of thought, both patent law and competition laws share a common goal of promoting consumer well-being, although they pursue this goal through divergent paths.[60]

### *1.4 Basic Principles Governing Interaction between Patent Rights and Competition Policy*

The current economic thinking regarding the interface of patent protection and competition policy embraces a number of principles. These principles originate from the 1995 Antitrust Guidelines on Licensing of Intellectual Property Rights drafted by the US Department of Justice (USDOJ) and Federal Trade Commission (FTC).



[58] *Id.* at 20.
[59] Palmer, *supra* note 38, at 818.
[60] *See* Sherman Act, 15 U. S. C. §§ 1-7 (1994) (prohibiting trusts in restraint of trade and monopolies); Patent Act of 1790, ch. 7, §1, 1 Stat. 109 (codified as amended at 35 U.S.C. §§ 100-376 (1994))(granting patents to inventors and discoverers of new and useful processes, machines, manufactures or composition of matter); *see generally* BOWMAN *supra* note 18 (stating that both antitrust law and patent law have a common central economic goal to maximize wealth by producing what consumers want at the lowest cost, also discussing the distinction between total welfare and consumer welfare, while providing an explanation of the superiority of total welfare to non-economic objectives as the goal of the antitrust system).

The general rule is that patents have no market power in and of themselves.[61] This rule eliminates the view that the conflict between patent protection and competition policy rests on the presumption that the existence of an intellectual property right can be equated to the existence of market power.[62] This presumption does not necessarily hold since the availability of substitutes and entry conditions in the market may well mean that an IP holder does not have market power.[63] The US Supreme Court in *Illinois Tool Works Inc. et al v. Independent Ink Inc.* set aside the presumption that intellectual property rights confer market power.[64]

The second principle stresses that the overall goals of intellectual property and competition policy are essentially the same, and therefore there is no fundamental incompatibility between the two policy instruments. The current thinking is therefore that, there exists a complementary relationship which aims at encouraging innovation and competition.[65] It was illustrated in *Atari Games Corp v. Nintendo Inc.*, that antitrust and intellectual property are two bodies of law aiming at encouraging competition and innovation therefore are complementary.[66] This prevailing view has been explained however to be based on the assumption that the patent rights have been properly obtained in compliance with the substantive and procedural requirements for patentability. As Carlos Correa contends, the presumption is,

> [P]remised on the assumption that the intellectual property is properly obtained. Problems arise when particular intellectual property rights have not been obtained in the proper manner or are not deserved. For example, patent protection in the absence of novelty and non-obviousness can harm innovation by eliminating the incentives for the patent holder and others to engage in further pursuit of something that is novel and non-obvious.[67]



[61] *See* FTC REPORT *supra* note 2 (reiterating the rule of market power).
[62] *Id.*
[63] *Id.*
[64] Illinois Tool Works Inc. v. Independent Ink Inc., 126 U.S. 1281 (2006).
[65] *See* Dart Wielsch, *Competition Policy for Information Platform Technology*, 25 EUR. COMPETITION. L. REV. 99 (2004).
[66] Atari Games Corp. v. Nintendo Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990); *see* FTC REPORT, *supra* note 2
[67] Carlos Correa, Intellectual Property and Competition Law: Exploration of Some Issues of Relevance to Developing Countries, *at* http://www.iprsonline.org/resources/docs/corea_Oct07.pdf (last visited Jan. 04, 2010).

These basic principles governing the patent and competition interaction as illustrated in the court treatment of cases dealing with intellectual property and antitrust are widely accepted.

### *1.5 Limited Conditions Likely to Present Tension in the Patent –Competition Interaction*

The objectives of competition policy and patent rights can have underlying tensions under certain limited conditions. Competition policies and patent protection interact at three instances. The first interaction is to be viewed in determination, interpretation and analysis of patentability thus requiring an analysis of the statutory and substantive standards for patentability.[68] The substantive and statutory standards of patentability are novelty, non-obviousness and inventive step, industrial applicability and usefulness, disclosure and prior use requirements.

Increase in patent applications in the US and EU, has given rise to fear that many low quality patents with broader scope are being issued, without taking into consideration the substantive standards of patentability. This has the impact of prolonging monopolies over the patent rights and even more crucial, it has the impact of slowing innovation since it results in the blocking innovation for example biotechnology or software patents issued during the early stages of research may create an obstacle to downstream research and commercialization.[69]

Noncompliance with substantive standards for patentability affects competition in that it presents a barrier for other competing inventors to develop competing products for fear of infringing on patent rights since it is uncertain to what parameters the granted rights extend. This therefore makes the products more costly for the consumer to purchase.[70] To avoid

[68] Bonito Boats Inc. v. Thunder Crafts Boats Inc., 489 U.S. 141, 147 (1989).
[69] FTC REPORT ch.4.
[70] According to the FTC, substantive standards and procedural standards may either promote entry into the market by fostering innovation or may impede entry and give rise to market power thus patent rights have the ability to confer economic benefits or cause net economic harm.

unnecessary restraints on competition, substantive standards of patentability should aim to support patentability for those inventions that were the patent not issued; the invention would not have been forthcoming.[71]

The second interaction takes place in terms and conditions of licensing agreements.[72] Agreements between patentees and licensees may in numerous instances restrict competition by their operation in imposing stringent conditions and terms with regard to territorial restrictions, requirements to pay royalties extending past the protection period, some field of use restrictions and in some circumstances patent tying, refusals to deal and patent pools.[73]

It is mainly within this framework that developing countries are able to view the effects of the patent protection and competition interaction in their efforts to acquire patented technologies from industrialized countries.

It has been noted that the interaction between patents and competition policies occurs within licensing agreements. Licensing is crucial for developing countries in that it allows the dissemination products and processes under patent protection.[74] However, certain forms of licensing may be anti-competitive where the terms and conditions of the license tend to unfairly bind the licensee preventing and restricting open competition. In analyzing the different terms of licensing agreements that may be anti-competitive, we look to rules and legislations providing guidelines and governing licensing agreements, namely the TRIPS



[71] *See Bonita Boats Inc.*, 469 U.S. 141 (1989).

[72] In developing countries, anti-competitive practices are usually analyzed within the basic framework of horizontal and vertical restraints.

[73] *See* Carene E. Hardler, *Antitrust Implications of Settlement and Patent Disputes*, 792 PRAC. .L. INST. 491(2001) (finding that the vast majority of patent licenses do not warrant or invoke antitrust scrutiny, the basic principle is that because licenses surrender some lawful exclusionary rights inherent in the patent, they increase competition and are therefore pro-competitive).

[74] *See* Constance E. Bagley & Gavin Clarkson, *Adverse Possession for Intellectual Property: Adapting an Ancient Concept to Resolve Conflicts between Antitrust and Intellectual Property Laws in the Information Age*, 16 HARV. J.L. & TECH. 329, 330 (2003).

Agreement,[75] US Federal Trade Commission guidelines[76] and European Commission guidelines.[77]

It is seen that in some instances, restrictive licensing practices serve useful, pro-competitive purposes. Notwithstanding this, there is also wide recognition that intellectual property rights and related licensing practices can restrict competition in some limited circumstances. There is also recognition that competition policy has a crucial role to play in addressing the anti-competitive effects of licensing and other practices in these circumstances. As will be discussed in the subsequent sections, these perspectives are illustrated in the TRIPS Agreement and national competition or antitrust enforcement policies relating to the interaction between patents and competition policy. Another instance where the interaction between patents and competition policy is evidenced is in standard setting organizations, where there is acquisition of patents by deception.[78] The members of the standard setting organisation whose technology has been incorporated into a standard can engage in ex post patent hold up practices which give rise to antitrust questions.[79] Within the standard setting organisation, there is also the tendency for inventors to secure whole patent portfolios for the purpose of profiting from the essential patents contained therein or alternatively using the

[75] TRIPS Agreement art. 8.2, 40, 31(k) (the relevant provisions of TRIPS include Articles 8.2 , 40 and 31(k). Article 8.2 is part of the "General Provisions and Basic Principles " and should be read as a complement to the first paragraph of Article 8 which authorizes Members to adopt measures to protect public health and nutrition and promote public interest in sectors of importance to their development. Article 40 is concerned with substantive law relating to anti-competitive practices and matters of enforcement while Article 31(k) deals with compulsory licenses as a remedy for anti-competitive abuses of rights).

[76] DOJ Antitrust Guidelines 1995, *supra* note 24.

[77] In 1996 the EC adopted a Regulation which superseded the two block exemptions covering patent licensing and know how licensing. Commission Regulation 240/96 on Application of Article 85(3) of the Treaty to Certain Categories of Technology Transfer (Text with EEA relevance), 1996 O.J. (L 31) 2 which is no longer relevant and has been replaced by Commission Regulation 772/2004 on the Application of Article 81(3) of the Treaty to Categories of Technology Transfer Agreements 2004 O.J. (L 123) 47.

[78] *See* Rambus Inc., v. FTC, (D.C. Cir. 2008); *see generally* Joseph Drexl, *Deceptive Conduct in the Patent World*, *in* PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALISED WORLD 138 (Josef Drexl et al. eds., 2009) (for a detailed discussion on the Rambus Decision in the US finding antitrust violation due to withholding relevant information on patent policies in a standard setting organization which had the effect of monopolizing the market. *Rambus* resulted in the European Commission starting an investigation on the actions of Rambus in 2007, alleging a violation of Article 82 EC).

[79] *See id.* Drexl, at 139.

patents contained in the portfolio as bargaining chips or a defence against patent hold ups by rival firms.[80]

The interaction between patent rights and competition policies has substantial implications on developing countries. The points where the interaction occurs are in the substantive and statutory patentability standards and within licensing agreements. This is because developing countries to a large extent, are consumers of technology and not so much innovators especially in knowledge based industries such as biotechnology, computer hardware and software and communications technology, they therefore lack the requisite experience and resources to properly analyse patent claims before granting such patents. The patenting procedures are also not established to handle inventions from such industries in the case of developing and least developed countries.

The acquisition of patent rights by deception in relation to patenting of traditional knowledge resources in developed countries that has been fraudulently acquired may have anti-competitive consequences in that it eliminates legitimate competition through limiting access to the fraudulently patented resources.

### *1.6 Statutory Standards of Patentability*

The standards of patentability govern the granting and upholding of a patent through outlining the proper scope of a patents claim. The patentability standards also manage the patent system to ensure it fulfills its objectives of providing incentive for research and development and promoting innovation for the benefit of the consumer and society at large. According to the FTC, the standards of patentability provide, "a careful balance between the need to promote

[80] The Qualcomm case is a good illustration of this where Qualcomm derived huge profits from their patent portfolio covering CDMA technology, http://www.eetimes.com/showArticle.jhtml?ArticleID=172901195 (last visited Mar. 24, 2009).

innovation and the recognition that imitation and refinement through imitation are both necessary to invention and are crucial to ensuring a competitive economy."[81]

The standards of patentability are basically uniform in all jurisdictions due to the TRIPS Agreement, which as part of the WTO Agreement is equally applicable to developed and developing country members.[82] In addition to the TRIPS Agreement governing the applicable minimum standards of patentability, there exist other international intellectual property agreements such as the Paris Convention, administered by the WIPO and which contains provisions governing patentability standards. The objective of these intellectual property conventions and agreements, specifically TRIPS was provision of minimum standards for the protection of intellectual property rights. These rights cover a wide range of rights including but not limited to patents, copyright, trademark, geographical indications and undisclosed information. TRIPS Agreement makes reference to the Paris Convention provisions and incorporates some of these provisions.

Much of the focus in this study is on provisions of the TRIPS Agreement. The discussion will focus on the new obligations with regard to patent rights introduced by TRIPS as well as the measures relating to enforcement of patent rights and abuse of patent rights which are not included in the Paris Convention.

The patentability standards as set forth in TRIPS and other national intellectual property legislations specify the patentability requirements which include the invention must be new and not have existed previously (novelty). An invention must also be useful and industrially applicable in that it should be able to serve a purpose and be put to use for the benefit of the consumer. An invention must also be non-obvious and should constitute an inventive step. An important requirement that must also be fulfilled is the disclosure requirement, this



[81] FTC REPORT ch. 4.1.

[82] WTO had 149 members as of 11 December 2005, and 32 observer members who must start accession negotiations within 5 years of becoming observers, http//www.wto.org/English/thewto_e/whatis_e/tif_e/org6_e.htm.

requirement requires that the invention be disclosed to the public such that any person having ordinary skill in the art can work the invention and reproduce the invention. TRIPS in dealing with those inventions and processes which are patentable states under Article 27 that "patents shall be available for any inventions, whether products or processes in all fields of technology provided they are new, involve an inventive step (non obvious) and are capable of industrial application (useful)" it goes further to provide that patent rights should be available and enjoyed without discrimination. In laying out this discrimination principle, TRIPS specifies the kinds of discrimination prohibited against patent rights to be, any discrimination based on the place of invention, on the field of technology and the place of production as well as discrimination based on whether the patented product is locally produced or imported.

The standards of patentability should aim to achieve four major policy objectives which have been repeatedly set out by the FTC in relation to patent protection. The standards of patentability seek to achieve the objectives of namely, seeking to provide incentive for innovation, disclose the patent, prevent the unnecessary restraints on competition through monopolistic practices and provide certainty of patent rights in order to eliminate those costs that are likely to accrue due to another inventor unknowingly infringing patent rights.[83]

The definition of invention is done in national legislation with the individual Member States left to define the scope and breadth of the specified criteria for patentability under Article 27 of TRIPS Agreement. Developing countries are encountering difficulties as to how they should define the criteria for patentability so as to meet the objectives of providing incentives for innovation while avoiding unnecessary restraints on competition through supporting only those inventions whose disclosure and development would not have occurred without patents and thirdly to safeguard the disclosure requirements so as to ensure certainty for inventors to recoup on research and development costs as well as profit from their inventions.

[83] FTC REPORT ch. 4.

The existence and enforcement of patents that do not comply and meet patentability standards acts as a hindrance to competition and ultimately goes against consumer welfare.[84] It is in the interest of developing countries to engage in studies of how substantive standards of patentability affect competition law and policy and consequences that patentability standards might have on anti-competition. Developing countries however suffer the limitation of lacking adequate human resource and capacity in their patent offices and other technical specialists. The effect of this is that they tend to issue patents without due regard to the substantive requirements for patenting which later results in anti-competitive abuse of patent rights to the detriment of consumer welfare.

### *1.7 Patent Rights and Competition Policy in Developing Countries*

Competition policies in developing countries are generally tailored to suit their specific and unique development objectives. This is illustrated in a situation where a country is dependent on agriculture; the competition policies will mostly deal with agricultural aspects and trade, to some extent neglecting other areas of industry and development.[85] Another observation is that many developing countries mirror their competition laws with the laws of their former colonial masters and have maintained the same laws with minor amendments such that the laws as they stand today do not provide a sound foundation for establishing good competition policies that are beneficial to the countries development.

A new trend for developing countries has been to establish regional economic unions one notable monetary and economic union is the East African Community (EAC), the Common Market for Eastern and Southern Africa (COMESA) and the West African Monetary and Economic Union (WAEMU), which treaty was signed in 1994 (revised Treaty signed in 2003). The WAEMU Treaty aimed at setting up a common market among its Member States

[84] *Id.*
[85] A general analysis of competition policies in Kenya provides evidence of this observation.

through regulating competition in the market place. Another treaty having the same objectives is the Economic and Monetary Community of Central Africa catering for central African Member States. These regional economic unions have undertaken the role of regulating competition. Under the WAEMU Treaty, the regulation of competition is carried out through establishing competent competition commissions having exclusive competence to legislate on the issues of competition. It is modelled after the EU competition legislation. The advantage of such a body is the uncertainties regarding the co-existence of different legal systems and enforcement bodies is overcome which is advantageous in that it enhances development and is attractive for foreign investors.[86]

Another economic union namely COMESA which emerged from the Preferential Trade Agreement Treaty as well as the EAC Treaty is of interest in sub Saharan countries. Both treaties are aimed at regional integration and trade facilitation and development through encouraging trade and eventually attaining a common market and economic community in east Africa, with the COMESA region extending to South African States. The COMESA court of Justice as the judicial organ of COMESA has the jurisdiction to adjudicate on matters pertaining to the COMESA Treaty especially unfair trade practices and adjudication of disputes among member countries regarding interpretation and application of the treaty. The decisions of the COMESA Court take precedence over decisions of national courts thus ensuring the treaty is applicable uniformly. The COMESA Treaty with regard to competition policy has formulated regional competition policy consistent with the internationally accepted principles of competition mirroring those recommended by the WTO. The objective of this competition policy is to provide consistency and facilitate the objective of ensuring lower tariffs and enhanced trade and competition within the region. The COMESA Court has the



[86] *See* Mor Bakhoum, *Delimitation and Exercise of Competence between the West African Economic and Monetary Union (WAEMU) and its Member States in Competition Policy*, 29 WORLD. COMPETITION. 653, 661 (2006).

role of interpreting competition provisions and ensuring compliance with competition legislation in the region.[87]

Competition policy agencies in many developing countries are not well established nor do they function independently as compared to the US and EU as illustrated previously.[88] As to whether or not there is a standard competition policy that developing countries can individually apply, there is a rejection of this notion of one size fits all competition policy for developing countries.[89] All developing countries are encouraged to ensure that they comply with certain guidelines which will allow them to establish clear competition policies that will enable them compete effectively in today's markets.

### *1.8 North –South Gap with Regard to Differences in Patent Protection*

With adoption of the TRIPS Agreement, there has been an increase in issues where developing and industrialized countries adopt diverging positions. Economic growth and development in developing countries is impacted by trade with the developed countries and a historical analysis of free trade in patents between developed and developing countries illustrates the uneven development and ever widening gap in terms of wealth and living standards.

The conflicting positions between developed and developing countries is illustrated by debates covering a wide range of issues relating to patents, beginning with whether patent



[87] *See* Charles L. Chanthunya, *The COMESA Free Trade Area: Concept Challenges and Opportunities*, *in* THE FREE TRADE AREA OF THE COMMON MARKET FOR EASTERN AND SOUTHERN AFRICA 26 (Victor Murinde ed., 2001).

[88] The Competition Commission in Kenya has some overlapping functions with the Minister for Trade and Industry. In cases of anti-competition relating to patent rights, there are overlapping powers between the Director of KIPO and the Minister for Trade and Industry. In South Africa, the question relating to what falls under the mandate of the Competition Commission has been addressed in the case of GlaxoSmithKline SA v. David Lewis and Others, 61 (C.A.C. 2006) (the contention that the Competition Commission does not have a mandate to agree to the terms of an order after referring a complaint to the Competition Tribunal).

[89] The WTO dropped attempts to discuss an international competition law after implementation of TRIPS Agreement. *See generally* Waller Spencer Weber, *An International Common Law of Antitrust*, 34 NEW ENG. L. REV. 163 (1999).

protection is necessary for developing countries. The WIPO Development Agenda report of 2004 that was proposed by Brazil and Argentina revived the debate on the different positions with regard to the necessity for patent protection for developing countries.[90] The developing countries have always expressed reluctance to comply and sign treaties dealing with intellectual property due to the fact that intellectual property protection mainly benefits foreign applicants and registrants.[91]

In the 1960's the question as to the benefit of adopting a patent system by developing countries was tabled before the UN General Assembly. During this period developing countries lead by Brazil, India and Mexico sought to have in place a document aimed at regulating technology transfer in the form of a code of conduct for technology transfer.[92] This however never came to pass. These leading developing countries also shared a common feature in that they selectively provided for patents in some fields and declined granting patent rights in other fields as seen in the case of India, whose laws did not provide patent protection for pharmaceutical and agricultural chemical compounds and did not have a system or procedure for filing patent applications for pharmaceutical and agricultural chemical products, nor did they have provisions for the granting of exclusive marketing rights for such products. Brazil also only provided for patents for manufacturing methods.[93]

During the TRIPS Agreement negotiations, there was severe opposition from the developing countries to the TRIPS Agreement mainly based on the argument that developing countries considered "the priority of the right a people to their livelihood to take precedence over



[90] *See* http://www.cptech.org/ip/wipo/wipo10042004.html providing a short summary of the United Nations General Assembly Development Agenda of 2004 (last visited Mar. 10, 2010).
[91] *See* Peter D. Siemsen & Ivan B. Ahlert, *Patents and Developing Countries*, *in* PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALISED WORLD 650 (Josef Drexl et al. eds., 2009).
[92] *Id.* at 647 *discussing* U.N. Doc. A/C.2/L.565, (1961) which concerned an extensive debate as to the suitability and benefits of patents for developing countries. The report concluded that a study be undertaken on the issue of patents for developing countries which was completed in 1964).
[93] *Id.* at 648.

[property] rights".[94] In the former colonial States in the developing world, the issue of sovereignty was still considered to take precedence over all other issues. Taking this background into consideration, the TRIPS Agreement was only concluded after promises were made to reduce subsidies for agricultural products so as to make it possible for developing countries to export agricultural products to industrialized countries mainly the EU and US.

Taking these developments between the North and South countries into consideration, the more recent debate regarding the cost for patented AIDS drugs became a major dispute during the Doha round of negotiations. This included the disputes between the US and Brazil on pharmaceutical products, the threat to use special Section 301 as well as the dispute between Pharmaceutical corporations and the government of South Africa. This was only resolved through the allowing of compulsory licensing for patented drugs in cases of national health emergencies.[95]

In 2002, developing countries once more tabled the issue of importance and necessity of intellectual property rights for developing countries which interestingly laid down some basic concepts for intellectual property rights for developing countries while stressing that the standards applicable to developing countries should be different from those of developed countries due to the different levels of development and differing trade and economic objectives. On the role played by WIPO in promoting intellectual property rights, the paper requested the organization promote the general rights of society as well as the rights of the intellectual property owners. This need for ensuring societal benefit of intellectual property rights by developing countries is understandable, taking into consideration the attempts made by developing countries to procure collective intellectual property rights in traditional

[94] *See* Steidlmeir, P. *The Moral Legitimacy of Intellectual Property Claims: American Business and Developing Country Perspectives*, 12 J. BUS. ETHICS. 157, 164 (1993).
[95] WTO Declaration on TRIPS Agreement & Public Health, Nov. 14, 2001, WT/MIN (01)/DEC/2 [hereinafter Doha Declaration] *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (last visited Nov. 9, 2009).

knowledge, genetic resources and folklore which are resources usually not owned by a single entity but by a community.

It is suggested that developing countries should take the route followed by India, Korea and Japan which have made huge technological leaps in innovation and intellectual property rights through education so as to have the ability to recognize innovations and opportunities for innovations and utilize them for the benefit of their development. As stated by Peter D. Siemsen and Ivan B. Ahlert, "the difference between countries is not only rich and poor, but the capacity to generate technology."[96] In agreement with this view, developing countries need to establish basic skills and technologies on which new developments can be deployed. This is because even when technology is acquired from developed countries, the knowledge to utilize this technology may not be fully developed thus the technology cannot be utilized to its capacity rendering it uneconomical. In addition to the evidence of debates and legal conflicts that expanded the north-south divide with regard to intellectual property, some legal scholars in addressing this divide have focused on the social aspect. The concentration being made on the social welfare consequences as a result of north-south divide and patent protection levels. Diwan and Rodrik in their paper on patents and north-south trade concluded that although patent protection through patent laws affects the quantity of innovation by increasing innovation in both developed and developing countries, the two regions have differing technological needs. In addition to this they found that for the welfare of the developing countries, there is need to have differential treatment.[97]

Some scholars are clearly against patents for developing countries, maintaining the opinion that patent protection should be minimized to spur innovation and development through imitation and reverse engineering.[98] An analysis of whether strengthening intellectual

[96] *See* Siemsen & Ahlert, *supra* note 91 at 651.
[97] *See* Ishac Diwan & Dani Rodrik , *Patents, Appropriate Technology and North- South Trade, in* THE WTO, INTELLECTUAL PROPERTY RIGHTS AND THE KNOWLEDGE ECONOMY. 387 (Keith E. Maskus ed., 2004).
[98] *Id.*

property rights in developing countries limits imitation and affects foreign direct investment by multinational firms finds that having stronger intellectual property laws makes multinational firms no less secure. It in fact makes imitation costly which results in a resource wasting effect in the developing countries with strong patent protection against imitation acting as a tax thus making imitation costly.[99]

The north south divide cannot therefore be minimized through only legislative means since it is evident that these are unlikely to be successful. The solution could possibly lie in developing countries undertaking an analysis of their individual technological needs and striving to spur innovation in their countries through means such as reverse engineering which requires some form of technological base that is lacking in many developing countries. Therefore the first step would be to develop a technological base, following which adopt policies supporting reverse engineering and manufacturing based on the disclosed technologies.

### *1.9 Theories Resolving Conflicts Arising from Patent Rights and Competition Policy Interaction*

The question remains which approach may be applicable in resolving those anti-competitive effects likely to result from the patent and competition policy interaction in developing countries. The suitable option is to find a solution within the TRIPS provisions which addresses competition policy and abuse of patent rights. The relevant provisions that refer to competition law regulations are Articles 8, 31(k), and Article 40. These provisions of TRIPS Agreement however do not contain an international obligation to introduce national

[99] *See* Amy J. Glass & Kamal Saggi, *Intellectual Property Rights and Foreign Direct Investment*, 56 J. INT'L. ECON. 387, 410 (2002) (the paper develops an economic model to determine how strong intellectual property protection affects innovation imitation and FDI in developing countries and finds that strong IP protection helps to prevent imitation but ultimately results in reduced FDI since more resources that could have been invested are used to prevent imitation).

competition rules.[100] The provisions only authorize WTO members to provide for such rules within certain limits.[101] The reliance on TRIPS Agreement in resolving resulting problems of the interaction between the two legal bodies despite the varying national competition laws and policies seems plausible considering the fact that the TRIPS Agreement in essence seeks to uphold and promote a global, harmonized intellectual property regime while leaving the issues of competition law to national jurisdiction and competence based on individual country economic needs. In the case of EU, the approach is slightly different since competition matters lie within the competence of the EU and are not entirely left to national competence.

The second approach lies in within conducting a review of the TRIPS Agreement. Such a review would encompass those issues of conflict and of interest to both developing and developed countries with the aim of assisting developing countries achieve their developmental objectives and not running counter to these objectives.

The third theory would involve drafting of international agreements governing issues arising out of the intellectual property and competition law interaction. This however would result in more rules for contracting parties to the WTO Agreement especially developing countries, which would raise difficulties with regard to coping with the increased rules. This solution involves drafting new agreements and can be illustrated by the Doha Declaration on Public Health which came into being to resolve the problem of inaccessibility of cheap medicines for countries lacking manufacturing capacity to enable them exploit the flexibilities inherent in TRIPS that relate to compulsory licensing.[102] In addressing the problems resulting from the interaction between patent protection and competition Member States of the WTO may also



[100] *See* Wolfgang Fikentscher, *Historical Origins and Opportunities for Development of an International Competition Law in the TRIPs Agreement of the World Trade Organization (WTO) and* Beyond, *in* FROM GATT TO TRIPS 226 (Friedrich-Karl Beier *et al* eds.,1996).
[101] *Id*. at 233-238.
[102] Reviewing the adequacy of the TRIPS Agreement was initially launched in Doha after protests by developing and least developing countries on some issues.

adopt new agreements or declarations resolving anti-competitive effects and implications these effects may have on developing countries.

The common theme of the described approaches is that they all give an allowance to WTO members to introduce specific competition law provisions aimed at resolving the abuse of dominant position and controlling restrictive clauses in licensing agreements.

The third approach relies on competition law and policy for a solution. The approach relies on the application of competition law in event of abuses of patent rights which in their exercise result in anti-competition effects. In applying competition policy to remedy and mitigate the effects, the solution should focus on an effects based approach which takes into consideration the consumer welfare aspects. It analyses whether the so called anti-competitive effects are contrary to consumer welfare or not. An example of such an effects based approach is the US Licensing Guidelines which replaced the Nine No No's and the 2004 revised EU Transfer of Technology Block Exemptions. Thus the competition enforcement agencies and courts should focus on the effect rather than the form when analyzing whether a particular licensing arrangement amounts to a violation of competition law and policy.[103]

The harmonization of competition policy in the face of diminishing tariffs and duties today resulting from bilateral and regional trade agreements may be a solution to resolving some issues arising out of the patent and competition policy interaction.[104] How this may be a solution however is yet to be deeply analyzed. A number of barriers however exist which are based mainly on issues of national sovereignty, an important issue for many developing and least developed countries.

Whichever solution is applied in resolving the conflicts, the theory of complementarity should be applied according to which the intellectual property system should be designed and implemented such that it is in close collaboration with competition policy and should "not be

[103] *See* Masoudi, *supra* note 55 at 19.
[104] OECD, http://oecd.org/dataoecd/61/48/34306055.pdf

immunized against competition."[105] It should in fact be to the contrary, where the two legal regimes operate together to ensure the relevant product market is competitive and serves to maximize the incentives for innovation.

***Summary***

Patent rights and competition share a common goal in that they both have consumer welfare objectives. A historical analysis of the development of patent law shows that patent rights are a western concept, based on the philosophy of enlightenment having evolved in the industrialized countries over a long period of time. The concept of intellectual property rights in developing countries is seen to be difficult to incorporate in their legal system. This is largely due to the different development in legal philosophy, cultural and social developments. This is evident in the different forms of property rights in existence in developing countries such as collective rights in traditional knowledge and communal ownership of land and genetic resources. In addition to this is the acceptance of customary law which is characterized by its dynamic nature as legally enforceable. The effect of the difficulty to incorporate intellectual property rights into the legal systems of developing countries is evident in the weak enforcement of intellectual property rights, low numbers with regard to inventions, as well as lack of incentive to innovate. As a consequence, the wealth gap between the developing and developed countries continues to widen. In spite of the difficulties encountered by developing countries, the adoption of the TRIPS Agreement has proved beneficial in the sense that to some extent developing countries are able to compete in the global market place. The TRIPS Agreement therefore provides a basis from which the solution for resolving the anti-competitive effects of the interaction between competition and patent rights can be formulated. A TRIPS Agreement based solution seems feasible largely

[105] Josef Drexl et al., *Comments of the Max Planck Institute for Intellectual Property, Competition and Tax Law on the Directorate General Competition Discussion Paper of December 2005 on the Application of Art. 82 of the EC Treaty to Exclusionary Practices*, 37 INT'L. REV. INTELL. PROP. & COMPETITION. L. 558 (2008).

due to the fact that TRIPS is an international agreement setting minimum standards for intellectual property rights and is uniformly applicable to Member States of the WTO which includes both industrialized and developing countries. The applicability of TRIPS in resolving the conflicts arising out of the interaction between patent rights and competition policy is further strengthened by the availability of the dispute settlement body of the WTO in event of conflicts involving Member States.

## 2 REGULATORY FRAMEWORKS GOVERNING PATENT RIGHTS AND COMPETITION POLICY

### *2.1 Introduction*

This chapter seeks to outline the regulatory frameworks governing the patent and competition law and policy interaction. The examination of the regulatory frameworks governing patent and competition law and policy allow for a comparative analysis of the interaction to be carried out. An examination of the judicial approach by the courts in the US, EU, South Africa, Kenya and India illustrates the different approaches used by the courts in resolving the anti-competitive abuses that may result from the interaction between patent rights and competition policy. A comparative analysis is critical in that it aids to highlight weaknesses in the legislations of developing countries that contribute to difficulties arising from the competition and patent protection interaction. According to Daniel Gervais, adequate competition law measures should form part of a well-functioning intellectual property system.[106]

The sources of intellectual property law are classified as national, regional and international. National sources being the statutory legal instruments enacted in the individual States that are aimed at regulating the protection and exploitation of intellectual property rights. National sources also include guidelines issued by governmental agencies established to create policies relating to intellectual property and to some extent dealing with the interaction between competition policy and intellectual property rights. In the US these government agencies include, US Patent Trademark Office (USPTO), DOJ and FTC. National sources of intellectual property are important because they indicate the intellectual property framework adopted by individual States to suit their objectives relating to innovation and development. In the different jurisdictions, depending on their level of development it will be seen that

[106] *See* DANIEL GERVAIS, THE TRIPS AGREEMENT DRAFTING HISTORY AND ANALYSIS 21 (2003).

different objectives are pursued. In the US and EU, intellectual property legislation mainly seeks to protect the inventions from imitation so as to encourage further innovation and research, whereas in developing country jurisdictions such as India, intellectual property laws are geared towards protecting the national industries and encouraging innovation through allowing imitations and reverse engineering.

International sources of intellectual property law are important in this analysis in that they are external influences on national intellectual property law, derived from the fact that trade is no longer confined to the national borders of the State, but extends to the international market hence the need for international intellectual property laws. In this study the relevant national and international sources of intellectual property laws will be addressed with some emphasis on international intellectual property laws taking into consideration those peculiarities in some national jurisdictions that are of interest to developing countries.

There exist three international and regional bodies of interest in this paper providing for and governing intellectual property protection namely, World Intellectual Property Organization (WIPO),[107] European Patent Office (EPO) and World Trade Organization (WTO).[108] These intellectual property bodies are administrators of the main intellectual property rights treaties and conventions.

The interpretation and application of international agreements dealing with intellectual property rights is based on the principles of international agreements. From these principles of international agreements, four main principles emerged these being the principles of reciprocity, priority, national treatment and independent treatment as well as the most favored



[107] World Intellectual Property Organization [hereinafter WIPO] is the first international intellectual property body, predating the European Patent Office [hereinafter EPO] and the WTO. WIPO is a complex organization but is largely independent, despite being a UN Agency WIPO has a three level governing structure comprised of a General Assembly, Conference and Coordination Committee. With upwards of 151 Member States whose interests and priorities vary across the patent trademark and copyright realms. The functions of WIPO include; Setting norms and advancing the standards of intellectual property across the world, administering the various treaties or intellectual property conventions and cooperating activity coordination for developing countries.

[108] G. Bruce Doern, *Global Changes in Intellectual Property Agencies, An Institutional Perspective*, *in* SCIENCE TECHNOLOGY AND THE POLITICAL ECONOMY, (John de la Mothe ed., 1999).

nation treatment.[109] These principles are of interest in this study because the application of the principles in a uniform manner may be to the detriment of developing countries. This is largely due to the different levels of development existing amongst countries. Some developing countries when strictly applying the principles may leave their markets vulnerable to exploitation by transnational corporations which have sound financial backing, unlike the national small and medium sized enterprises. The principle of reciprocity mandates that one Member State of an agreement will provide parallel protection to nationals of another Member State of the agreement the same protection as that of its own nationals. The principle of priority is concerned with the granting of protection. In intellectual property rights, being able to apply for protection as early as possible is of utmost importance. Taking this into consideration, the principle of priority enables the intellectual property owner to make an early application by giving a priority date to the first application in one State. The date of the first application is applied to subsequent applications as in other States as long as they are filed within the prescribed time period.[110]

The national treatment principle mandates that nationals of one Member State to an agreement shall receive the same treatment as the nationals in any other Member States irrespective of level of protection offered in the first State. This principle is set out in the Paris Convention and TRIPS Agreement of 1994.[111]

Independence of Rights is a principle that ensures that an intellectual property right that is legitimately acquired in one State will not be automatically affected by decisions regarding that right that are taken in other Member States. This right includes the country of origin of the right.



[109] CATHERINE COLSTON & KRISTY MIDDLETON, MODERN INTELLECTUAL PROPERTY LAW 7 (2d.ed. 2005).
[110] The Paris Convention for example gives a priority period of 12 months for patent applications and 6 months for Trade Mark applications. *See* Paris Convention *supra* note 47.
[111] TRIPS Agreement art. 3.

The most favored nation treatment is a fairly new principle in intellectual property law compared to the other principles and was first laid out in the TRIPS Agreement. The principle states that all advantages favors immunities and privileges granted to nationals of any country must be accorded to nationals of all WTO Member States.

### *2.2 Treaties and Conventions Governing Patent Rights*

With international trade and the need for legislation governing intellectual property in the international sphere, there was need to have multilateral agreements so as to enable States to cater to their multilateral obligations. The international convention governing industrial property was the Paris Convention for the Protection of Industrial Property of 1883 as revised at Stockholm in 1967. The Paris Convention although of international and regional scope was limited to some extent because it lacked an enforcement procedure that could force non-compliant Member States to grant and enforce adequate intellectual property protection. To administer these first intellectual property rights regional and international agreements, the WIPO was established in Stockholm on July 14, 1967.[112]

The need for an international Convention governing intellectual property rights was first realized in 1873, when the then Austro-Hungarian Empire organized an international exhibition of inventions. Difficulties were encountered in that, due to the inadequate legal protection offered to exhibited inventions, visitors were reluctant to display their inventions.

The result was the enactment of an Austrian law to secure temporary protection to all foreign inventors exhibiting their goods and this also resulted in the Congress of Vienna for Patent



[112] *See generally* WORLD INTELLECTUAL PROPERTY ORGANIZATION, WORLD INTELLECTUAL PROPERTY HANDBOOK: POLICY, LAW AND USE (2001) (discussing the history of WIPO and the WIPO treaties).

Reform.[113] An objective of the Vienna Congress was that it aimed at highlighting the need for patent protection and to bring an international understanding on patent protection.[114]

In 1883, a Conference in Paris was convened and the end result was the Paris Convention for the protection of Industrial Property.[115] The Paris Convention is of importance because it holds most provisions set out under the TRIPS Agreement, including the important provision allowing for compulsory licensing to counter anti-competitive abuses of patent rights.[116]

### 2.2.1 WTO and TRIPS Agreement

The TRIPS Agreement is considered the most comprehensive international agreement aimed at harmonising intellectual property law. TRIPS as previously stated came about during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT).[117]

Through the TRIPS Agreement, all contracting parties to the WTO Agreement undertook to incorporate and provide mechanisms for the protection and enforcement of intellectual property rights in their countries. The objective of incorporating intellectual property issues under the GATT was because the different protection and enforcement of intellectual property rights within the member states was a non-tariff barrier that was seriously interfering with international trade. The TRIPS Agreement may be said to have been much broader in scope than any other previous intellectual property agreement, in that it rejuvenated those intellectual property treaties that failed to protect rights adequately and provided intellectual

[113] *Id.* at 241.
[114] *Id*.
[115] Following the Vienna Congress of 1873, an International Congress Industrial Property was convened that aimed at analyzing the feasibility of having in place a uniform legal system governing industrial property the result was a draft that was presented in Paris in 1880 that ultimately became the Paris Convention, which later underwent amendments culminating in the Paris Convention as amended in Stockholm of 1967.
[116] The Paris Convention specifically refers to compulsory licensing in Art. 5A, and allows for compulsory licenses to be used to remedy anti-competitive practices. The Convention remains an important treaty because firstly, it has a broad membership of currently 151 member states. Secondly, Article 2.1 of the TRIPS Agreement makes reference to the provisions of the Convention by requiring compliance with Articles 1-12, and 19 of the Paris Convention. Article 5A (2) states that each member country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.
[117] General Agreement on Tariffs and Trade, Oct. 30, 1947, 55 U.N.T.S. 194 [hereinafter GATT].

property protection on a multilateral sphere. In addition to this, TRIPS set out detailed rules regarding enforcement of intellectual property rights which were applicable multilaterally. In the case of developing countries TRIPS was important in that it was applicable uniformly to all WTO Member countries irrespective of the level of development. This uniform applicability is both an advantage and disadvantage for developing countries. This is because it tends to treat developing countries on an equal level with industrialised countries which may not be beneficial for developing countries in the long run. The unique nature of the TRIPS Agreement has been reiterated by legal scholars stating that

> The TRIPS Agreement is unique in the WTO context; it is the only WTO agreement that requires the members to affirmatively (or positively) incorporate complex substantive legal standards into national laws that govern both domestically produced and imported goods. It relies for many of its rules on cross-reference to an existing body of multilateral conventions administered outside the WTO. The substantive rules imposed by the TRIPS Agreement are the subject of existing bodies of judicial opinion in the national and regional territories that are now subject to its discipline. Underlying the superficial certainty of the TRIPS Agreement substantive prescriptions are existing gulfs of interpretative difference regarding the meaning of many of its rules.[118]

TRIPS notably provides the minimum requirements for intellectual property protection and while so doing the agreement recognises that intellectual property rights can be subject to anti-competitive practices and may have anti-competitive consequences as a result of their legitimate exploitation of the rights.For this reason, TRIPS incorporates some relevant provisions governing anti-competitive practices and addresses some ways through which intellectual property rights may be abused or exploited to result in anti-competitive abuses.[119] The TRIPS Agreement does not introduce rules of competition law requiring the Member States to adopt these rules. Rather TRIPS makes a reservation in favor of the States national competition policy rules. Under TRIPS, Members are authorized to establish and maintain



[118] *See* ERNST-ULRICH PETERSMANN, INTERNATIONAL TRADE LAW AND THE GATT/WTO DISPUTE SETTLEMENT SYSTEM 415 (1997); s*ee also* GERVAIS, *supra* note 106 at 210.
[119] *See* Ullrich, *supra* note 12, at 403.

competition rules.[120] The following section will outline the relevant TRIPS provisions and their interpretation including those provisions dealing with licensing practices relevant to the interaction between patent rights and competition policy.

#### *2.2.1.1 Provisions Relating to Competition and Abuses of Patent Rights under TRIPS*

The provisions governing anti-competitive practices under the TRIPS Agreement can be distinguished into two groups, prohibitive and remedying. The prohibitive group is composed of those provisions which prohibit anti-competitive practices and abuse of intellectual property. The second group is composed of remedying provisions which are those provisions aimed at remedying anti-competitive practices and abuses of intellectual property rights. The TRIPS Agreement in its preamble also recognizes that the measures and procedures used to enforce intellectual property rights can be barriers to effective trade.[121]

#### *2.2.1.2 The general Principles: Article 8*

The basic principles of TRIPS are set out under Article 8.[122] The provision allows WTO Members to take specific actions in the protection of public health including those measures which are aimed at preventing the abuse of intellectual property rights and practices that unreasonably restrain trade. Article 8 addresses anti-competitive practices in contractual licenses. Daniel Gervais in his analysis of the TRIPS Agreement makes an argument that



[120] During negotiations leading to the TRIPS Agreement, developed countries conceded to the provision authorizing members to establish or maintain competition rules following the failure of developing countries to push for enactment of a Code of Conduct for the Transfer of Technology; *see* GERVAIS s*upra* note 106 at 182.
[121] The Preamble reads as follows "Desiring to reduce distortions and impediments to international trade and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."
[122] TRIPS Agreement art. 8.1 states, "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."; *see* GERVAIS, s*upra* note 106, at 121.

Articles 7 and 8 now have higher legal status. This higher legal status is due to special reference made to Articles 7 and 8 in paragraph 19 of the Doha Declaration[123] with regard to interpretation of the TRIPS Agreement in the context of dispute settlement procedures or such like situations.[124] According to Gervais, Article 8 is "essentially a policy statement that explains the rationale for measures taken under Articles 30, 31 and 40".[125]

Under Article 8.2, WTO Member countries have the power to implement and enforce their rules on anti-competitive practices without violating their obligations under TRIPS. The provision provides that,

> Appropriate measures provided that they are consistent with the provision of this Agreement, may be needed to prevent the abuse of intellectual property rights by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.[126]

Article 8 in allowing members to adopt laws and regulations is a remedying provision because it gives a general consent to member states to implement measures aimed at remedying anti-competitive intellectual property practices.

#### *2.2.1.3 Article 40 TRIPS Agreement*

Article 40 (1) deals with licensing practices and conditions relating to intellectual property rights and in essence acknowledges that some of these licensing practices and conditions may be restrictive to competition and therefore affect trade and technology transfer. The provision under subsection 2 provides a remedy to this anti-competitive practices resulting from licensing practices and conditions by allowing members to specify in their legislation those



[123] *Id*.; *see also* Doha Declaration.
[124] Doha Ministerial Declaration, Nov. 14, 2001 para. 19 instructs the Council for TRIPS to review art. 27.3 and examine the relationship between TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council is to be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and should take into account the development dimension.
[125] *See generally* DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS (3 ed., 2008) 1998
[126] *See* TRIPS Agreement art. 8.2.

licensing practices and conditions which may in some instances result in anti-competitive effects and adopt appropriate measures to prevent and control such anti-competitive practices. Article 40 is a remedying provision in that it recognizes the possibility of licensing practices being anti-competitive. The provision allows the member countries to enact legislation aimed at preventing and controlling such anti-competitive practices.

Other provisions in the TRIPS Agreement dealing with competition policy include the provision allowing the Member States to impose compulsory licenses on intellectual property rights owners so as to remedy anti-competitive practices.[127]

As regards new technologies related to computer programs and other technologies in a standard setting environment, a question to be considered is whether the TRIPS Agreement provides adequate rules against abuse of intellectual property rights that are applicable to new technologies since it is these new technologies that attract scrutiny under competition law because the legislators fail to adequately legislate and define the parameters of these exclusive property rights.[128]

The competition rules set out under the TRIPS Agreement give rise to some principles which can be used as guidelines. These are firstly that intellectual property related competition policy is reserved to the States national legislation or regional legislation where applicable. Secondly, there is a requirement that national or regional intellectual property related competition policy be consistent with the TRIPS Agreement's principles of intellectual property protection. Thirdly, the so called dissemination concern where under the TRIPS Agreement provisions tension is evident between its goal of promoting and protecting



[127] *See* TRIPS Agreement arts. 31(c), (k).
[128] *See* Ullrich, *supra* note 12, at 403; *see also*, controversies surrounding the legal protection of computer programs Council Directive 91/250/EEC, 1991 O.J. (L 122) 9, 13; *see also*, Council Directive 96/6, 1996 O.J. (L 77) 20.

innovation through uniform international standards and the goal of safeguarding dissemination of information to developing countries on reasonable terms.[129]

Article 8.1, 8.2 and 40.2 of the TRIPS Agreement read together in keeping with the consistency requirement provides that Member States take measures under their domestic legislation to prevent abuses of intellectual property rights and restrictive practices. These provisions as stated in the previous section do not provide substantive and procedural measures that the State should undertake to prevent such practices, nor do they provide exhaustive remedies that should be available in event of violation other than compulsory licensing. Article 8.2 in giving the Member States full powers to implement rules on anti-competitive practices as previously stated, indicates the stance taken by drafters of the TRIPS Agreement in allocating such powers to national jurisdictions.

Under Article 40, Member States are obligated to protect their intellectual property rights systems against those practices which limit and undermine the proper functioning of the intellectual property rights system in the domestic market. According to Gervais, the provision does not amount to some form of minimum step towards harmonization of intellectual property competition rules. This however was the wish of developing countries who have sought such an agreement. Developing countries have not had success on this issue as illustrated by the failure of competition issues to be discussed in Doha and the matter actually being removed from the agenda. This failure to harmonize intellectual property rules related to competition at a multilateral level leaves the issue to national and regional jurisdiction for the time being. Under Article 40(2) reference is made to some anti-competitive practices however the list is not limited to the mentioned practices, they are only examples leaving the members with the freedom to impose more specific competition rules. Within the same provision, the Member States are granted the power to regulate abusive

[129] *See* Ullrich, *supra* note 12, at 405 (discussing the guiding principles emerging from competition rules set out in the TRIPS Agreement in detail).

licensing practices. No duty is imposed on the Member States to expressly legislate on competition issues and regulate anti-competitive practices affecting intellectual property. This view is substantiated by an analysis of the provisions mentioned relating to competition practices. Whereas Article 8.2 recognizes the authority of Member States to define what amounts to an abuse of intellectual property rights, the provision is broad and therefore creates uncertainty. Taking into consideration its drafting history, the intention of the provision was to provide for misuse of intellectual property rights in general.[130] The reason why the provisions relating to anti competition and intellectual property rights are not specific and leave the issue to national jurisdiction is because the objective of the TRIPS Agreement as evident in its drafting history is to safeguard adequate levels of national intellectual property protection and not regulate competition. Another reason could be because the TRIPS Agreement is a trade agreement, hence is based on principles of territoriality, protecting domestic markets and trade reciprocity as opposed to principles of protecting intellectual property and competition in the national and international markets.[131]

#### *2.2.1.4 Consistency Requirement for Competition Policy*

Under Article 8.2, those measures implemented by Member States to control abusive or anti-competitive practices relating to intellectual property rights must be consistent with the provisions of TRIPS. This provision serves as an impediment to prevent the use of competition policy provisions by the Member States to undermine intellectual property protection as guaranteed by TRIPS. Thus competition law and policy cannot be arbitrarily used to outlaw legitimately granted intellectual property rights. The consistency requirement

[130] Ullrich, *supra* note 12, at 407.
[131] *Id.* at 408.

in essence creates certainty for intellectual property rights owners which then translate to increased innovation and investment in research and development.[132]

### 2.2.2 Developments in Patent Protection under WTO/TRIPS: Doha and the Aftermath

The 4th Ministerial Meeting of the WTO during 2001 held in Doha launched the Doha Development Agenda. The intention of the members during the Doha ministerial meeting was to initiate a reform process and liberalize trade policies, rejecting the notion of protectionism with regard to trade. In essence the meeting aimed at broadening the markets for products and services. During the previous Seattle ministerial meeting, there was revealed to be genuine differences of opinion on a wider range of issues related to trade liberalization, with the differences forming a divide between developed and developing countries.[133] In an effort to iron out some of these differences there were various issues related to trade ranging from agriculture, competition and intellectual property rights addressed in the subsequent ministerial meetings. During the 5th ministerial meeting in Cancun, decisions were made to start negotiations on a number of issues collectively referred to as the "Singapore Issues" which dealt with investment, competition policy, government procurement and trade facilitation. The Cancun conference was a failure in the sense that the developing countries having experienced disappointments with previous promises made by industrialized countries teamed together to form the G21+ group of countries. These developing countries refused to negotiate on any of the four Singapore issues. Agriculture was the main focus of this failed conference, the main bone of contention being that developed countries mainly the US and EU provide subsidies for their farmers. In allowing such heavy subsidies on agricultural products, they are able to sell their products at very low prices which results in a fall in

[132] *Id.* at 410.
[133] *See* PITOU VAN DIJCK & GERRIT FABER, THE DOHA DEVELOPMENT AGENDA: DEVELOPING COUNTRIES AND DOHA DEVELOPMENT AGENDA OF THE WTO 1 (Pitou van Dijck and Gerrit Faber eds., 2006).

international prices. The farmers from developing countries therefore are subjected to these low prices resulting from developed countries government subsidies in agriculture. The Doha Ministerial Declaration on Public Health was adopted in 2001 and was accompanied by guidelines for achieving developmental related results in a stipulated time frame. Deadlines were set for opening core market sectors such as agriculture and other non-agriculture sectors and services sectors. The Doha Declaration was an important stage in development of patent rights under TRIPS because it dealt with the problem of developing countries lacking manufacturing capacity in the pharmaceutical sector. The Doha Ministerial Declaration was followed by the WTO General Council Decision of August 30 2003, which provided a framework for the interpretation of TRIPS Agreement flexibilities.

Following the Implementation Decision of 2003 it is evident that to date theoretically the Implementing Decision although allowing compulsory licensing of patented drugs introduces intricate, time consuming and burdensome procedures for the exportation of drugs to those countries lacking manufacturing capacity.[134] In practice, it has been seen to be unworkable as evidenced after Canada's implementation of the Decision in its national law and passing of the regulation in April 2007.[135]

### 2.2.3 Compulsory Licensing as a Remedy to Anti-Competitive Patent Abuses

Patents are granted so as to give the patent owner a period of exclusivity of 20 or more years during which no one is permitted to work the patented invention without the patentees express permission. This exclusivity is granted through issuing of a patent so as to maintain the incentive to innovate since inventors are assured of recouping their research and development

[134] Mèdicins Sans Frontières, Neither Expeditious nor a Solution: The WTO August Solution is Unworkable, http://www.msf.ch/fileadmin/user_upload/uploads/communiques/images_2006/pdf/came_Neither_expeditious_nor_a_solution_-_August_30_and_the_JCPA_single_page.pdf (last visited Jan 06, 2010).

[135] Bill C- 9: An Act amending the Patent Act and Food and Drugs Act (2004) (the Jean Chrètien Pledge to Africa). Referred to also as the Canadian Access to Medicines Regime (CAMR) [hereinafter CAMR].

costs and protecting their invention from free riders seeking to benefit without having invested time, effort and money in the invention. This right to exclusivity is enforced in most countries by the judicial system. The judicial systems deem as infringement the unauthorized manufacture, use, sale, offer to sale, or import of a patented technology.[136]

Compulsory licenses are basically a cancellation of the patentee's exclusive rights where the State or a third party is allowed to exploit the patented invention without the consent of the patent owner. Compulsory licenses may be issued specific conditions and not arbitrarily as this would amount to gross violation of property rights.[137] In addition to this it would destroy the foundations of patent rights by creating uncertainty in ownership of inventions which would be a disincentive to innovate. Compulsory licensing also harms the inventor's ability to recover research and development costs as it hampers the patentee's ability to control pricing and distribution of the patented technology across markets. Since compulsory licensing has such adverse effects on technology creation and protection, there needs to be significant reasons for running counter to the basic patent theory to justify issuing of such licences. The justification for issuing a compulsory license must fulfil social and political objectives centred on enhancing social welfare or consumer welfare.[138] An analysis of the practice and frequency of the use of compulsory licensing indicates that while the actual use of compulsory licensing has been rare, the threat of this measure has been quite effective in addressing public health emergencies.[139]



[136] *See, e.g.*, 35 U.S.C. § 271(2005), *see* EPC art. 64 (in the EU, art. 64 EPC provides that ownership, validity, and infringement, are determined independently under respective national laws of Member Countries).
[137] *See* Cotropia Christopher Anthony, *Compulsory Licensing under TRIPS and the Supreme Court of the United States' Decision in eBay v. MercExchange*, *in* PATENT LAW: A HANDBOOK OF CONTEMPORARY RESEARCH, (Toshiko Takenaka & Rainer Moufang eds., 2008).
[138] Implementation and Scope of issuing compulsory licensing differs for example Brazil having in its Industrial Property legislation Article 69 which allows the government to issue a compulsory license if the patentee does not manufacture the patented technology locally within three years of the patent's issuance is more of an efficiency and consumer welfare enhancing reason. Contrast this with the decision of South Africa to allow for the issuing of compulsory licenses for much needed HIV/AIDS drugs being more of a social welfare reason and not so much for economic efficiency objectives.
[139] For example, both the US and Canadian governments used the threat of compulsory licenses to spur Bayer, the holder of the patent on the antibiotic drug *ciprofloxacin ("Cipro")*, to make sufficient quantities to respond to

### 2.2.4 Analysis of Compulsory Licensing under TRIPS

Article 8 of TRIPS outlines the principles under which exceptions to exclusive patent rights may be allowable. Under Article 8 a Member State is granted the right to protect public health and nutrition and other "public interests in sectors of vital importance to [a states] socio economic and technological development."[140]Under the same provision, a Member State may also take measures to minimise the abuses of intellectual property rights which aim or have an effect of "unreasonably restraining trade and affecting international transfer of technology".[141] Under Articles 30 and 31, the mechanism for issuing of compulsory licensing is outlined. Article 30 is substantive in nature and details the three criteria which must be met before exclusive patent rights are infringed. Article 31 is procedural in nature and details a list of requirements for limiting exclusive patent rights. For developing countries, compulsory licensing has been identified as an instrument through which the excessive patent rights can be limited in some industries, such as the pharmaceutical industry. In the pharmaceutical industry, the use of compulsory licensing is however rare since the threat to impose a compulsory licence usually encourages the patent owner to agree to issue a voluntary licence.[142] Developing countries have thus interpreted Articles 30 and 31 to allow countries to grant compulsory licenses to third parties to manufacture the necessary pharmaceuticals that



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the anthrax scare that followed the September 11, 2001 attacks; *see* Charles T. Collins-Chase, *The Case Against TRIPS-Plus Protection In Developing Countries Facing Aids Epidemics*, 29 U. PA. J. INT'L. L. 763 (2008).

[140] TRIPS Agreement art. 8.1 (Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors beneficial for their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.).

[141] TRIPS Agreement art. 8.2 provides that "Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

[142] A compulsory license may be described as a license granted by the owner of a patent where the license to use the patent has been unreasonably refused or offered on unreasonable terms by the holder of patent rights.

would be able to address public health problems ranging from malaria, tuberculosis and HIV/AIDS.[143]

Developed countries generally discourage the granting of compulsory licensing due to fear of the other Member States arbitrarily stripping patent holders of their rights, this taking into consideration that majority of patent holders originate from the developed countries while the developing countries desperately need access to this patented technology usually beyond their means. However TRIPS provides that the patent holder in event of compulsory license is entitled to receive a reasonable compensation that is to be determined by the country granting the license.[144] The rationale behind developing countries' granting compulsory licenses in the pharmaceutical industry is their belief that the exercise of pharmaceutical patent rights has adversely affected public health by denying citizens access to life-saving, brand-name, prescription drugs due to high unaffordable costs.[145] Under the TRIPS Agreement compulsory licensing is allowed under limited conditions. The first of which that it must be limited, secondly, the license must not unreasonably conflict with the normal use of the patent and thirdly, the legitimate interests of the patent owner must be protected while also taking into account the legitimate interests of third parties.[146]

Under Article 30, Member States may provide limited exceptions to the patent rights granted under TRIPS. Article 30 provides that "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties."[147] The provision is best interpreted following the interpretation of the Dispute



[143] Samantha Shoell, *Why Can't the Poor Access Lifesaving Medicines? An Exploration of Solving the Patent Issue*, 4 MINN. INTELL. PROP. REV. 151, 180 (2002).
[144] TRIPS Agreement art. 31(h).
[145] The WHO Model List of Essential Drugs, *available at* http://www.who.int/medicines/organization/par/edl/infedlmain.shtml (last visited Nov. 8, 2009).
[146] TRIPS Agreement art. 30; *see also* Cotropia, *supra* note 137.
[147] TRIPS Agreement art 30.

Settlement Body in the case of *Canada-Patent Protection of Pharmaceutical Products Case*.[148] In this case, it was determined that under Article 30, the exceptions permitted should be firstly, limited, secondly, the exception should not unreasonably conflict with the normal exploitation of the patent and thirdly it should not be unnecessarily prejudicial to the legitimate interests of the patent owner. With regard to limited exception, the dispute settlement panel decided that the scope of the permitted exception should only slightly diminish the right in question which should be determined on a case by case basis. The second condition that the exception must not unreasonably conflict with normal exploitation of the patent was determined to mean that the exception must not interfere with the "right of the patent owner to exclude all form of competition that could detract significantly from the economic return anticipated from a patents grant of market exclusivity"[149] The third exception dealing with legitimate interests was interpreted to refer to "justifiable interests supported by public policies and social norms."[150]

In this case it was determined that Article 30 does not allow for exportation of drugs under the compulsory licensing exception. The decision posed serious consequences for developing countries in that it had an effect on countries with no manufacturing capacity. The inaccessibility to cheap medicines was somewhat resolved by the decision of pharmaceutical companies to provide cheaper drugs in developing countries by carrying out price differentiation and adhering to regional or national exhaustion principles as opposed to the once popularly advocated for international exhaustion of patent rights. The problem of inaccessibility of cheap drugs through export of compulsorily licensed pharmaceutical products has also been solved by the WTO Implementation Decision of 2003 which provided for compulsory licensing allowing countries lacking manufacturing capacity to import compulsory licensed medicines.

[148] Canada-Patent Protection of Pharmaceutical Products, WT/DS/114/R.
[149] *See* GERVAIS, *supra* note 125
[150] *Id.*

Article 31 provides a detailed means for a WTO Member State to grant use of the subject matter of a patent without the consent of the patent-holder.[151]

Article 31 lists procedural requirements that should be met before a government can issue a compulsory license. This includes the procedural requirement that the government before issuing the compulsory license must make the decision to authorise use of patented technology on case by case basis and such issuing of compulsory license must be limited in scope and duration. In addition to this, there must have been an attempt made to obtain licences for the patented process or technology before the compulsory license is issued. The compulsory license is only limited to the domestic practice of the patented technology.

Section (b) of Article 31 provides three exceptions for countries to compromise a patent-holder's rights under certain circumstances, including a national emergency exception.[152] The problem with the national emergency exception is that there is no definition in TRIPS that specifies what a national emergency is. Before the amendment of TRIPS Article 31, to include Article 31bis Article 31(f) presented a problem to countries that do not have the ability to manufacture pharmaceuticals because it limited their ability to import pharmaceutical products under compulsory license. This amendment of the provision limiting the use of compulsory licenses for the domestic market resulted from protests by countries such as India and Brazil which had well established manufacturing capacity and could take advantage of compulsory licensing for the benefit of other developing and least developed countries with little or no manufacturing capacity. Under Article 31bis exporting country obligations are suspended with respect to the grant of compulsory licences for pharmaceutical



[151] Grace K. Avedissian, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions In a New Era of "Super Terrorism"*, 18 AM. U. INT'L L. REV. 237, 263 (2002).

[152] TRIPS Agreement art. 31 (b) ("…such use may only be permitted if, prior to such use, the proposed uses has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.")

products subject to other conditions such as reasonable remuneration, attempts to procure voluntary licenses and considerations on case by case basis.

### *2.3 TRIPS Agreement and the Convention on Biological Diversity*

The implementation of the TRIPS Agreement by developing countries raised some concerns with regard to the exploitation of biological resources in these countries. The concern centered on how intellectual property rights in biological resources that were considered common could be exploited for the benefit of the society or community in a sustainable manner taking regard of the environment as well as cultural aspects of the communities in these countries. Countries adopting both the TRIPS Agreement and Convention on Biological Diversity (CBD) must endeavor to ensure that both intellectual property rights and rights in biological resources are respected and exploited for the benefit of the society.

The CBD is founded on the principle that States have the sovereign right over their own biological resources. It is a convention with the objective of conserving biological diversity and ensuring sustainable use and benefit sharing of these biological resources through access and technology transfer. The TRIPS Agreement on the other hand is concerned with private property rights which seem to run counter to the objectives of the CBD. Debate centered on the supremacy regarding the two treaties has somewhat been settled with the accepted view that the two treaties are compatible and neither supersedes the other nor do their objectives undermine each other. This study has interest in the protection of intellectual property rights under TRIPS and the protection of similar rights under CBD, most interesting of which is the issue of technology transfer which is addressed under both treaties. Under the CBD, dealing with technology transfer, it requires access to technology transfer to be provided on terms that recognize and are consistent with intellectual property rights and that the parties to the Convention are obligated to ensure that intellectual property rights granted do not undermine

the objectives of the Convention. The CBD also addresses access to genetic resources, plant breeders' rights and traditional knowledge. With respect to genetic resources, there are two sets of rights identifiable, the first dealing with the exercise of these rights and the second dealing with the technologies related to genetic resources as well as the ownership rights of traditional communities regarded as custodians of these rights, holding the knowledge and skills to exploit the genetic resources in a sustainable manner hence in keeping with the objectives of the Convention. Following the description of international regimes, developing countries can rely on both CBD and TRIPS to facilitate the acquisition and diffusion of technology necessary for achieving their developmental objectives.

### *2.4 Patent Rights and Competition Policy in the US*

In addressing the US legislation governing the patent antitrust interaction, mention of the historical and economic foundations of patent law in the US is necessary. In the US, intellectual property rights have constitutional foundation in addition to the statutory, institutional and regulatory norms relating to patent rights and antitrust. Under the US Constitution congress is granted the power "[T]o promote the progress of science and the useful arts by securing for limited times, to authors and inventors, the exclusive right to their respective writings and discoveries"[153] According to Rudolf Peritz[154] competition policy has thoroughly covered intellectual property rights protection in the US to the extent that competition is recognized as a fundamental engine for driving innovation in the effort to encourage the progress in science and useful arts as specified under the US Constitution.[155]



[153] U. S. CONST. art. 1, § 8, cl. 8.
[154] STEVEN D. ANDERMAN, THE INTERFACE BETWEEN INTELLECTUAL PROPERTY RIGHTS AND COMPETITION POLICY 128 (2007).
[155] *Id.*

In addition to the constitutional provisions supporting intellectual property rights, there is the Patent Act.[156] The first Patent Act was passed by the US Congress in 1970 and it provides that anyone who invents or discovers any new and useful process, machine or composition of matter, or any new and useful improvement, may obtain a patent for his invention from the US Patent Trademark Office (USPTO).[157]

Statutory requirements for patentability under the US Patent Act §101 and § 102 include; utility, novelty and non-obviousness.[158] An individual may seek a patent for "any process, machine, manufacture or composition of matter or any improvement thereof."[159] The statutory requirements of patentability are interpreted in a progressive manner by the US Courts. The landmark case of *Diamond v Chakrabarty*, illustrates how these requirements for patentability are understood and interpreted. In this case, the US Supreme Court determined live human made microorganism to be patentable subject matter.[160]The Courts reasoning was partly because the claim was based on an invention that was not naturally occurring and while the doctrine that an idea itself is not patentable rather an invention made using that idea that is of practical use is patentable.[161] The US Supreme Court has held that "phenomena of nature, mental processes and abstract intellectual concepts are not patentable as they are basic tools of scientific and technological work".[162] Although this decision has been slightly changed

[156] Patent Act, 35 U.S.C. (2005) (Utility patents in the US are governed by Patent Act codified in Title 35 of the US Code).
[157] When a patent application is successful, an individual is granted the right to exclude others from making using or selling the patented invention for a period of 20 years. These patent grants are however not affirmative rights and are subject to some limitations such as antitrust limitations and in the case of drugs the patent is subject to Food and Drug Administration [FDA] approval.
[158] Product claims under § 101 involve tangible things such as machines, manufacturers or compositions of matter. Process claims on the other hand are stated to refer to a series of steps methods or techniques used to produce a particular result. Under § 112 the standard for sufficient description of the invention is specified.
[159] Patent Act, 35 U.S.C. (2005)
[160] Diamond v. Chakrabarty, 447 U.S. 303 (1980).
[161] *See* ANDERMAN, *supra* note 154.
[162] Gottschalk v. Benson, 409 U.S. 63 (where the court viewed software as an abstract concept in denying the patentability of software. The Supreme Court claimed that allowing software patents would wholly pre-empt the mathematical formula and the practical effect would be a patent on the algorithm itself. In a different case however where the software was characterized as part of an industrial process the court viewed the software as more than an abstract idea since it was linked to a physical process.); *see e.g.*, Diamond v. Diehr, 450 U.S. 175 (1981).

following the *State Street Bank and Trust Case* in which the Federal Circuit considered patentable any software that produces useful, concrete and tangible results including mathematical calculations.[163]

Novelty has been determined by economist Joseph Schumpeter to serve two important goals in the patent system, which are firstly to maintain a public domain of knowledge and technology which serves to foster competition as well as provide a suitable environment for further research and development. Secondly, novelty serves the purpose of encouraging further knowledge of a particular field and discouraging duplicative research efforts through motivating researchers to research into chosen fields and gain knowledge on prior technologies.[164]

The Patent Act under § 102 deals with two aspects of prior art, the first being the so called statutory bars which deal mostly with procedural issues such as penalties for late filing and the second being previous inventions.[165]

On usefulness, it is established that usefulness is best determined by the market mechanism. Therefore an invention that is not useful has no value to society and does not have market value as such. Justice Story aptly put it in *Lowell v. Lewis* speaking on usefulness, he stated that an invention "be more or less useful is a circumstance very material to the interest of the patentee, but of no importance to the public. If it be not extensively useful, it will sink into contempt and disregard."[166]

The description and enablement requirement under §112 of the Patent Act enables skilled technicians to make use of the invention. Description in other jurisdictions is generally



[163] State Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F.3d 1368 (Fed. Cir. 1998).
[164] *See* ANDERMAN, *supra* note 154 at 132 for a general discussion on Joseph Schumpeter's theories on monopolies.
[165] Statutory bars in the US included the printed publication bar where an invention is barred from patent rights if printed in the US or a foreign country, other statutory bars include the public use bar, where the owner uses or allows others to use the invention before the patent is granted, also included is the "on sale" bar where the grant is refused on the basis that the invention has been offered for sale.
[166] Lowell v. Lewis, 15 F. Cas 1018, 1019 (C.C.D Mass 1817); *See* ANDERMAN, *supra* note 154 at 132 (for detailed discussion on utility).

referred to as disclosure. The description requirement is fulfilled when it shows the invention, its components and use such that interested parties skilled in the art can be able to make use of the invention without further research. The importance of description is that it informs the public of the existence of the invention and gives proper notice to competing manufacturers of the invention, thus allowing them to compete and to make research trials and developments without infringing the patent.

### 2.4.1 Antitrust Legislation in the US

The key US antitrust statute is the Sherman Act adopted in 1890. Antitrust laws geared towards the preservation of competition in the US date back to more than a century ago when the Sherman Act was enacted in 1890.[167] The Sherman Act has been referred to as the "*Magna Carta*" of free enterprise due to its importance in preserving free and fair competition.[168]

Prior to 1890, competition policy issues were addressed in examining cases of contract and property disputes which had overreaching contractual restrictions. The US courts when dealing with these overreaching restrictions developed the rule of reason concept. Section 1 of the Sherman Act imposes restrictions on collective action and agreements that restrain trade. These agreements that restrain trade may involve direct competitors (horizontal agreements) and those agreements between suppliers and their customers (vertical agreements). Section 2 of the Sherman Act is concerned with control of dominant behaviour. The interpretation of Section 2 however is not a strict and literal interpretation as it has been held by the Supreme Court that a strict interpretation may result in punishing even those firms which have acquired market power through legitimate means. It has also been determined that "the mere existence

[167] Sherman Act 15 U.S.C. §§ 1-7 (1988).
[168] United States v. Topco Assoc., 405 U.S. 596, 610 (1972).

of unexercised power does not amount to an offence."[169] In the *Alcoa Case*, the court held that "[T]he successful competitor having been urged to compete must not be turned upon when he wins."[170]

### 2.4.2 US Antitrust Regulatory Agencies and Guidelines

The regulatory agencies of interest in the patent and competition policy interaction are namely the Federal Trade Commission (FTC)[171] and Department of Justice (DOJ), Antitrust Division. A brief overview of these regulatory agencies and their peculiarities for comparative purposes follows. The two agencies cooperate in an important task through their overlapping statutory authority to enforce the Clayton Act and in the issuing of joint guidelines such as the Patent Antitrust Guidelines that were issued by the FTC in 2003 and 2005.[172]

The key antitrust provisions in the antitrust statutes are contained in the Sherman Act and the Clayton Act. These provisions are open ended in nature which serves to ensure the evolution of law over time in keeping with the societal, economic and cultural changes. Thus it is delegated to federal judges and federal enforcement agencies the role of elaborating the substance of the doctrines so that it is at par with the constantly changing times. The FTC has the power to enforce the Statute with "cease and desist" orders. The FTC is also authorised to sue as *parens patriae* on behalf of the citizens.

The Department of Justice had primary authority for enforcing the Sherman Act since its enactment in 1890.[173]



[169] United States v. U.S. Steel Corp., 251 U.S. 417, 451 (1920).
[170] United States v. Aluminum Co. of America, 148 F.2d 416, 430 (2d Cir 1945).
[171] The Federal Trade Commission Act was adopted in 1914.
[172] Both the FTC & DOJ, Antitrust division have subpoena and discovery powers. They also have powers to reach settlements which are legally enforceable in court. DOJ powers detailed in 15 U.S.C. §§ 4, 16, 23, 25 (2000); FTC powers, 15 U.S.C. §§ 45, 46 (2000).
[173] In 1933, President Franklin D. Roosevelt created the Antitrust Division of the Department of Justice which was responsible for investigating antitrust violations. The Antitrust Division has the responsibility to investigate and initiate proceedings for antitrust violations in Federal Courts under the Sherman and Clayton Acts. The

The licensing guidelines issued under the joint cooperation of the FTC and DOJ analyse patent competition policy interaction in a comprehensive manner. Under these guidelines, the principles relating to the interaction between patent rights and competition policy are reiterated, beginning with the recognition that intellectual property rights are comparable to other forms of property.[174] The guidelines also recognise the principle that intellectual property rights do not necessarily create market power and that licensing is pro-competitive. Most importantly, the guidelines place emphasis on the principle of intellectual property rights and antitrust law sharing the same goals of promoting innovation while enhancing consumer welfare.

In addition to the licensing guidelines in the US, the courts jurisprudence is reliable in analyzing the patent protection and competition policy interaction. The US Supreme Court has highlighted the importance of both competition and patent protection and the need to find a balance between the two spheres of law in cases where there seems to be an apparent clash between competition and the exercise of patent rights.[175] The courts have also found that where patent rights are extended beyond the granted scope there is a possibility for violation of competition law. History shows that the FTC has intervened in cases of fraudulently obtained patents.[176] Previously, with the enactment of the Sherman Act, and later the Clayton Act[177] and Federal Trade Act, competition was viewed to be in tension with the rights



Division acts as an advocate in both Federal regulatory hearings and private antitrust litigation. It is important to note that the Division can enter into enforcement agreements with other States.

[174] *See* ANDERMAN, *supra* note 154 at 192; *see also* DOJ & FTC Antitrust Guidelines, *supra* note 23.

[175] Bonito Boats Inc v. Thunder Crafts Boats Inc., 489 U.S. 141, 146 (1989) (recognizing that the substantive systems of patentability are necessary to manage the balance between the need for innovation and competition).

[176] Charles Pfizer & Co. v. FTC, 401 F.2d 574 (6th Cir. 1968), *cert. denied*, 394 U.S. 920 (1969) In this case, the Court upheld an FTC order requiring nondiscrimination compulsory license at a fixed rate of 2.5 percent royalty rate of two antibiotic patents procured by material misrepresentations. Pfizer had made misrepresentations and withheld essential information from the patent examiner thus deceiving him into granting a patent that would not have been granted.

[177] Clayton Act, 15 U.S.C. (1914); § 2 prohibits price discrimination, § 3 deals with vertical restraints prohibiting tying, exclusive dealing and stock mergers where the effect of the merger would be to substantially lessen competition or create a monopoly in a particular market. The Clayton Act is enforced by the FTC concurrently with the DOJ, Antitrust Division.

conferred by patents.[178] In those cases involving tension between antitrust and the exercise of patent rights, the Supreme Court rejected the defences based on justification of patent rights for inherently anti-competitive behaviour. The court held instead that such anti-competitive behaviour was *per se* unreasonable.[179]

Like the judicial attitude to the interaction between patent rights and competition policy in the US, the enforcement policies have changed over time. In tracing the enforcement policy changes the most important step in enforcement policies was the 1975 pronouncement of the Nine No No's of licensing that resulted in a challenge of the licensing agreements on antitrust grounds. Under the Nine No No's, the Justice Department would prosecute as *per se* antitrust violations certain specified restrictions in licensing agreements.[180] It will be evident later on that the Nine no-no's somewhat vanished during another shift in enforcement policy changes during the Regan era.

Change in the treatment of intellectual property and antitrust interaction is illustrated in first, a change in antitrust doctrine itself such that vertical restraints between firms at different levels of production not related to price were no longer treated as *per se* unreasonable and were examinable under rule of reason.[181] Licensing agreements were regarded as vertical restraints

[178] *See* Bemet v. National Harrow Co., 186 U.S. 70 (1902) (which concerned formation of patent pools, summarily, when harrows were invented, there were about 22 different ones from different inventors and the competitors realised that competing with many competitors was not very comfortable. The inventors decided to form a patent pool under which all inventors with their separate patents put them into the pool and could then license back their own patents, the patent pool however was of no benefit to the consumer since the pool allowed the inventors to do what they could have done themselves without the pool. This pool would be considered unlawful since it did not result in economic efficiency; however the 1902 Supreme Court upheld this pool. In doing so it stated that the general rule is the right of owners to use and sale rights under patent law in the US and that the object of these patent laws is to provide the owner with a monopoly).

[179] *See* United States v. National Lead Co., 438 F2d 935 (8th Cir. 1971) (the court prohibited a series of restrictive licensing agreements between competitors due to the fact that the licensing terms were beyond the scope of the patent granted, indefinite in duration and nature and applied to patents not yet granted, thus were merely agreements in restraint of trade).

[180] Requiring a licensee to purchase unpatented material from a licensor; Requiring a licensee to assign any patent which may be issued after the licensing agreement is executed; Attempting to restrict a purchaser of a patented product in the resale of that product; Restricting a licensee freedom to deal in the product or services not within the scope of the patent; Agreeing not to license other persons without the licensees consent. Requiring mandatory package licenses; Requiring loyalties in an amount not reasonably related to the actual sales covered by the patent; Placing restrictions on the use of products made by the use of a patented process; Requiring resale price maintenance for the sale of the patented products of the licensee.

[181] *See* ANDERMAN, *supra* note 154.

and viewed favourably except where there were issues involving restraint of trade and unjustified substantial market power. On the question of intellectual property rights and market power, the US Congress in 1988 amended the Patent laws to make proof of patent misuse involving tying require proof of market power as a requirement of misuse.[182] This resulted in the acceptance that patent rights do not amount to market power in and of themselves.

Third, intellectual property protection and exploitation both abroad and nationally became an important part of US trade policy. This was done through establishing the Court of Appeals for the Federal Circuit as a specialised court to handle intellectual property matters on appeal on a nationwide scale.[183] In addition to this the US stretched its reach to other countries by enacting and enforcing Section 301 of the Trade Act of 1974 as a threat against foreign governments whose trade practices were injurious to US intellectual property rights.

Fourth, the antitrust division of the US Department of Justice, during Regan and Bush administrations supporting and encouraging the pro-competitive benefits of the exploitation of intellectual property.

The evolution and development of antitrust law in the US is not only evident within the borders of the US but has far reaching effects facilitated by Section 301 of the Trade Act, which has been used against developing countries in various circumstances to coerce them to comply with intellectual property laws following the wishes of the US. The threat to use special Section 301 was made against South Africa and Brazil among other developing countries. The dynamic nature by which the US legislation and the Courts interpretations have changed over time to suit its economic and developmental needs should be an example to developing countries indicating that the legislation governing intellectual property rights



[182] *See* 35 U.S.C. § 271(d) (2005).
[183] Judiciary & Judicial Procedure 28 U.S.C. § 41 (1993).

should not remain static but should be amended to ensure protection guaranteed suits the level of development and is beneficial to the individual State's needs.

### 2.4.3 US Courts Approach to Antitrust and Patent Rights Cases

The US courts have dealt with the interaction between patent rights and competition in a rather erratic nature, never adopting a concrete position but rather determining cases dealing with patent and competition interaction depending on the economic times and needs. The cases dealt with by the courts cover anti-competitive exploitation of patent rights through patent bundling, patent tying, illegally obtained patents, refusal to deal and patent misuse.

Following the enactment of the Sherman Act, antitrust challenges against patent rights were dismissed on the basis that patents were like other forms of property giving the owner the power to utilize them as he wished.[184] The courts later abandoned this position and resorted to the position that patents are monopolistic in nature and in fact automatically conferred market power.[185] The diversity of the courts approaches to the patent and competition interaction is further revealed in the case law.[186]

## *2.5 Patent Rights and Competition Policy in the EU*

Post war Europe saw a wealth of legal rules and negotiations progressively aimed at establishing a single market. The economic goals were previously focused on removing market barriers and harmonizing the internal market of the European Community member countries. In an effort to achieve this goal, competition rules were adopted. During this period

[184] *See e.g.* Bemet v. National Harrow Co., 186 U.S. 70, 91 (1902) (where the court upheld a patent pool that set prices and required members to use technology licensed in the pool stating that it was the general rule in the absolute freedom in the use and sale of rights under patent laws).
[185] International Salt Co. v. United States, 332 U.S. 392 (1947).
[186] *re* Independent Service Organizations Antitrust Litigation 203 F 3d 1322 (Fed. Cir. 2000); *see also* Eastman Kodak Co. v Image Technical Services Inc., 125 F. 3d 1185, 1218 (9th Cir. 1997); Schorr v. Abbott Laboratories, 457 F. 3d 608 (7th Cir. 2006); Schorr v. Abbott Norvir Antitrust Litigation, 442 F. Supp: 2d 800 (N.D. Cal. 2006).

within the EU, intellectual property rights still remained within national competence. Property rights within the EU are provided for under the Treaty on the Functioning of the European Union (TFEU). The provisions of the TFEU Article 345 (ex Article 295 EC Treaty) prescribe that the Treaty shall in no way prejudice the rules in Member States governing the system of property ownership.[187] Intellectual property rights are included under these property rights.

The European Community economic goals with regard to the interaction focused on corporations and businesses owning the patented inventions rather than the licensees. The approach tended to focus on large industrial structures which could compete with the US and Japan ignoring independent licenses and the intrinsic pro-competitive nature of transfer of technology and know-how during contractual relationships between licensors and licensees.[188]

It was recognized that competition and intellectual property rights which were considered tools that imposed or expanded market dominance were crucial in promoting cooperation, removing trade barriers and promoting growth of the European Community as well as disseminating innovation.[189]

In the EC the recognition of the importance of the intellectual property rights and competition policy interaction is manifested though the 1996 Transfer of Technology Block Exemption followed by the 2004 Transfer of Technology Block Exemption no 772 of 2004 relating to licensing of technologies protected by intellectual property rights or industrial secrets.

These two block exemptions aim at controlling anti-competitive practices in contractual licenses and they indicate the EC was reflecting the differences between horizontal agreements involving actual competitors and vertical agreements involving non actual competitors which had previously not been considered to have anti-competitive effects on competition. In the EU the current trend is to promote technology licensing as a means of

[187] Consolidated Version of the Treaty on the Functioning of the European Union, Sep. 5, 2008, 2008 O.J. (C 115) 47[hereinafter TFEU].
[188] GUSTAVO GHIDINI, INTELLECTUAL PROPERTY AND COMPETITION LAW: THE INNOVATION NEXUS 100 (2006).
[189] *Id.* at 101.

sharing technology. In doing so a licensing agreement will not be exempted where the market share exceeds 40 percent. In such circumstances, the license is rendered void. The aim here is to prevent those agreements where the licensed product is not faced with real competition in the licensed territory; in this case 40 percent of market share is large enough to ensure a firm does not face any real competition.[190] The EC recognizes the role played by intellectual property rights in fostering innovation and encouraging competition. It is with this recognition that a number of presumptions can be highlighted.

First, there is the presumption that intellectual property creates incentives to innovation which produce new competition and creates new products therefore new markets in the EC. Second, is the presumption that intellectual property licensing is pro-competitive and pro innovative and serves to facilitate diffusion of technology thorough out the EC market. Third is the recognition by the EC competition authority that heavy regulation of intellectual property discourages investment in intellectual property rights in the EU.

EC competition policy interacts with intellectual property rights in some instances and when this interaction takes place the competition policy regulates intellectual property rights in such a way that only where abusive conduct occurs is the exercise of intellectual property rights limited. In line therefore with this rule, the exercise of patent rights is only limited in those instances where abusive conduct is determined to take place.

The first instance where this may occur is where patent rights are rights of individual owners in a standard market where the patent rights affect downstream innovators. These include instances such as refusals to deal, refusals to license and tie-ins.[191]

Second, competition policy may also regulate bilateral trade agreements such as technology licensing agreements which are then regulated under Article 101 of the TFEU and Block Exemption Regulation.

[190] *See* Biggers et al., *Intellectual Property and Antitrust: A comparison of evolution in the European Union and the United States*, 22 HASTINGS INT'L & COMP L. REV. 209, 276 (1999).
[191] Competition policy under TFEU art. 102 are used to intervene in such situations.

Third, competition policy may regulate competition in joint ventures and multilateral agreements involving several parties, these are agreements such as patent pools, standard setting organizations and cross licensing agreements. Under the EC issues relating to intellectual property rights are not specifically singled out for special treatment. An analysis of EU legislation and case law will indicate that in instances where patents and competition law and policy interact and conflict arises the solutions can be found not only in the national courts under national authorities which grant, withdraw and enforce patents but there are also solutions to be found in competition law and policy. Under the jurisprudence of the ECJ, in dealing with anti-competitive abuse of patent rights, the court has established that the solution to resolving any such conflict lies in distinguishing between the exercise of intellectual property rights and the existence of intellectual property rights.[192]

### 2.5.1 The EU Patent System

The patent system in the EU unlike the US has constellations among the national, supranational and international levels.[193] The EU is yet to have a comprehensive and unified patent system. The European Patent Convention (EPC) constitutes the legal framework on which European patents are granted.[194]. In the year 2000, the contracting states of the EPC which total 34 including 27 Member States of the EU undertook revisions of the EPC which led to changes in the Convention affecting both procedural and substantive laws. The new text referred to as EPC 2000 entered into force on 13 December, 2007. The EPC provides the law

[192] P. Sean Morris, *Patent Licensing and No-Challenge Clauses: A Thin Line between Article 81 EC Treaty and the New Technology Transfer Block Exemption Regulation*, 2 INTELL. PROP. Q. 217, 225 (2009).
[193] *See* EPO: Failure of the European Community Patent to come into existence. http://documents.epo.org/projects/babylon/eponet.nsf/0/F172DE5BB2B9B15BC12572DC0031A3CB/$File/Interview_Schneider.pdf (last visited Mar. 2, 2009).
[194] Convention on the Grant of European Patents Oct. 5, 1973 [hereinafter EPC] contains the texts of the Convention on the Grants of European Patents (version as of 1 January 2006) and its Implementing Regulations (version as of 1 July 2005), the Protocol on Centralisation of 5 October 1973, Protocol on Recognition of 5 October 1973, the Protocol on Privileges and Immunities of 5 October 1973, and the Rules relating to Fees (version as of 1 April 2006).

that governs the application, granting and opposition procedure for patents in the contracting States of the Convention. The EPC provides a central examination of patent application for a European patent by the European Patent Office (EPO) which is the patent granting authority for the parties to the EPC.[195] The EPO grants patents which have effect on all contracting States of the EPC that are designated by the patent applicant. The patents issued are enforceable by national courts in the individual states. The EPC system of granting patents does not replace the national patent system but exists parallel to it. Therefore an applicant can choose to apply directly through the national patent office. The patent granted can only be revoked by the national courts of the State, although there exists for a limited time after the grant a European patent the possibility to challenge a patent centrally in an opposition procedure before the EPO. If the EPO decides the patent was wrongly granted then it revokes the patent in all contracting member countries.

The patent system in the EU therefore has a dual structure and there exists some uncertainty as to clear governing rules at the supranational level with regards to patents procedural and substantive requirements with both the EPO and the EU performing overlapping functions.[196] An example of these different governing structures is illustrated in the procedure that allows the EPO to grant European patents, whose enforcement and validation is left to the jurisdiction of the national courts.[197]



[195] Its mission statement proclaims that its mission is to support innovation, competitiveness and economic growth for the benefit of the citizens of Europe.

[196] The grey area emerges with the EU attempting to legislate on patent issues which the EPO a semi-autonomous institution of the EC has authority to deal with.

[197] The EPO is a hybrid system playing dual roles of executing the law of the European Patent Convention on the one hand and playing a quasi-judicial role on the other hand through its Board of Appeals which plays a role similar to that of a court, developing case law and interpreting the EPC. The EPO has an inter-governmental character of the EPO and is headed by an Administrative Council. The Administrative Council is made up of the presidents of the National patent offices of EU member States. No substantive patent issues are discussed by the Council and it is mainly concerned with bargaining between national and EU levels regarding the distributions of shares of revenue and workload.

The EPC primarily sets out the statutory requirements for patentability under Article 52.[198] The provision lays down the fundamental principles upon which other provisions relating to substantive patentability are based. The four essential requirements for patentability namely that there must be an invention, which must meet the requirements, must be new, involve an inventive step, be capable of industrial applicability, as set out in Articles 54, 56 and 57. Specific exceptions to patentability are set out under Article 53. The EPC like the TRIPS Agreement does not define "inventions" although the relevant provision indicates those inventions which shall not be applicable.[199] In analyzing the relationship between patent rights and competition policy in the exercise of patent rights through contractual licensing as provided under Article 73, the provision reiterates the right of a patent owner to exploit the patent in whole or part with the choice of limiting the territorial scope of the license within designated EPC States. In addition to the EPC there exists a Patent Cooperation Treaty (PCT), which was signed on June 19, 1970 and came into force on June 1 1978 and has undergone several amendments, 1979, 1984 and 2001. The PCT provides for a single international application but leaves the substantive examination to the specific countries where patent protection is sought and the patent granted filed under the EPC. The PCT is basically a procedural treaty not concerning the actual grant of patents which is left to the competence of national patent offices. In addition to the TTBER there are other Regulations of particular interest in relation to the patent rights and competition policy interaction namely, Regulation concerning the creation of a supplementary protection certificate for medicinal products of June 18, 1992, Regulation Concerning creation of a supplementary protection for plant protection products of July 23, 1996, Directive on enforcement of intellectual property rights

[198] EPC art. 52 provide the requirements for patentability. Under this provision, European patents are granted for any inventions which are susceptible of industrial application and which are new.

[199] These include discoveries, scientific theories and mathematical methods, aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business and programs for computers, presentations of information. EPC art. 52(4) provides that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on human and animal bodies shall not be regarded as inventions which are susceptible of industrial application. EPC art. 53(b) provides that patents shall not be granted for plant or animal varieties or essentially biological processes for the production of plants and animals.

of April 29 2004 and the Directive on the patentability of biotechnological inventions of July 6 1998. These legislations relate to the interaction between patent rights and competition policy where they extend the patent protection period in an effort to provide a fair and level playing field thus enhancing competition or in instances where the scope of patentability is widened allowing for more competition such as in the biotechnology industry.

The TRIPS Agreement and applicability in the EU is based on the fact that WTO Agreement to which the TRIPS Agreement is annexed was signed by the EC and subsequently approved by Decision 94/800. The implication of this is that TRIPS forms an integral part of the legal order in the European Community as has been illustrated by the jurisprudence of the ECJ which in its case law reiterates that a Convention once signed by the Community and approved by Decision accordingly forms part of the Community legal order.[200] The ECJ also has jurisdiction to give preliminary rulings on issues concerning interpretation of TRIPS.[201]

The interaction between patent protection and intellectual property in the EU when analyzed will illustrate the paradox between the goals of promoting innovation on the one hand and the preservation of freedom of access to the market on the other.[202]

### 2.5.2 EU Technology Transfer Block Exemption Regulations

Block Exemption Regulations are a template for agreements covering the subject of concern for the Regulation. Such Block Exemption Regulations are accorded direct applicability by Article 288 of the TFEU (ex Article 249 EC Treaty) in that they are enforced by national courts and impose rights and obligations on private parties.

The Transfer of Technology Block Exemption Regulation 240/96 is of particular interest in the patent rights and competition policy interaction.[203] The 1996 TTBER was significant

[200] Case C-344/04 IATA v. ELFAA, [2006] ECR I -0000.
[201] *Id.*
[202] The interaction between intellectual property rights and competition in the EU is based on the limitations applied on the rights of owners of IPR, specifically their freedom of contract.

because it defined other intellectual property rights such as utility models, semi-conductor topographies and plant breeder certificates referring to them as patents for the purpose of the Regulation.[204]

The 2004 TTBER has a wider scope of application and offers more flexibility and longer period of protection as well as reducing the list of non-exemptible hard core restraints that were in the 1996 TTBER such that the presence of a non-exemptible hard core restraint does not render the agreement in its entirety void and non-enforceable. The new regulation also introduced market share limits. The market share rules essentially states that if the product which is the subject of technology transfer agreement is such that it exceeds the market share ceiling at any one time in the course of the contract, it loses the benefit of the block exemption after a transitional period of two years.[205]

The 2004 TTBER distinguishes agreements between competitors and between non competitors. The licensor and licensee will be viewed as competitors in a situation where in the absence of an agreement they both deal with the same relevant product in the same geographical market.[206]

Historically, EC competition policy like the old school of thought in the United States concerning patent protection and competition policy interaction, assumed that the legal monopoly conferred by patent laws amounted to an economic monopoly and conferred market power. To counter this, EC competition policy placed stringent rules and very strict

[203] The Block Exemption Regulations [BER] have been established by the EC for various categories of agreements and they are in place so as to exempt certain agreements from the prohibitions set out under art. 81 (1). Examples of BER include the Commission Regulation 2790/1999, Vertical Agreements block exemptions regulation, 1999 O.J. (L 122) 21; Commission Regulation 418/85, Research and Development Block Exemption Regulation 1986 O.J. (L 535); Commission Regulation 2658/2000, Application of Article101(3)of the Treaty to Categories of Specialisation Agreements 2000 O.J. (L 304) 3,6 and their respective accompanying guidelines. The guidelines are put in place to enable parties comprehend the regulations and the rules for the application of TFEU art. 101(3).

[204] The first EC BER was the Patent Licensing Regulation in 1984, which was followed by the Know-how Licensing Regulation in 1989. In 1996, the first Transfer of Technology Block Exemption Regulation [TTBER] was implemented which dealt with patent licensing and know-how agreements. The purpose of the Agreements falling under the TTBER dealt with licensing of patents and know-how and not trademarks or copyright.

[205] *See* ANDERMAN, *supra* note 154, at 89.

[206] *Id.* at 92.

limits on the exercise of patent rights in particular patent licenses. Today a different opinion reigns where the EC competition policy does not presume the existence of market power as a result of IP rights, instead the existence of market power is established empirically.[207] Accordingly, EC competition policy acts as a regulator of patent rights in extreme cases where the patent rights are used by rights owners to exclude competitors from the market. In such cases EC competition policy has a right to intervene and restrict the prohibited anti-competitive conduct. These instances when competition policy may intervene include situations of restricting abusive conduct by individual owners of patent rights by applying Article 102 of the TFEU especially where the patent rights are a market standard which have an effect on downstream innovation.[208] Second, EC competition policy regulates patent rights by regulating certain terms of bilateral licensing agreements and technology transfer agreements under Article 101 of the TFEU and Block Exemption Regulations.

### 2.5.3 Regulation of Anti-Competitive Abuses of Patent Rights under TFEU

#### *2.5.3.1 TFEU Article 102(formerly EU Treaty Article 82)*

Article 102 of the TFEU addresses abuses of competition by dominant firms. The European Court of Justice has defined dominant position as

> [A] position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers.[209]

Under Article 102 the abuses are determined first where the market share threshold exceeds the specified 20 percent for competing firms and 30 percent for non-competing firms.

[207] *See generally* Damien Geradine, *Pricing Abuses by Essential Patent Holders in a Standard Setting Context: A View from Europe available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1174922.
[208] This includes refusal to deal, refusal to license and tie-ins. S*ee* ANDERMAN, *supra* note 154, at 178; *see also* Jean-Michel Coumes, *IP Rights and EU Competition Law: Can Your Licensing Agreement Benefit from Safe Harbor?*, 28 EUR. COMP. L. REV.23, 25 (2007).
[209] Case 27/76, United Brands v. Comm'n, 1978 E.C.R. 207.

Following the analysis of the market share threshold is the requirement that the firm satisfies requirements for dominance in that particular market. The Competition Commission determines the issue of dominance by using a pre-determined threshold.[210] The case law of the ECJ illustrates the position adopted by the court in addressing intellectual property rights and competition policy interaction. The ECJ has dealt with the question of whether competition violations occur when a dominant undertaking refuses to enter into a licensing agreement with its competitor in the *IMS Health Case.*

*a. The IMS Health Case*[211]

The *IMS Health Case* involved a refusal by a sole collector of regional sales data to the pharmaceutical industry in Germany to license the brick system database form it had developed. The refusal to license this brick system was determined to be anti-competitive. This is because the database system had become an industry standard and no other firm could compete effectively with IMS without using a variation of this database system. Hence the Commission in deciding the case found IMS to have abused its dominant position in the market by refusing to license its brick system to competitors. This decision was however later set aside by the Court of First Instance.[212] The ECJ in addressing preliminary questions submitted by the Frankfurt court determined that for a refusal to license to be considered an abuse of dominant position, it must fulfill some specific requirements which include, that the refusal is preventing the emergence of a new product for which there exists a market and demand, such refusal is not justified by objective considerations and third the refusal is one which reserves the market to the intellectual property owner eliminating all other competition



[210] Market share is a presumption of dominance but does not automatically amount to dominance. There are other factors that are looked at in addition to market share in determining dominance. These include the market share of competitors, the barriers of entry into the market, access to supply and distribution as well as the response of the firm to prices. This means that if the firm has a large market share but responds to competition by lowering of prices then it does not necessarily display dominance as opposed to a firm which has a large market share and does not respond to prices but has persistently high prices which implies dominance.
[211] Case T-184/01 R, IMS Health v. Comm'n, 2001 E.C.R. II-3193.
[212] Commission Decision 2001/165, 2001 (L 060) 61

in the market.[213] The ECJ in its ruling brought forth the rule that refusal to license by an undertaking holding dominant position does not in itself constitute anti-competitive behavior and abuse of dominant position.[214]

The *IMS Health Case* illustrates the tension between competition and intellectual property protection which can be resolved where both legal systems are respected. The case also demonstrates that dominant undertakings can exercise their intellectual property rights without the underlying assumption that the undertakings are abusing their intellectual property rights to gain monopoly advantage.

*b. The Qualcomm Case*

An analysis of the *Qualcomm case* in the EU presents an example of the possible patent abuses that may result in anti-competitive behavior. The case involved refusal to license an essential patent. Qualcomm is a chip set manufacturer owning patents over technology that is an essential part in 3G handsets. Six leading phone communication companies filed separate complaints with the European Commission alleging anti-competitive practices and patent abuse by Qualcomm.[215] Qualcomm had made a commitment to the standards body which resulted in adoption of the wideband CDMA 3G standards. The six claimed that Qualcomm was infringing EU regulations by trying to stop other mobile phone chip set manufacturers from competing or entering the market. The allegations covered competition abuses specifically allegations of refusal to license essential patents to competitors on standard terms. Another allegation against Qualcomm was the accusation that Qualcomm offered lower royalty rates to those who bought exclusively from Qualcomm as well as other allegations of charging excessive and disproportionate royalty rates. Under Article 102 of the TFEU, a refusal to license patents on reasonable terms may amount to an abuse where it results in an

[213] Case T-184/01 R, IMS Health v. Comm'n, 2001 E.C.R. II-3193.
[214] *Id.* at 34.
[215] Broadcom Corp. Ericsson, NEC, Nokia, Panasonic Mobile Communications and Texas Instruments Inc. http://www.eetimes.com/showArticle.jhtml?ArticleID=172901195 (last visited Mar. 24, 2009).

exclusion of all competition from a particular competitor due to a cessation of all commercial relations. It has been found that under Article 102 TFEU, a dominant undertaking has a duty to license its technology and intellectual property in a situation where the refusal to license is a barrier to competition in the downstream market. This is because in these circumstances refusal to license will prevent the emergence of a new product for which there exists demand and market and where the refusal is not objectively justified.[216]

*c. The AstraZeneca Case*[217]

The European Commission has dealt with anti-competition practices resulting from abuse of patent rights where there is acquisition of patent rights by deception in the *AstraZeneca Case* where the commission penalized *AstraZeneca* for misuse of government procedures in an attempt to exclude competition from generic manufacturers.[218]

In this case, *AstraZeneca* provided misleading information in its patent application of extended protection for its product "Losec" in its application for a supplementary protection certificate. The failure to reveal its earliest dates of marketing authorizations to the relevant authorities in the application for supplementary protection certificates was determined to be an abuse of dominant position since the action had the effect of blocking out competition from generics and unlawfully extending its dominance in the market. The Commission in arriving at its decision determining there was harm to competition referred to case law and held that Article 102 had been violated and the requirement that the conduct be capable of



[216] *See* Magill Case *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61991J0241:EN:HTML#SM (last visited 29 March 2009); Case T-184/01 R, IMS Health v. Comm'n, 2001 E.C.R. II-3193.

[217] Commission Decision 2006/857 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A. 37.507/F3-Astra-Zeneca notified under document number C (2005) 1757), 2006 O.J. (L 332) 24.

[218] *See* Drexl, *supra* note 78, at 151(detailed analysis of the AstraZeneca case and giving a comparative analysis of the EU and US approach to the circumstances of the case).

having the effect of restricting competition has been established by the conduct of AstraZeneca intentionally providing misleading information in different countries.[219]

*d. The Rambus Case*

Patent ambush and charging unreasonable royalties has been dealt with in the *Rambus Case*.[220] The case involved a standard setting organization (SSO) namely JEDEC (Joint Electron Device Committee) for computer memory technology. Rambus, a member of this SSO participated and in essence concealed its own research activities and patent policies which distorted the standard setting process when it obtained patents for technology that was contained in the business wide standard. Rambus on acquisition of these patents was in a position to impose monopolistic royalty rates on other manufactures of computer memory technology which included JEDEC members. The JEDEC members instituted complaints against Rambus both in the EU and before the FTC in the US. The European Commission instituted investigations against Rambus to determine whether the firm had engaged in patent ambush as a result of its failure to disclose the existence of patents and pending patent applications. Rambus however reached a settlement with the EC Competition Commission where Rambus agreed to lower its licensing rates. In the US, the FTC found Rambus to have engaged in illegal monopolization and ordered imposition of royalty rates much lower than Rambus rates at that time. The FTC determined the *Rambus Case* based on the requirements for monopolization as determined by the Supreme Court under Section 2 of the Sherman Act. It found Rambus to have engaged in exclusionary conduct leading to the acquisition of monopoly power.[221] The FTC also found a causal link between the conduct of Rambus and monopoly power. The FTC concluded that the actions of Rambus had significantly caused

[219] The Commission relied on the recent decision of the Court of First Instance (CFI) in Joined Cases T-24/93, T-25/93, T-26/93 and T-28/93, Compagnie Martime Belge & Others v. Comm'n, 1996 E.C.R. II-1201, para 149.
[220] The European Commission in 2007 sent a Statement of Objections (SO) to Rambus alleging that Rambus concealed key patents and patent applications for Dynamic Random Access Memory (DRAM) chips from Joint Electron Device Engineering Council [JEDEC] which is a private standard-setting organization in the computer chip industry. Rambus is also alleged to have enforced those intellectual property rights after they were incorporated into JEDEC's standards.
[221] *See* Drexl, *supra* note 78, at 139.

harm to competition since Rambus had resorted to deceptive conduct which significantly contributed to its acquiring monopoly power through distorting JEDEC's technology and weakening its member's capacity to shield themselves from patent hold ups.

The decision by the FTC did not apply to companies active in Europe hence the need for the European Commission to step in.[222] The FTC decision was later overturned by the D.C Circuit, and the decision set aside under the reasoning that for an exclusionary conduct undertaken to be found to be a violation of competition law, the actions must have an anti-competitive effect to the extent that there is harm to the competitive process and in so doing harm the consumers. The members in the JEDEC did not amount to end user consumers and the resulting harm to one or more consumers was determined not to amount to harming the competitive process.[223] In the EU, Article 102 TFEU requires market dominance to be established during the period the abusive conduct is carried out by an undertaking, such that if as in the case of Rambus there is no market dominance then no abusive conduct is found. It is therefore left to the domestic laws to address issues of protection against patent holdups and ambushes exercised by those undertakings that are non-dominant.

#### *2.5.3.2 TFEU Article 101 (formerly EU Treaty Article 81)1*

Regulation of bilateral licensing agreements and technology transfer agreements under Article 101(1) prohibits anti-competitive behaviour by individuals and undertakings it states that,

> The following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which: (a) directly or indirectly fix purchase or selling prices or any other trading conditions; (b) limit or control production,

[222] *See* http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/objectid/bf75a3b3-dee6-46cd-b8c1-4cd87cbe53a8.cfm (last visited Apr. 17, 2009).
[223] *See* Rambus Inc. v. FTC., 522 F3d. 456, 469 (D.C. Cir. 2008), *cert. denied*, U.S. U.S.L.W. 3346 (2009) *available at* http://pacer.cadc.uscourts.gov/common/opinions/200804/07-1086-1112217.pdf.

> markets, technical development, or investment; (c) share markets or sources of supply; (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.[224]

Article 101(2) makes prohibited agreements void and unenforceable.[225] Article 101(3) provides exemptions for certain types of agreements that have been prohibited by Article 101(1) but are otherwise allowed.[226] This provision is of particular interest in the interaction between patent rights and competition policy since most intellectual property licensing agreements fall under Article 101(3). However, Article 101 does not specifically single out intellectual property rights for special treatment. Rather an interpretation of Article 101 accommodates intellectual property rights through "[T]he incidental benefits of the logic of its interpretation."[227]

### 2.5.4 Comparative Perspective of Patent Rights and Competition Policy Interaction in the US and EU

The general position in the US is that intellectual property does not confer market power and that market power by itself does not offend antitrust laws. In addition to market power there must be an abuse which has an effect of restricting competition and an effect on consumer

[224] TFEU art. 101
[225] TFEU art. 101(2) provide that any agreements or decisions prohibited pursuant to this Article shall be automatically void.
[226] TFEU art. 101(3) The provisions of paragraph 1 may, however, be declared inapplicable in the case of: any agreement or category of agreements between undertakings; any decision or category of decisions by associations of undertakings; any concerted practice or category of concerted practices, which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not: (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives; (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.
[227] *See* ANDERMAN, *supra* note 154 (explaining that intellectual property rights are accommodated in the Transfer of Technology Block Exemption regulations in such a way that they are not specifically given special treatment. Rather they are accommodated within the logic of the doctrines of competition law. The TTBER and Guidelines do not specifically state that intellectual property rights are treated like any other form of property rights like stated in the US Guidelines relating to intellectual property licensing).

welfare.[228] Indeed as with any other tangible or intangible asset that enables its owner to obtain significant competitive profits, market power or even monopoly, that is solely the consequence of a superior product, business acumen or historic accident does not violate antitrust laws.

The US courts have under the Sherman Act Section 2 determined that exclusionary practices that exclude competitors are restricted as being monopolistic while in circumstances where they impose excessive terms and prices on competitors but do not exclude the competitors, they are not termed monopolistic. This has been illustrated in the *Rambus case* where the D.C Circuit overturned the FTC finding of anti-competitive practices on the part of Rambus. On the other hand Article 102(a) TFEU is quite explicit under these circumstances and bans the imposition of unfair prices or trading conditions

With regard to patent ambushes and holdups by non-dominant undertakings in the EU, the domestic legislation of individual member states is applicable. Under the modernized competition laws, issues requiring judicial determination can now be dealt with not only by the European Commission on competition but also by the national courts of Member States. Under Article 102 TFEU, unilateral conduct will be considered anti-competitive in two explicit circumstances, firstly where for the undertaking allegedly performing anti-competitive practices, market dominance is seen to exist in the relevant market and secondly abusive conduct is proved. The stark difference between the judicial interpretations of anti-competitive conduct relating to but not limited to intellectual property in the two jurisdictions is evidenced in their approach as to whether a conduct harms consumer welfare. In the US, a consumer welfare approach is adopted under which for a Section 2 violation to be found, a showing of harm to consumers must be shown. In the EU, the ECJ and CFI have only recently begun showing an interest in adopting the consumer welfare approach. This has been done when the ECJ and CFI confirmed that Article 102 TFEU also prohibits conduct which

[228] *See* DOJ & FTC Antitrust Guidelines.

indirectly prejudices consumers by impacting competition negatively in *British Airways v. Commission*.[229] Justification of violation under EC law may be easier since proof of direct detrimental effect on consumers is not required. In addition to this, the Commission in determining anti competition cases does not carry out an analysis of the pro-competitive and anti-competitive effects of the undertaking through carrying out an efficiency analysis, similar to that undertaken by the US Courts when making a determination under Section 2 of the Sherman Act. The lack of analysis together with the non-requirement that there be a causal link between the abuse and the existence of market power in the US allows EU law to be applicable in instances of deceptive conduct that would otherwise be considered unfair competition.

### *2.6 Patent Rights and Competition Policy Legislation in Selected Developing Countries*

Like the US, EU and other industrialized countries, developing countries have accepted the new and dynamic view of the role of intellectual property rights in economic development. In so doing, the developing countries have extensively incorporated the standards set out by the WTO TRIPS Agreement in their respective national legislation. Developing countries encounter a unique problem with relation to the interaction between patents and competition policy. The problems encountered are founded on the procedures and determination of patentability or acquisition of patents due to the assumption that the granting of a US or EU patent is often invoked as evidence that the invention meets patentability standards. A number of developing countries based on the reasoning that patents have already been granted in industrialized country jurisdictions automatically grant patent rights without due consideration of the patentability requirements under national legislation. An exception of this can be evidenced by India which has on several occasions refused to grant patent rights based

[229] Case C-95/04 P, British Airways v. Comm'n, 2007 E.C.R. I-2331.

on grounds that the invention does not meet with patentability requirements under its national legislation. The three developing countries under review are namely India, South Africa and Kenya which although differing in manufacturing and industrial capability as well as research and development capacities all have intellectual property legislation in place and adequate enforcement procedures. In addition to this they have effective competition laws and policies**.**

### 2.6.1 Patent Rights in India

India is a former British colony that adopted majority of its legislation mirroring the English legislation including its intellectual property legislation. It is a unique developing country having the 4th largest pharmaceutical industry in the world coupled with the fact that it has a large percentage of its population living under the poverty line. India is advanced with regard to knowledge and skills in organic chemistry. The result of this skills and knowledge is that the generic drug industry in India has been able to develop and flourish massively to world class standards surpassing those of some developed countries.

In India, patent law is governed by the 1970 Patent Act of India. The 1970 Patent Act which has undergone amendments was interesting due to the fact that it contained provisions exempting certain pharmaceutical products from patents. Following drafting and adoption of TRIPS, there was resistance to its implementation by some developing countries led by India, which foresaw the problems posed by TRIPS for developing countries and especially its generics pharmaceutical industry. This resistance culminated in the *Mailbox Case* and ultimately compliance with TRIPS for India.[230] India complied by amending its Patent Act and implementing the Indian Patent (Amendment) Act of 2005. The implementation of the

[230] Report of the Panel, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS79/R (Aug. 24, 1998) *available at* www.wto.org/english/tratop_e/dispu_e/79r.doc (complaint involved India's lack of patent protection for pharmaceutical and agricultural chemical products and the absence of a system or procedure for filing patent applications for the pharmaceutical and agricultural chemical products as well as the provision for the granting of exclusive marketing rights for such products).

new legislation also solved the problem of mailbox applications allowing product patents in pharmaceutical and other fields where no patents were granted. The mailbox applications were essentially those product patents that were filed with the Indian Patent Office from 1995 to 2005 prior to the amended Patent Act coming into force. These were held in limbo and unexamined pending resolution of policies and laws regarding treatment of these product patents. The Patent (Amendment) Act of 2005 contained many important provisions including recognition of product or composition of matter patents for chemicals including drugs; it granted applications 20 years protection from the filing date.[231] The Patent Act is regarded as model legislation for developing countries because it contained safeguards especially for generic medicines. The Indian Patent Act of 2005 is impressive to the extent that it contains expansive provisions prohibiting "ever greening" of patents, in addition to provisions governing the issuing of compulsory licences and allowing for parallel imports.

#### *2.6.1.1 Safeguards Inherent in the Indian Patent Act of 2005*

The Patent Act under Section 3 specifies those inventions which are not patentable. The provision subsection (d) is of special interest due to the fact that other developing countries contain no such provision. Under Section 3(d) patents are denied for substances which are a new form of a known substance unless they have undergone enhancement of the efficacy of the substance.[232] The purpose of the provision is to stop patent ever greening by inventors where they undertake minimal changes to patented molecules and then use these



[231] Patent (Amendment) Act, No 15 of 2005

[232] Patent (Amendment) Act, sec. 3 (d) (2005) states that, the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant.
For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

modifications as a reason for new patents thus extending patent protection past 20 years.[233] The reason for the clause preventing "ever greening" is that extending the protection period delays entry of generic competitors into the market. The Section 3(d) also forces firms to focus their efforts on research and development as opposed to concentrating on known substances. The provision has the objective of ultimately preventing patenting of products simply because insignificant changes were made. It makes the product unable to meet patentability requirement of novelty hence not patentable. Also important, the provision prevents monopoly practices through preventing patent extension beyond the stipulated 20 years. In the pharmaceutical industry, the provision also acts as a barrier preventing pharmaceutical companies from engaging in insignificant incremental changes that divert the focus of the pharmaceutical companies from research and channelling resources on real innovation and new drug discoveries.

To eliminate Section 3(d) would allow companies to patent molecules that were discovered before 1995. Under TRIPS agreement, India has no obligation to provide patent protection to these molecules.

#### *2.6.1.2 Analysis of Section 3(d) and the Glivec Drug Patent Dispute in India*

The discovery of a chromosomal abnormality that produced a cancer causing enzyme prompted research into the separation of the enzyme from other healthy enzymes in an effort to procure treatment. Norvatis researchers then succeeded in creating a test to determine a molecule that could target this enzyme exclusively without attacking healthy cells and found a molecule which was named *"Imatinib"* for which a patent was obtained covering this enzyme

[233] *See* Shamnad. Basheer & T. Prashant. Reddy, *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTED 232 (2008) http://www.law.ed.ac.uk/ahrc/script-ed/vol5-2/basheer.asp (last visited May. 05, 2010) ("Ever-greening" occurs when a manufacturer 'stockpiles' patent protection by obtaining separate 20-year patents on multiple attributes to a single product).

as a free base and also in the form of salts.[234] The salt as a polymorph was developed and formulated in the Glivec drug (Gleevec in US). The *Glivec case* arose out of the problem created by mail box applications.[235] Because India did not grant drug patents until January 1 2005, Norvatis application for its polygraph was part of a mailbox application which was examined following the coming into force of the Patent (Amendment) Act of 2005. The patent application was rejected during examination under the amended patent legislation. The reasoning given for rejecting the patent application being that there was lack of novelty and that there was no significantly enhanced efficacy as stipulated under Section 3(d), and lastly that the application lacked obviousness and wrongful priority. Following this decision Norvatis appealed to the Madras High Court seeking a declaration that the provision was unconstitutional and in violation of India's obligations under TRIPS. The court decided that the provision was constitutional and with regard to the question of non-compliance of India with TRIPS obligations, the court recommended the issue be addressed by the WTO Dispute Settlement Body since the issue falls within the competence of the WTO.

In India, an analysis into the effect of patents on the pharmaceutical industry revealed several things, firstly that the industry did not engage in more research and development into new drugs as had been anticipated following the adoption and implementation of TRIPS.[236] Secondly, the pharmaceutical industry shifted resources to the development of more drugs suited to developed countries where there was a lucrative market and virtually ignored drugs needed for developing country diseases such as malaria and tuberculosis.

Research into these drugs necessary for developing countries was mainly funded by the public sector or philanthropic funding. Indian pharmaceutical companies are currently focusing on



[234] *Id.*

[235] *See* Novartis v. Union of India, (2006) 24759 (Madras H.C.); *see also* Novartis, *G*livec Patent Case in India: FAQs: http://www.novartis.com/downloads/about-novartis/india-glivec-patent-case-faq.pdf (last visited on Nov. 28, 2008).

[236] Sudip Chaudhuri, *Is Product Patent Protection Necessary in Developing Countries for Innovation? R & D by Indian Pharmaceutical Companies after TRIPS* http://www.iprsonline.org/ictsd/Dialogues/2007-10-11/2007-10-11_desc.htm (last visited Nov 23, 2008).

generics and incrementally modified drugs. This has little to do with the TRIPS Agreement as the pharmaceutical companies are focused on increasing research and development efforts towards developing products and processes so as to get regulatory approvals for entry into patent expired generic medicines markets in developed countries where the market for drugs exists.

The Indian pharmaceutical companies are therefore increasingly focused on diversifying to regulated markets such as the US and EU which provide large markets for their products. The trends of the pharmaceutical industry in India are interesting in that they illustrate that trade objectives and profit motivations are more valuable than consumer welfare objectives and the need to meet the basic health needs of the population.

Section 3(d) from a competition perspective serves the purpose of preventing anti-competitive practices that may result from "ever greening" which has anti-competitive consequences as it discourages the competition from research and development in a particular area.

India as a model for developing countries is faced with severe challenges. On the one hand the need to provide incentives to innovate and produce new products and on the other hand the need to protect its large and growing generics industry. Finding a balance between these two objectives has been difficult. In spite of this, the pharmaceutical industry keeps growing and India remains a major supplier or pharmaceutical products for many developing countries.



#### *2.6.1.3 Compulsory licensing in India*

The Patent Act of 1970 provided for compulsory licensing although the provision was rarely put in use. Section 88 provides for patented processes for manufacturing substances capable of being used for medicine and food being automatically endorsed as licences of right which

could be issued 3 years after grant of patent protection.[237] Section 84 of the Patent (Amendment) Act 2005 provides for conditions under which a compulsory license may be granted. These include the grounds where the reasonable requirements of the public with respect to the patented invention have not been satisfied, or the patented invention is not available to the public at a reasonable and affordable price, the patented invention is not worked within the territory of India. The first ground dealing with reasonable requirements of the public having been met has been explained under the Act. The reasonable requirements of the public shall be deemed to have not been met if due to a patentees refusal to license there are implications on the establishment of a new trade or industry in India, where the demand for the patented product cannot be met by the patentee, where a market of export of patented Article manufactures in India has not been supplied and where the refusal to license is prejudicial to the development of commercial activities in India.

The procedure for the grant of compulsory licenses as contained in the Act provides that an application can only be made for compulsory licenses 3 years after the grant of the patent and the applicant for a compulsory licence can only do so after making efforts to obtain a license from the patentee on reasonable terms and conditions and having been unsuccessful within a reasonable period which is interpreted to mean a period not exceeding 6 months. Under Section 92 A of the amended Patent Act compulsory licensing for export of pharmaceutical products is provided for. The provision implements Article 31*bis* of TRIPS Agreement. It provides that compulsory licenses shall be available for manufacture and export to countries having insufficient manufacturing capacity in the pharmaceutical sector as per the procedure described in the Implementation Decision.



[237] *See* S. K. Verma, *New Patent Regime of India and Pharmaceutical Patents*, *in* JOSEF DREXL ET AL., TECHNOLOGY AND COMPETITION 350 (Josef Drexl et al., eds. 2009)

### 2.6.2 Competition Law and Policy in India

In India, the competition law is set out under the Competition Act of 2002 which has been amended in 2009. The Competition Act of 2002 replaced the Monopolies and Restrictive Trade Practices Act of 1969. Under the Competition Act of 2002 the objectives of the Act includes prevention of practices in adverse of trade, promotion and sustaining of competition in the market, protection of the interests of consumers and finally to look into factors that suppress free trade carried out by other participants in India.[238]

Section 3 of the Act deals with anti-competitive agreements and section 4 deals with abuse of dominant position. The Competition Act is explicit in section 3(5) where it upholds that intellectual property rights legitimately granted are not to be considered as anti-competitive as a result of the exclusive rights afforded through the intellectual property rights. The provision provides that

From the foregoing it is evident that India strives to put in place adequate competition rules which are aimed at protecting and encouraging fair competition. In the interaction between competition policy and patent rights it is evident from the case law and the courts approach to patent rights that pro competition interpretations are adopted by the courts in an effort to protect local industries through preventing ever greening. The creating of a competitive atmosphere in the pharmaceutical industry is beneficial for consumers in developing countries and has positive implications in the accessing of cheap drugs for the treatment of HIV/AIDS, malaria and tuberculosis.



[238] A. Damodaran, *Implications of Competition Policy on Biotechnology Industry in India*, *in* TOWARDS A FUNCTIONAL COMPETITION POLICY FOR INDIA: AN OVERVIEW 244 (Pradeep S. Mehta ed., 2005)

### 2.6.3 Patent Rights in South Africa

Intellectual property protection is available in both regional and national legislation. On the regional level, there are two organizations dealing with industrial property, namely the African Regional Industrial Property Organisation (ARIPO) and the African Intellectual Property Organisation (OAPI)[239]. From the 1970s African countries could provide for the protection of industrial property, namely inventions, trademarks and industrial designs through these organisations. OAPI was established in 1962 under the Libreville Agreement. It was subsequently revised at Bangui in 1977 and has 14 members from French speaking African countries.[240] The agreement helps coordinate intellectual property activities in French speaking Africa.

ARIPO was specifically meant for English Speaking African countries and was established on 9 December 1976. It was initially known as the African Regional Industrial Property Organisation as it only covered industrial property. In 2003 the protocol was revised to include copyright and related rights. ARIPO offered its members the opportunity to file for patents through their national offices and unlike OAPI, national patent offices of member countries could issue patents.[241] ARIPO provides a centralised service for patent application. The peculiarity with ARIPO as a patent issuing body is that member countries have a right to reject patent applications from ARIPO within 6 months of being notified of the application. Generally, the intellectual property regime as governed by the two regional bodies' legislations in sub-Saharan Africa is weak. The main role played by the regional bodies is in training of government officials on issues related to intellectual property rights as well as



[239] Agreement Revising the Banjul Agreement on the Creation of an African Intellectual Property Organization of Mar. 2, 1977 Banjul, Feb. 24, 1999 [hereinafter Banjul Agreement].
[240] These include Benin, Burkina Faso, Cameroon Senegal, Ivory Coast, Central African Republic, Togo, Congo, Mali, Gabon, Niger, Guinea, Mauritania and Chad.
[241] Members of ARIPO are Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Sierra Leone, Somalia, Swaziland, Uganda, Tanzania, Zambia and Zimbabwe. South Africa and Nigeria are not members of ARIPO.

providing some form of model legislation and issues relating to procedures taken in issuing intellectual property rights.[242]

Intellectual property law in South Africa dates as far back as 1860 when the first patent Act was enacted.[243] Intellectual property law in South Africa is governed by statute and supported by common law, based on internationally accepted principles. South Africa subscribes to the Patent Cooperation Treaty (PCT) and is not a member of either ARIPO or OAPI. South Africa has incorporated the TRIPS flexibilities in its Patents Act of 1978 and subsequent amendments including the Medicine and Allied Substances Control Amendment Act of 1997. In addition to its TRIPS plus intellectual property legislation, the Competition Act of 1998 is applicable in addressing alleged patent abuses.[244] South Africa has a court of the commissioner for Patents with exclusive jurisdiction over patent matters.

### 2.6.4 Competition policy in South Africa

Competition law in South Africa is mainly governed by the Competition Act 89 of 1998 which has undergone amendments giving rise to the Competition Amendment Act 1 of 2009.[245] In South Africa the Roman Dutch law and English common law have strongly influenced competition law. Agreements in restraint of trade are regulated by common law. The interaction between intellectual property law and competition policy in South Africa is



[242] *See generally* PATRICK L. OSEWE ET AL., IMPROVING ACCESS TO HIV/AIDS MEDICINES IN AFRICA: TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS FLEXIBILITIES (2005).
[243] L. T. C. Harms, *The Role of the Judiciary in the enforcement of Intellectual Property Rights: Intellectual Property Litigation under the Common Law System with Special Emphasis on the Experience in South Africa*, 26 EUR. INTELL. PROP. REV. 483 (2004).
[244] *See, e.g.,* OSEWE ET AL., *supra* note 242, at 37. South Africa provides TRIPS plus intellectual property legislation as evident in that the compulsory licensing provisions require the agreement of the patentee or a hearing when such an agreement is lacking. Section 4 provides that "A patent shall in all respects have the like effect against the State as it has against a person; provided that a Minister of State may use an invention for public purposes on such condition as may be agreed upon with the patentee, or in default of agreement, on such conditions as are determined by the Commissioner on an application by or on behalf of such Minister and after hearing the patentee." In addition to this provision section 78 provides that "The Minister may on behalf of the State, acquire, on such terms and conditions as may be agreed upon, any invention or patent."
[245] *See generally* PHILLIP SUTHERLAND & KATHARINE KEMP, COMPETITION LAW OF SOUTH AFRICA (2009).

illustrated by the case of *Mossgas (Pty) Ltd v. Sasol Technology (Pty) Ltd*.[246] Where a process license granted to Mossgass for the so called synthol process provided that the licensee could use the process only for fuel manufacture. The licensee objected to the restriction on the grounds that it restricted the manufacture of other products the court found there was no restriction of trade as there was no limitation of trade as such including the issue that there were no implications on consumer welfare arising from the licensing agreement terms and conditions.[247] The provisions relating to abuse of dominance in the Competition Act 89 of 1998 are derived from existing law in other jurisdictions particularly the EU and US. The abuse provisions under the Competition Act of 1998 are dictated by Section 3 and Sections 6-9 of the Act. Section 3 dictates the territorial applicability of the Act in that the Act applies to all economic activity within South Africa or having an effect within South Africa and Section 6 deals with a determination of whether the firm has exceeded the financial threshold laid down which is that its gross annual turnover in, into or from South Africa is valued at or above R5 million or its gross assets in South Africa are valued at above R5 million.[248] This is the first stage where dominance is determined. Once a firm is found to hold a dominant position, it falls under Section 7 which lists those circumstances under which a firm will be found to be dominant. Issues determined under this provision include the identification of a relevant market and definition of the relevant market; meaning of market power and the calculation of the market shares.[249] Thus the dominant firm is assessed to determine whether it contravenes the prohibited conduct under Sections 8 and 9. Section 7 in codifying the circumstances under which a firm may be held to be dominant provides three categories.



[246] [1999] 3 All SA 321 (W).
[247] *See* SUTHERLAND & KEMP, *supra* note 245, at 3-19.
[248] *Id.* at 7-10 (the provision in contrast to the TFEU does not geographically limit the market in which the alleged anti-competitive practice has occurred. The TFEU refers to abuse of dominant position within the common market or a substantial part of it).
[249] *Id.* at 7-8.

First, Section 7(a), where a firm has a market share of at least 45 percent in the relevant market, there is a rebuttable presumption of dominance. Second, Section 7(b), where a firm has a market share of at least 35 percent but not exceeding 45 percent in the relevant market then the firm must provide that it does not have market power, failing this the presumption of dominance prevails. Third, Section 7(c) a firm with less than 35 percent of market power has no dominant position. A party alleging dominance of a firm falling under Section 7(c) has the onus of proving the existence of dominance, failing which the firm is not considered dominant.[250] To determine whether a firm has engaged in prohibited conduct, the list of prohibited conduct under Sections 8 and 9 is utilized. Sections 8(a) and (b) deal with excessive pricing and refusal to grant an essential facility. Section 8(c) prohibits the exclusionary acts set out in 8(d) which are five specific types of acts listed. The alleged anti-competitive conduct is only upheld where it is proven that the anti-competitive effects outweigh the pro-competitive gains. Section 8(d) provides that it is prohibited for a dominant firm to require or induce a supplier not to deal with a competitor, refuse to supply scarce goods to a competitor when it is economically feasible to do so, selling goods or services on condition that the buyer purchases separate goods or services unrelated to the contract or forcing a buyer to accept a condition unrelated to the contract, selling goods and services below the average variable cost and buying up a scarce supply of intermediate goods and resources required by a competitor so as to sabotage the competitors business. Under Section 9, price discrimination is prohibited by a dominant firm where it has an effect on competition under various circumstances. South Africa unlike other developing countries has utilized its competition legislation in an attempt to curb the anti-competitive practices of dominant pharmaceutical companies.



[250] *Id.* at 7-11

### 2.6.5 Interaction between Patent Rights and Competition Policy in South Africa: Pharmaceutical Patents Controversy

In South Africa the interaction between patent rights and competition policy is better illustrated through case law, where violation of the Competition Act of 1988 was alleged in cases involving pharmaceutical patents. The background leading to the cases was the contention that pharmaceutical companies practices were resulting in HIV/AIDS infected persons not being able to afford necessary anti-retroviral drugs to help combat the disease. This was after South Africa had declared HIV/AIDS a national disaster making emergency measures applicable to help curb the spread of the disease.

The complainants instituted proceedings against pharmaceutical companies on the grounds that they were engaging in anti-competitive practices and abusing their patent rights and that the actions of the pharmaceutical companies contravened some constitutional protections.

The complaint on excessive pricing was levelled against two leading pharmaceutical companies namely, GlaxoSmithKline South Africa and Boehringer Ingelheim

The facts of the case are that in September 2002, Treatment Action Campaign (TAC) initiated a complaint with the Competition Tribunal of South Africa alleging that GlaxoSmithKline and Boehringer Ingelheim had contravened the Competition Act by excessively pricing its anti-retroviral drugs. The parties were found to have contravened Section 8 of the Competition Act. Under Section 8(a), a dominant firm is prohibited from charging excessive prices, Section 8(b) prohibiting the dominant firms from refusing access to essential facilities and Section 8(c), under which exclusionary acts that have an anti-competitive effect that outweighs technological efficiency or other pro-competitive gains are prohibited.[251] The Competition Commission in upholding the complaint found both pharmaceutical companies to have charged excessive prices for their patented ARV drugs and unlawful refusal to issue

[251] IRINA HARACOGLOU, COMPETITION LAW AND PATENTS: A FOLLOW-ON ON INNOVATION PERSPECTIVE IN THE BIOPHARMACEUTICAL INDUSTRY 197 (2008).

voluntary licenses to generic manufacturers therefore restricting production of ARV drugs and competition thereof. Three competition issues were illustrated, first that drug companies imposing monopoly prices impede access to medicines, secondly, the refusal to issue voluntary licenses and enable generic production is an abuse of competition and third, such refusals to grant licences affect access to fixed dose combination drugs and treatment regimens for affected patients.

GlaxoSmithKline reacted to the decision of the Competition Tribunal and impending competition from generic manufacturing companies by further lowering their prices and extending voluntary licences that had been issued to the company Aspen Pharmacare permitting the sale of HIV/AIDS drugs in both the public and private sector as well as extending the territory where sales may be made to the entire sub Saharan Africa region. The Menzi Simelane, a commissioner at the Competition Commission, commented on the case to finding that abuse of patent rights to be detrimental to the consumer and competition, while acknowledging the benefit of generic drugs in the treatment of HIV/AIDS,

> Our investigation revealed that each of the firms has refused to license their patents to generic manufacturers in return for a reasonable royalty. We believe that this is feasible and that consumers will benefit from cheaper generic versions of the drugs concerned. We will request the Tribunal to make an order authorising any person to exploit the patents to market generic versions of the respondents patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty. In addition, we will recommend a penalty of 10% of the annual turnover of the respondents' ARV in South Africa for each year that they are found to have violated the Act.[252]

The second case involved threatening litigation against Bristol Myers Squibb on a drug called *amphotecerin B* which is used to treat opportunistic infections in patients with HIV. The case was resolved without having to file legal papers, although it resulted in a massive reduction in

[252] *See* http://www.healthgap.org/press_releases/03/101703_HGAP_PR_RSA_competition_commish.html.

prices in both the public and private sectors. To illustrate the successful outcome the price fell from $20 to $5 in the private sector.[253]

The cases are significant to the extent that they illustrate the progress and developments of the TRIPS Agreement implementation, following the Doha Declaration on public health and the prioritisation of public health over absolutist patent protection. The cases also set an important precedent which could be followed by other developing countries. Following this case, developing countries began to access cheap pharmaceuticals resulting from the voluntary licenses issued by pharmaceutical companies.

### 2.6.6 Patent Rights and Competition Policy in Kenya

In Kenya, patent and competition issues are governed by two statutes, namely the Industrial Property Act of 2001[254] and the Restrictive Trade Practices Monopolies and Price Control Act.[255] The Industrial Property Act was published in 2001 following presidential assent.[256] It provides that patents are available generally for inventions whether processes or products. The objective of enacting the Industrial Property Act was to incorporate the provisions of TRIPS into Kenyan legislation.

The Act contains a provision on competition law under Section 80.[257] Section 80 empowers the managing director of Kenya Industrial Property Institute (KIPI) with authority to recommend the Minister for Trade to issue a government use order where the managing director following analysis and examination of a patent license determines the patent owner or licensee has been exploiting the patented invention in an anti-competitive manner. In addition to the provisions aimed at preventing abuse of competition there is also specific competition



[253] *Id.*
[254] Industrial Property Act, (2001) Cap. 509 (Kenya).
[255] Restrictive Trade Practices, Monopolies and Price Control Act, (1988) Cap. 504 (Kenya).
[256] KENYA GAZETTE SUPPLEMENT No 60 (2001); *see* Industrial Property Act, § 1 (2001); *see also* LEGAL NOTICE NO. 53 (2002).
[257] Industrial Property Act, § 80 (2001).

legislation governed by the Restrictive Trade Practices, Monopolies and Price Control Act.[258] The Act establishes the office of the Commissioner for Monopolies and Prices which has authority over all competition related matters. The legislation does not distinguish between competition issues related to intellectual property and other competition issues hence the Commissioner has mandate over such issues should they arise. On the other hand the managing director of KIPI also has mandate over issues relating to intellectual property and competition. In a situation where the relationship between competition and patent rights gives rise to anti-competitive effects, these two officers have mandate over the competition related intellectual property rights abuses which results in considerable scope for conflict.

The Industrial Property Act 2001 contains provisions dealing with both contractual licensing and compulsory licensing. Contractual licenses generally comply with the principle that the rights issued cannot exceed the rights possessed by the patent owner. Under the Kenyan legislation there exists a requirement for mandatory verification of the terms and conditions of licences. The Industrial Property Act requires that all contractual licensing agreements be registered with KIPI. KIPI then examines the licensing agreements and determines whether the agreement is suitable and has the authority to refuse registration and invalidate any contract that does not satisfy the laid down requirements.

As a result of this provision, KIPI tends to be involved in patent licensing negotiations although they are not party to the contract, simply because the patent owner wishes to avoid KIPI opposing the registration of the license. A number of problems with this provision are evident in that it tends to infringe on the rights of individuals to freely contract due to the lack of privacy and likely disclosure of confidential information. For this reason some potential licensors dealing with technology whose value is dependent on secrecy and confidential information is unlikely to enter into licensing agreements in Kenya.



[258] Restrictive Trade Practices Monopolies and Price Control Act, (1988) Cap. 504 (Kenya).

The requirement of KIPI approval of the terms and conditions of any license leads to other conditions and requirements in the Act. Where the managing director is of the opinion that a licensing contract contains a clause or clauses imposing anti-competitive restrictions on the licensee and as a result are harmful to the economic interests of the country, he is obliged to refuse registration of the license and therefore block its execution.[259] Section 69 of the Industrial Property Act 2001 provides a detailed list of 33 prohibitions where the managing director of KIPI may refuse to register a licensing agreement. Section 69(ii) outlines other reasons for which registration of a licensing agreement may be refused. These are where the prices or royalty payable are unreasonably high, tying agreements that are aimed at eliminating the competition and conditions requiring purchases from licensor approved suppliers or limiting the products that can be produced using the licensed technology. In addition to these are those agreements imposing territorial and field of use unreasonably.[260]

#### *2.6.6.1 East African Community Competition Rules*

The East African Community is an integration of the countries of east Africa aimed at progressing from a customs union to a common market, a monetary union and ultimately a political federation as set out under Article 5(2) of the Treaty on the Establishment of the East African Community (EACT). The EACT was signed in 1999 and came into force in 2000. Under the EACT, competition is governed under the Customs Union Protocol which is established pursuant to Article 75 of the Treaty to deal with matters of competition *inter alia*. The competition authority of the EAC as established under the protocol is supranational and deals with competition issue which have cross border implications and effects. An example of such issues is the anti-competitive implications that the agreements between South African

[259] Industrial Property Act, § 69 (2001).
[260] Robert Lewis- Lettington & Peter Munyi, Willingness and Ability to use TRIPS Flexibility. A Kenya Case Study (2004), http://www.dfidhealthrc.org/publications/atm/Lettington2.pdf

Breweries and Kenya Breweries Ltd colluding to allocate the market within the East African region and in essence hampering competition. The Competition authority however is not fully functional and the modalities of its workings are still under discussion by the member States of the EAC. Due to the lack of a regional competition body to address these anti-competitive practices, the anti-competitive practices extending outside national borders have to be addressed at national level with the different countries applying their national competition legislation. The functioning of the EAC competition policy and authorities will rely heavily on the availability of efficient and functioning national competition authorities of member countries. The effectiveness of the EAC competition authority is therefore yet to be determined.

***Summary***

The TRIPS Agreement in its provisions recognizes that patent rights can be exploited in an abusive manner such that they give rise to anti-competitive effects. The regulatory frameworks governing the interaction between patents and competition illustrate first and foremost that a well-functioning intellectual property system must include some measures protecting competition and curbing abuse of patent rights. The measures protecting competition must be consistent with the intellectual property rights, specifically patent rights in that they should not undermine the patent rights as protected by national legislation and international conventions of the TRIPS Agreement and Paris Convention.

The development and progression of the TRIPS Agreement through the Doha Declaration on Public Health of 2001 and the subsequent WTO Implementation Decision of 2003 illustrate the difficulties encountered by developing countries in their quest for adoption of patent rights and effective exploitation of the same rights. This is accentuated by compulsory licensing remaining a difficult solution to adopt in an effort to resolve anti-competitive abuses of

patents in the pharmaceutical industry and in the quest to procure cheap medicines for the treatment of HIV/AIDS. The problems encountered in exploiting the compulsory licensing option are further emphasized by the reluctance of developing country governments to utilize compulsory licensing due to fear of repercussion from developed countries through other restrictions on trade.

A comparative analysis of EU and US legislation and case law governing the interaction illustrates the dynamic changes that have taken place with regard to the interaction between patent rights and competition policy in industrialized countries. The differing objectives of the US and EU, with US goals centering on consumer welfare and the EU goal of maintaining an open market without barriers in the EU illustrate the different considerations that have been taken by regulatory agencies and judicial bodies in analyzing the anti-competitive effects of the interaction.

The developing countries legislation has progressed in the last 10 years from being merely static legislation adopted in an effort to fulfill requirements for joining the WTO, to legislation that is implemented for the benefit of the citizens. The changes that have been achieved by the patent legislation have far reaching and beneficial consequences as illustrated by cases in South Africa and India. In South Africa, the utilization of competition legislation to attack anti-competitive patent practices in the pharmaceutical industry resulted in the lowering of HIV/AIDS drug prices making them affordable for the population in sub Saharan Africa. The Glivec drug patent dispute in India illustrates that patent legislation in developing countries can be drafted in such a way that it includes provisions aimed at protecting and promoting innovation and development of domestic industries.

# 3 POINTS OF PATENT RIGHTS AND COMPETITION POLICY INTERACTION

## *3.1 Introduction*

The objective of patentability standards is to provide incentives for innovation as well as avoid the unnecessary restraints on competition through supporting patent rights only for those inventions whose disclosure and commercial development would not have occurred without patent protection. Patentability standards also aim at safeguarding the disclosure requirements necessary for incentives and inventors to recoup on their research and development costs and profit from their inventions. The interaction between patent rights and competition policy can first be evidenced in the determination and examination of patentability of an invention. The patentability standards have an effect on the scope of patent rights and therefore are able to influence competition either by encouraging competition or being a barrier to competition.

The interaction between patent rights and competition is also evident in licensing of patent rights. A licensing agreement has been defined as a permit or authorization granted by the rights holder that allows the transfer of intellectual property rights to another party for exploitation subject to specified terms and conditions in exchange for consideration in form of fees.[261] Patent licenses can be exclusive or non-exclusive, with exclusive rights being the right to exclude others from exploiting the patent in the relevant field. The patent grant generally includes the right to license the patent, and the validity of the license is determined by standard contract principles, including the requirement of good consideration.[262] The interaction between patent rights and competition is evident especially where the licensing

[261] Hector Diaz-Bastien, *What Can Be Licensed?*, *in* INTERNATIONAL TECHNOLOGY TRANSFER FOR PROFIT 13 (David Campbell et al. eds., 1992).
[262] Davis Airfoils v. U.S., 124 F. Supp. 350, 352 (Ct. Cl. 1954).

agreement contains arrangements that result in price restrictions, tying practices, cross licensing, territorial restrictions, patent pools, parallel trade and refusals to deal.

This interaction can also be seen in the context of standard setting organizations. Where the patent owners are part of the standard setting organization as members and their patented technology is incorporated into a standard. In such standard setting organizations, the patent owner may be in a position to engage in ex post patent holdup which has anti-competitive effects. Anti-competitive abuses of patent rights in standard setting organizations are of interest to developed countries and developing countries with sound technology industries.

### *3.2 Substantive Standards of Patentability: Non Obviousness and Competition Policy*

The non-obviousness standard defines the level of development beyond the prior art required for a patent to issue. Non obviousness can also be said to define the size of the required patentability step.[263] The importance of the non-obviousness requirement is illustrated through the label it has attained of being the "ultimate condition for patentability."[264] Non obviousness is afforded such importance because it ensures that a measurable technological advancement has taken place that is beyond what has already been achieved in the market. The non-obviousness requirement is important to the extent it maintains the incentive for inventing by not affording protection for inventions where only minor improvements have been made. This is because granting protection for those minor and frivolous improvements deters innovation thus proving to be harmful to the society.[265]



[263] *See* FTC REPORT ch. 4.1.
[264] *See* JOHN F. WITHERAPOON, NON OBVIOUSNESS: THE ULTIMATE CONDITION FOR PATENTABILITY: PAPERS COMPILED IN COMMEMORATION OF THE SILVER ANNIVERSARY OF 35 U.S.C. 103 (1980).
[265] *See* Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 812 (1988).

Thus the non-obviousness requirement analyses the size of required patentability step which has an effect on competition.[266] In follow on inventions, if the size of obviousness is small, there is reluctance to improve on the invention by other inventors because improvers of the initial innovation risk having their improvements appropriated by the initial inventor.

Patent proliferation is an issue likely to occur when the non-obviousness requirement is not observed. Patent proliferation problems such as patent thickets, stacking of royalties, anti-commons and patent flooding may occur if the patentability step is too small. According to the FTC Report, such patent proliferation problems are likely to occur if only a small step is required for patentability. It follows from this, that "[t]here is a profusion of minor, "obvious" patents that require costly licensing negotiations and are a barrier to the innovating firm's freedom to innovate".[267]

Trivial patents have an effect on competition in that they extend the scope of patent breath by broadening the scope of protection. Due to this, competition is discouraged since competitors fear legal repercussions of patent infringement. On the other hand care should be taken not to withhold patent protection through an overly rigorous non obviousness standard as this may delay the contribution to competition by new inventors, and entrench the dominance of the initial inventor. Therefore finding the appropriate balance with regard to setting the standard for non-obviousness is crucial for encouraging innovation and maintaining competition.



### 3.2.1 Balancing Non Obviousness and Competition Policy using the "But For" Test

The US Courts developed the so called "but for" test in an attempt to ensure that only those inventions which fulfil the non-obviousness test in such a manner that it will not be detrimental to competition are patented.

[266] *See* FTC REPORT ch. 4.1.

[267] Patent trolls have been described as companies and individuals who use the patent system to obtain patents which try to capture not only the value of their inventions but the value of complementary assets and irreversible investments made by others; *see* Mark A Lemly, *Patenting Nanotechnology*, 58 STAN. L. REV. 601,630 (2005).

Where it occurs that even without the issuing of a patent the invention would emerge without significant delay then the invention does not warrant a patent. This test also referred to as the "but for" test has its beginnings in patent law.[268] When a patent has little social benefit due to the fact that it could be expected anyway, it is recognised that none issuing of the patent is beneficial to consumer welfare since it will minimise costs of innovation and competition that would have been incurred.[269] The "but for" test however is not recommended for some cases since it has been noted to have serious shortcomings in advanced technological innovations and for inventions emerging from a common base invention where other inventors are capable of independently bringing forth similar inventions. The test also fails in circumstances where although the invention is viewed as being technically straight forward, it may be extremely costly to achieve such that R&D costs are very high thus patent protection is needed to protect the inventor from imitators.

Despite the unsuitability of the "but for" test in the US, the test would be applicable in developing countries which require a straight forward test for non-obviousness. This is especially due to the reason that developing countries are lagging in technological development and are not yet technologically advanced to the extent where the base for inventions already exist and there is fear of multiple inventors coming up with identical inventions.



[268] *See* FTC REPORT ch. 4.2.

[269] *See* Graham v. John Deere Co., 383 U.S. 1, 11 (1966) ("The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent."); *see also* Edmund W. Kitch, *Graham v. John Deere Co.: New Standards for Patents*, 1966 SUP. CT. REV. 293, 301 (stating, prior to developing his prospect theory that the basic principle on which the non-obviousness test is based is that a patent should not be grated for those innovations that would have been developed anyway in the absence of the incentive brought about by patent rights.); *see also* ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 22, at 305, *cited in* ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 361(3d ed. 2002).

### 3.2.2 US Courts Treatment of Non Obviousness

In the US, the Court of Appeals for the Federal Circuit has dealt with non-obviousness and continues to do so. The treatment of non-obviousness by the court has resulted in criticism for allowing too broad patent protection through relaxing the non-obviousness requirement. The effect of too broad patent protection is the consequent harm to innovation as the broad patents are a disincentive for innovation. In the decided case of *Graham v. John Deere Co.,*[270] the court interpreted non obviousness as composed of a three part inquiry. First, a determination of the scope and content of the prior art, second part is ascertaining what differences exist between the prior art and the claims in the application and third, determining what is the ordinary level of skill in the art and then using this level determining the obviousness or non-obviousness of the claim.[271] Despite listing these elements, the court in *Graham* gave no direction of how to apply them. The Federal Circuit in an attempt to give such direction resorted to the so called "suggestion test".[272]

The suggestion test uses prior art and examines the extent to which such prior art would have influenced a person of the ordinary skill in the art that the invention should be made and would likely be successful.[273] Thus under the suggestion test the assessment of non-obviousness is focused on what prior art reveals.

> The suggestion test requires a finding that there was some suggestion before the invention's creation to combine or modify the prior art . . . things that have already been done . . . in such a way as to make the claimed invention. The suggestion test is meant to discern whether there already was a suggestion to create what is claimed to be patentable, and thus, patent protection was not needed to prompt the invention's creation.[274]



[270] *See Graham,* 383 U.S. 1 (1966).
[271] *See* FTC REPORT ch. 4.2; *see also* Paul Cole, *KSR and Standards of Inventive Step: A European View,* 8 J. MARSHALL REV. INTELL. PROP. L. 14, 21 (2008).
[272] *See* FTC REPORT ch. 4.2
[273] *See* Brown & Williamson Tobacco Corp. v. Phillip Morris Inc., 229 F3d 1120, 1124 (Fed. Cir. 2000).
[274] *See* Christopher A Cortropia, *Patent Law Viewed Through an Evidentiary Lens: The "Suggestion Test" As a Rule of Evidence,* BYU. L. REV. 1517, 1518 (2006).

The downside of the suggestion test is that it requires a search through technical papers and documentation in which the obvious has been stated. This is cumbersome and time consuming.

The suggestion test is interesting for developing countries in dealing with the issue of misappropriation of biological resources and traditional knowledge without the consent of the community or owners of the knowledge and resources. The applicability of the suggestion test and analysis of prior art will prove helpful in curbing the misappropriation of genetic resources and traditional knowledge resources from developing countries. In those cases where .there is dispute relating to resources misappropriated from developing countries and patented in industrialized countries, application of the suggestion test would assist in resolving these issues.

Under the European Patent Office (EPO), the examination guidelines at Part C Chapter IV contain five examples relating to the requirement for an inventive step. Under EPO guidelines, the determination of inventive step is an important process. It has been determined in *Metal BASF/Metal Roofing*[275] by the EPO Appeal Board that when assessing inventive step, the subjective achievement of the inventor is not to be assessed but rather the objective achievement.[276]

From the foregoing, the requirement of non-obviousness is given objective evaluation under both jurisdictions of the US and EU. This is especially important due to the fact that meeting the requirement determines that only those inventions having merit are patented, hence allowing for efficient competition in the market place. In observing procedural and substantive law regarding non obviousness, inventors can operate in an environment with certainty and cost efficiency, with limited opportunity of being subjected to patent

[275] *See* BASF Metal Roofing [1979-85] E.P.O.R. B354 (EPO (Technical Bd. App)).
[276] *Id*.; *see* Cole, *supra* note 271 at 41.

infringement suits by other inventors. This has the effect of encouraging innovation and protecting competition.

### *3.3 Disclosure and Competition Policy*

In exchange for receiving a patent, the patentee is under an obligation to disclose the nature of the invention and place the invention in the public sphere. The public may apply that knowledge in non-infringing uses and also apply such knowledge after expiration of the patent period and the invention is reverted to the public domain. Disclosure plays a major role in defining patent breadth which is how broad an inventor makes the patent claim. It is important to competition because patent breadth determines the extent of protection from competition that a patented invention receives since those inventions within the patent breadth infringe the patent while those inventions falling outside the patent breadth do not infringe the patent.[277]

If patent rights are defined too broadly, then those products that should be free to compete will infringe the patent. On the other hand, defining patent rights too narrowly may result in subdividing patent rights which follows with an increase in the number of patents therefore contributing to growth of patent thickets.

Flowing from this explanation, defining a patent broadly can affect the follow on innovation that may result. This is because broad patents give the initial innovator broad rights which reduce the incentive for other innovators to innovate because they fear infringing on the initial innovators patent rights.

> The role of disclosure requirements in shaping patent breadth and the consequences of that breadth for potential market power and cumulative innovation make the nature and effective application of the disclosure requirements a matter of significant competitive concern. Accurate, up-to-date assessments of the predictability of the art and of the abilities of the

[277] *See* FTC REPORT ch. 4.2.

> person having ordinary skill in the art in evolving industries are important elements for achieving efficiency goals and harmonizing the patent and antitrust regimes.[278]

Differences in the predictability of the art and differences in the nature of the person having ordinary skill in the art necessarily require different levels of disclosure in different fields. An industry or technology where the art is more predictable requires greater disclosure. In an industry or technology in which the person having ordinary skill in the art is unskilled, it requires greater disclosure than when the person possesses greater ability.[279]

Disclosure and patent breadth are also affected by filing of "continuing applications". Continuation practice can allow modification of the patent after patent filing. This modification however can allow the initial innovator to include competitor's products or processes which would not have infringed the patent hence have an effect on competition.[280]

The effects of the disclosure requirement on competition usually have very little direct effect on developing countries because they are typically consumers of the innovations and not inventors. The disclosure requirement however is a useful standard for developing countries to adhere to and utilise, in that it can enable the countries engage in reverse engineering and experimentation. In an ideal situation, the disclosure requirement can provide opportunities for improvement on initial innovations and modifications to suit local conditions which are beneficial for developing countries, especially since the inventions are usually originally intended for developed country markets.



[278] *Id.*
[279] *Id.*
[280] Allowing such modifications through continuing claims is also problematic in that it could result in a waste of resources in research and development which would have otherwise been used elsewhere. Continuing patents also reduces incentive to develop substitutes since the competitors are subject to uncertainty. Ultimately the consumer is deprived of the benefits of innovation and competition through continuing claims and resulting hold ups.

### *3.4 Interpretation Claim, Patent Scope and the Doctrine of Equivalents*

The doctrine of equivalent protects a patent holder against infringement of the patent where imitators seek to make insubstantial changes to a patented invention and then proceed to patent it hence invading liability for infringement.[281] The doctrine of equivalents allows a claim to be construed to cover more than its literal language thus extending the patent breadth. According to U.S. Judge Learned Hand in *Royal Typewriter Co. v. Remington Rand Inc.*, the purpose of the doctrine of equivalents is "to temper unsparing logic and prevent an infringer from stealing the benefit of the invention."[282]

Doctrine of equivalents as claim interpretation is centred on the scope of patent rights granted and therefore has implications on the interaction between competition policy and patent rights. In the US, the Supreme Court on analysis of the doctrine has found it to result in uncertainty of patent scope. In addition to this, the doctrine has been criticised for being vague and injecting unpredictability in the patent system.[283] The uncertainty aspect occurs because competitors are unsure as to the scope of the patent, which limits the likelihood of competitors engaging in manufacturing outside the patents and investments in competing products.[284] Countries have different approaches to claim interpretation, notable differences between the US approach and the EU approaches. In the EU, the applicable legislation governing claim interpretation is the EPC Protocol on Interpretation of Article 69 of the EPC which is applicable to contracting members of the EPC. The protocol requires a balance between interpreting claims with strict literalism (with descriptions and drawings only helping to resolve ambiguities), and regarding the claims as a mere guideline only.

The application of the doctrine of equivalents in developing countries may have disastrous consequences. This is because in many developing countries lacking skilled and experienced

[281] Narrow interpretation of the doctrine of equivalents.
[282] Royal Typewriter Co. v. Remington Rand Inc., 168 F. 2d 691,692 (2d Cir. 1948).
[283] *See* Werner-Jenkinson Co. v. Hilton Davis Chemical Co., 520 U.S. 17 (1997); *see also* Festo Corp. v. Shoketsu Co., 535 U.S. 722 (2002).
[284] *See Festo*, 535 U.S at 732.

human resources in the patent offices, the patent holder is likely to exploit the doctrine of equivalent.

The importance of substantive standards of patentability and its relevance for developing countries is evident. These standards of patentability both statutory and substantive are of relevance for developing countries since they can be able to exploit these standards to their advantage. A country can use the disclosure requirement to ensure that before granting a patent, complete disclosure is carried out. The disclosed information can then be applied to enable experimentation and reverse engineering such that after the patent rights lapse, the developing country can be able to legally imitate the invention and modify it to suit local circumstances and achieve its developmental goals. The developing countries can also rely on information regarding the patented invention in event of the issuance of compulsory licences on non-working grounds where allowable under national legislation.

The interpretation of patentability standards following the example of India so as to suit developmental objectives of the country is a model to imitate. This has been illustrated by Section 3(d) of the 2005 Patent (Amendment) Act of India which has specified patentability standard to include the prohibition of patents for new forms of substances that do not result in enhancement of the known efficacy of that substance or where merely a new use for a known substance is discovered. Putting into place suchlike provisions in developing country patent legislations will prove beneficial in the long run. India having this provision in place has made remarkable advances in its generic medicines industry, ensuring fair competition and preventing anti-competitive practices of pharmaceutical patent holders through unfairly extending patent rights.

### *3.5 Licensing of Patent Rights*

The interaction between patent rights and competition law and policy can be found in patent licensing practices. The licensing of patent rights is justified in that it allows the owner of the patent rights to exploit his rights reaping maximum benefits from his invention. This is so especially where the patent owner is unable to work his invention. In the knowledge economy where tremendous advances in technology occur within short periods of time, licensing is beneficial in acquiring new technology and for developing countries it is vital because many developing countries lack sufficient finances to purchase technology therefore they need to license technology under suitable terms.

The rationale for licensing patent rights are mainly economic based since it is beneficial for inventors in that it allows for further innovation by creating an opportunity for advancing the invention in one form or another which is positive for innovation and development. Licensing for developing countries is advantageous in that the grant of a license provides the recipient of the license with the option to use a patented technology it could otherwise not use. Many developing countries rely heavily on licensing of technology from developed countries. Another advantage is that licensing of the patent allows the patent owner to increase its financial reward from investing in the patent. This fulfills the objective for granting of patent rights by allowing the owner of the invention profit from his invention without having to work the invention himself. Licensing also protects the owner of patented technology from having his patent invalidated on the grounds of non-working in a country where the patent has been granted but is not economically feasible to exploit.

The licensing of patents has pro-competitive and anti-competitive consequences. Although licenses grant the right to exploit the intellectual property, they also typically include some type of restriction on the use of the property. Intellectual property licensing agreements often contain restrictions of competition, such as exclusivity or territorial restrictions.

The pro-competitive justifications for patent licensing are identical to the rationale for licensing, namely allowing the patent owner to increase its financial reward from investing in the patent and secondly allowing the owner of the patent to choose the most efficient means for commercialization of the patent. Such exploitation increased the value of the patents and hence the incentives to invest in the development of new technologies.

Therefore competition policy regarding licensing of patent rights can influence creation of new technology since competition policy may affect profitability of an invention by increasing the potential profits which will translate to increasing investments in research and development.[285]

International technology licensing is governed by legislation and guidelines of the parties involved. The TRIPS Agreement encourages the dissemination of technology through licensing as specified under Article 7 which calls for "the promotion of technological innovation and the transfer and dissemination of technology [for the mutual benefit of both] producers and users of [the] technological knowledge."[286] Article 40 goes further to allow members to adopt measures into their national law to prevent or control abusive practices including grant back conditions, conditions preventing challenges to validity, and coercive package licensing.[287]

Developed country jurisdictions, specifically the US and EU already have in place licensing guidelines which are adhered to for transfer of technology. The US licensing guidelines with regard to the objective of intellectual property licensing provide that,

> The owner of intellectual property has to arrange for the intellectual property's combination with other necessary factors to realize its commercial value. Often, the owner finds it most efficient to contract with others for these factors, to sell the rights to the intellectual property or to

[285] COMPETITION POLICY AND INTELLECTUAL PROPERTY RIGHTS [OECD REPORT] (1989), http://www.oecd.org/dataoecd/8/44/2376247.pdf (highlighting the benefits of competition through licensing in that licensing agreements terms may permit a licensor to increase the sales of his innovation to permit him increase sales, product quality or productive efficiency. These activities correspond with the licensors efforts to increase the profitability of his exploitation of his intellectual property rights).
[286] TRIPS Agreement art.7.
[287] TRIPS Agreement art. 40.

> enter into a joint venture arrangement for its development, rather than supplying those complementary factors itself.[288]

The EU has in place the TTBER where under Article 101 of the TFEU (ex Article 81 EU Treaty), bilateral licensing agreements and technology transfer agreements are regulated.

Anti-competitive effects of licensing agreements can be observed in many agreements. The licensing agreement may be a mere sham or a disguise for anti-competitive activity. This is where the licensing agreement forecloses competition in a market where a less restrictive alternative is available. Licensing agreements may also hinder competition by containing restrictive terms as part of the agreement. These are usually scrutinized by the courts and competition agencies.

### 3.5.1 Licensing Agreements and Competition Policy Interaction

In the recent years there has been a rejection by the courts that patent licensing agreements have got antitrust immunity.[289] The legality of a licensing agreement will depend upon the competitive relationship of the relevant firms and the terms and conditions of the agreement whether restrictive and anti-competitive. Some of the restrictions that are likely to block out competition are those that deal with price, territorial, field of use, among other restrictions. These are not however always anti-competitive and must be analyzed based on the circumstances.

*a. Price Restrictions*

Price restrictions are licensing provisions that in some way set parameters on the price which the patented Article is sold. There is considerable uncertainty regarding the circumstances

[288] *See* FTC REPORT ch 2.

[289] *See* United States v. Microsoft Corp., 253 F. 3d. 34 (D.C. Cir. 2001); *see also* Atari Games Corp. v. Nintendo Inc., 897 F. 2d. 1572, 1576 (Fed. Cir. 1990) (where the court stated that a patent owner many not take the property rights granted by the patent and use these rights to extend its market power improperly such that it is beyond the limits of what congress intended to give in the patent laws. The court further stated that the fact that a patent is obtained does not insulate the patent owner absolutely from the application of antitrust laws.).

when price restrictions can be considered anti-competitive. Price fixing for the patented product itself is considered legal under the circumstances where the price is reasonably within that which the patent owner is entitled to as returns for the investment.[290] The courts have therefore determined that it is *per se* illegal to have a licensing arrangement that has the objective of fixing prices among competitors with the exploitation of patents being incidental to this purpose. This has been held to constitute horizontal price fixing.

*b. Royalty Requirements exceeding the Patent Grant Period*

In analyzing royalty payments with respect to competition and patents, the question has been raised whether the charging of different royalties to different patentees gives rise to competition issues. In practice this is not considered anti-competitive although royalty requirements may become anti-competitive when they expand the patent grant in some way. Expanding patent grant beyond the patent term results in a disincentive for licensees to opt for licensing as a way of accessing patented inventions. It may also be a disincentive for fellow inventors since there is an element of uncertainty with respect to the expanded patent grant.

In the pharmaceutical industry, expanding the patent grant beyond the patent term for purposes of acquiring royalties may have an effect on the generic industry competition which bases its operations on the expiry of patents.[291]

*c. Territorial and Field of Use Restrictions*

In patent licenses, territorial restrictions which aim or result in market division among competitors amount to a violation of competition law. Territorial restrictions may also amount to anti competition is where there are several licensees and the restrictions are seen as being requested by the licensees themselves as a way of avoiding competition. In an attempt to limit territorial restrictions, the doctrine of exhaustion comes into play since it provides that the patent right is exhausted by the first sale of the patented product.

[290] General Talking Pictures Corp. v. Western Electric Co., 304 U. S. 175, 181 (1938).
[291] *See* Brulotte v. Thys Co., 379 U. S. 29 (1964) (the Supreme Court found that a requirement to pay royalties beyond the term of a patent is *per se* illegal).

In the US, territorial restrictions in patent licenses are considered permissible under the Patent Act which permits licenses for any specified part of the US.[292] In developing countries, territorial restrictions limiting the exploitation of the patent license has an adverse effect on competition and development because of poor infrastructure and accessibility to materials needed to fully exploit a patent license.[293] Where territorial restrictions affect competition, the licensing term should be prohibited.

A field of use restriction in a patent license limits the licensee's use of the patented invention to one or more specified fields. In some developing countries, state intervention in licensing agreements takes place for the purpose of improving the commercial conditions of agreements especially with regard to the price and secondly, to eliminate restrictive practices, as well as avoid the importation of technology that is locally available.[294]

### 3.5.2 Patent Pools and Cross Licenses

The pooling of patents ranges from cross licensing of closely related patents by two patent owners to the creation of giant patent holding companies which may have many pool members assigning patents covering different technologies.

In analyzing whether patent pools may have an effect on competition, competition agencies look to the degree of complementarity of the patents to each other. While the inclusion of complimentary patents in a patent pool is seen as desirable, the assembly or inclusion of substitute patents is seen as anti-competitive and also affected is the ability of the patent owner to license its patent outside the pool.



[292] *See* 35 U.S.C. § 261 (2005).
[293] *See* Industrial Property Act, § 92 (2001) Cap. 509 (Kenya) which deals with prohibited terms in license contracts. § 92(w) prohibits imposition of restrictions on territories, quantities and prices or markets arising out of patent pools or cross licensing agreements or other inter technology transfer interchange agreements which limit access to new technological development or which would result in an abusing domination of an industry or market with adverse effects on the licensee except for those restrictions appropriate and ancillary to cooperative arrangements such as cooperative research arrangements.
[294] Rohan Kariyawasam, *Technology Transfer, in* ANDERMAN, *supra* note 154, at 480.

The entry into a patent pool and access to its patents is sometimes limited to those who are willing to agree to certain restrictions on how and where the patented invention can be practiced or on the types of products that can be made through use of the patents from the pool. Restrictions on patent pools vary widely and may for this reason impact competition through extending to directly regulate products made using the patented license and placing restrictions relating to prices, territories and end users.

Patent pools can be pro-competitive to the extent that they are an efficient way of resolving legal conflicts relating to other patents. Where firms work in similar research or manufacturing fields, they may be involved in patent conflicts. These conflicts may include mutual patent infringement claims and conflicting ownership claims in patents interferences. Since it is often difficult to predict the outcome of such conflicts, and the high costs of litigation, it is more cost efficient and profitable for firms undergoing such conflict to resort to pooling the patents in dispute giving all parties an equal opportunity to exploit the patent.

Pooling patents in this manner where all parties can exploit the patent is beneficial for developing countries with capacity to innovate and engage in research and development. It is for this reason that UNITAID the international health financing agency has approved and financed a patent pool for HIV/AIDS antiretroviral drugs to increase availability and lower prices. Having in place such a patent pool has pro-competitive advantages that should be exploited not only in pharmaceuticals but also in other technology related industries.[295] The disadvantage of patent pooling is mainly that the patent owner loses the ability to license the patent outside the patent pool without the consent of other members of the pool.

Standard based pools are a beneficial concept that can result in great technological advances if exploited successfully by developing countries. The disadvantage is that the standard based pools require unreasonably high fees which are a barrier for the developing country firms.[296]

[295] Plus News, http://www.plusnews.org/Report.aspx?ReportId=87438.
[296] *See* Barton, *supra* note 6.

### 3.5.3 Tying Arrangements and Anti-Competitive Abuse of Patent Rights in the US and EU

A "tying arrangement" constitutes a commercial arrangement in which the seller of one product conditions its sale on the buyers purchasing a second product from the seller or a particular designated third party. The courts in the US previously found tying agreements to be illegal *per se*.[297] In *International Salt Co. v. United States*,[298] a patent owner licensed a patent covering salt making machinery on the condition that the licensee purchase unpatented salt from the licensor, the Supreme Court found the agreement to be illegal.[299] The decision was reached during a period when the presumption that a patent confers market power was still upheld by the court.[300] This presumption arose out of the patent misuse concept[301] and was incorporated into antitrust in the I*nternational Salt Case*.[302]

This view has now changed with the Supreme Court holding the view that, where a tying arrangement involves a patented product, such arrangement will be scrutinized under a rule of reason analysis. In the case *Illinois Works Inc. v. Independent Ink*,[303] the Supreme Court

[297] *See* Mathew W. Siegal & Claude G. Szyfer, *Supreme Court Relaxes View of Tying Patents*, 235 N. Y. L.J. 58 (2006).
[298] International Salt Co. v. United States, 332 U. S. 392 (1947); Rita Coco, *Patent Equals Market Power Presumption in Tying Cases Overruled in the U.S., Remarks from the European Experience*, CASRIP 2, (2007) *available at* http://www.law.washington.edu/Casrip/Newsletter/Vol14/newsv14i2Coco.html (last visited Aug. 3, 2010).
[299] Daniel Rubinfeld, Remarks before the Software Publishers Association, Competition, Innovation & Antitrust Enforcement in Dynamic Network Industries (Mar. 24, 1998), www.usdoj.gov/atr/public/speeches/1611.htm.
[300] *See* Illinois Tool Works Inc. v. Independent Ink Inc., 126 U.S. 1281 (2006).
[301] *See* Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 37 S. Ct. 416, 61 L. Ed. 871 (1917) (the leading case on patent misuse); *see also* R. C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L.J. 399, 450 (2003) (for a detailed analysis of the relationship between patent misuse and antitrust).
[302] Congress in codifying patent laws for the first time separated patent misuse doctrine and antitrust jurisprudence. The presumption that patents confer market power however still existed under the patent misuse doctrine until after the *Jefferson Paris Case*, when Congress amended the Patent Code to eliminate the presumption that patents confer market power in the patent misuse context; *see* Jefferson Parish Hospital Dist. No. 2 v. Hyde, 466 U. S. 2 (1984) *available at* http://caselaw.lp.findlaw.com/cgi-bin/getcase.pl?navby=case&court=US&vol=466&invol=2.
[303] *See Illinois Tool Works*, 126 U.S. 1281, at 1284, 1285.

brought forth the principle that a patented product in a tying arrangement does not amount to market power and that the existence of market power must be proved to be a fact.[304]

The *Illinois Tool Works* case, involved the manufacturing and marketing of printing systems which included a patented ink jet print head, patented ink container and unpatented replacement ink that was specially designed for the system. A licensing agreement had been entered into with the manufacturers under which they were to purchase the unpatented original ink from the printing system sellers. A competitor in printing ink production (Independent Ink) having developed an equivalent ink alleged that the manufacturers of the printing system and the licensee were engaged in an illegal tying agreement and monopolisation in violation of Sections 1 and 2 of the Sherman Act. On deciding the case the court undertook an analysis of precedent and held inapplicable the *per se* rule in analysis of tying agreements where there exists market power thus adopting the "rule of reason" approach. The court also held that patent tying raises antitrust concerns under circumstances where the tying is undertaken by firms holding dominant position and having large market power and where the tying results from horizontal agreements between competitors.[305] The adoption of the rule of reason approach in analysing patent tying arrangements by the courts was a step in the right direction to harmonize antitrust and patent law. By reversing the *per se* presumption, the Court brought the jurisprudence of patent tying arrangements into alignment with the rest of modern antitrust and economic views. The rule of reason approach allows courts to look at the actual effects of the patent tying arrangements on the economy, consumers, and the owners of such property.[306]



[304] *See* Coco, *supra* note 298.
[305] *Id.*
[306] *See* Tiffany L. Williams, *Illinois Tool Works Inc., v. Independent Ink Inc., The Intersection of Patent Law and Antitrust Law in the Context of Patent Tying Arrangements* 58 MERCER L. REV. 1035, 1067 (2007).

In the EU patent tying arrangements are listed under Article 101 TFEU as restrictive agreements and under Article 102 TFEU as an abuse of dominant position. Article 101.1 TFEU prohibits agreements between undertakings which have the objective or effect of restricting competition an affecting interstate trade within the common market above a *de minimis* threshold.[307] Cooperative tying arrangements are thus evaluated under Article 101 while unilateral tying arrangements are evaluated under Article 102 of the TFEU.

Anti-competitive agreements are allowed under Article 101.3 TFEU where the efficiency gains of the anti-competitive agreement outweigh the anti-competitive effects and the agreement benefits the consumers.[308]

The approach in the EU law illustrates a shift from a formalistic approach to an economic oriented approach, almost similar to that of the US. The definition of tying under the EC Regulations and guidelines is that they are vertical agreements that exist when a supplier makes a sale of one product conditional upon the purchase of another distinct product. Tying arrangements according to the general provision of vertical arrangements are exempted from being in violation of competition under Article 101.1 TFEU, where the market share of the supplier is not exceeding the 30 percent threshold. Where the agreement is between competitors, then their combined market share must not exceed 20 percent. Where market share exceeds this threshold, an evaluation is undertaken according to the cost balancing tests as provided for under the Block Exemption Regulations Guidelines. With regard to tying agreements involving technology transfer, these fall within the scope of the Technology Transfer Block Exemption and are basically those instances where the licensor makes the licensing of technology conditional on the licensee taking a license for another technology or



[307] *See* Coco, *supra* note 298 (many factors are taken into consideration in determining the dominant position held by a firm which are both structural such as market share, labor access and raw materials as well as intellectual property rights, ownership and behavioral factors such as being in a position to charge monopolistic and predatory prices. A market share of 40-50 percent in conjunction with other factors may be considered sufficient to presume dominant position in the market. Over 50 percent market share may be a rebuttable presumption of dominance and over 70 percent of market share is an unrebuttable presumption of dominant position.)

[308] *See* Coco, *supra* note 298.

alternatively requiring the licensee to purchase from the licensor or one designated by the licensor. Therefore the thresholds outline a barrier above which some implications are invoked either anti-competitive or pro-competitive. Where a tying arrangement produces anti-competitive effects, these effects may be manifested through the foreclosure of competing suppliers of the tied product or may result in rising of barriers to entry in the market of the tying product and raised royalties.

Under the Guidelines, pro-competitive effects arising out of tying arrangements include efficiency gains where the tied product allows the licensee to exploit the licensed technology more efficiently.[309]

Thus in the EU there is heavy reliance on market power assessment in determining anti competition actions related to tying agreements. Implications for developing countries where they are the target for tying practices are likely to occur where the tying arrangement raises the cost of the technology, making it difficult to acquire as well as when the tying arrangement leads to a monopoly in a market separated from that covered by the patent. This can be illustrated for example, when patented genetically modified corn is tied to herbicide no longer under patent by Monsanto. The effects of such tying arrangements on food production are dire, resulting in raised seed prices making them unaffordable for developing country farmers.[310]



### 3.5.4 Refusal to Deal and Anti-Competitive Abuse of Patent Rights

It is the prerogative of the patent owner to determine whether to grant a license or not. However, this right does not extend such that it allows the patent owner to gain market monopoly as a result of a patent grant. It is generally acceptable for a third party to access the intellectual property rights also so as to compete effectively. Under ideal situations the refusal

[309] *See* Coco, *supra* note 298.
[310] *See* Barton, *supra* note 6.

to deal is a prerogative, however where an essential facility is in question, a refusal to deal may give rise to some competition issues. The unilateral refusal to voluntarily license a patent can be sufficient grounds for granting a compulsory license.[311]

On a multinational level, the Doha Declaration on Public Health and the succeeding Implementation Decision of the WTO allowing for compulsory licensing also required a Member State exploiting the compulsory licensing option to first request for a voluntary license before issuing a compulsory license. In many jurisdictions, compulsory licenses are granted based on a refusal to deal where the refusal has anti-competitive effects. For example where a refusal to deal affects an export market, resulting in goods not being supplied, or the refusal prevents the working of any other patented innovation or prevents the establishment or development of commercial or industrial activities by unfairly prejudicing them.[312]

Under the legislation relating to patents in South Africa, Section 56(2) (d) of the Patent Act of 1978 allows the granting of compulsory license in event of refusal to deal. The provision allows the compulsory license in situations where there is refusal to grant the license on reasonable terms and the refusal is prejudicial to trade and industry or the establishment of a new trade or industry in the country and lastly where it is in the public interest that a license be granted.

#### *3.5.4.1 Judicial Action against Anti-Competitive Effects of Refusal to Deal in the US and EU*

With the changing trend in the treatment of the relationship between intellectual property rights and competition, judicial bodies and government agencies have respectively changed

[311] TRIPS Agreement art. 31(b) refers to refusal of a voluntary license as a condition for granting of compulsory license. The German Patent Law (Text of December 16, 1980), as amended by the Laws of July 16 and August 6, 1996, provides that a nonexclusive authorization to commercially exploit an invention shall be granted by the Patent Court in individual cases where the applicant for the license has been unsuccessful during a reasonable period of time to obtain from the patentee consent to exploit the invention under reasonable conditions usual in trade.

[312] U.K. Patent Act, § 48(3) (d) (1977).

from constraining intellectual property rights to a more pro intellectual property attitude which has considerably strengthened intellectual property rights.[313] In the US, the assessment of refusals to deal falls within Section 2 of the Sherman Act,[314] as monopolization or an attempt to monopolize. A dominant firm's unilateral refusal to deal with a competitor will constitute *prima facie* evidence of exclusionary conduct where it appears that such unilateral refusal to deal will harm the competitive process.[315]

In the EU, refusals to deal cases are assessed under Article 102 TFEU (ex Article 82 EC Treaty) as abuse of dominant position. The refusal to deal conduct can only be punished if a finding of abuse of dominant position is determined by the court. The precondition that dominance must exist first is crucial in the sense that finding of dominance is a fundamental guarantee that the courts only impose a duty to deal on those firms which are in a position to unduly distort competition by refusing to deal with their competitors. Where the refusal to deal produces its effects in a second related market where the firm does not have dominance or a position of economic strength, EU competition legislation recognizes that anti-competitive effects can be possibly found. The ECJ has determined that

> [A]n abuse of dominant position committed on the dominated product market but the effects of which are felt in a separate market on which the undertaking concerned does not hold a dominant position may fall within Article 82 EC [Article 102 TFEU] provided that separate market is sufficiently closely connected to the first.[316]

Therefore having a dominant position in the market is crucial in determining whether a refusal to deal constitutes anti-competitive practice in the EU.



[313] Antitrust legislation in the U.S. was previously based on the presumption that large industries and consolidations were inherently anti-competitive and resulted in antitrust infringement regardless of whether they were economical or not. This view has now changed and consumer welfare and economic efficiency are the basis on which anti-competitive behavior is measured.
[314] *See* 15 U.S.C. § 2.
[315] Arezzo Emanuela, *Intellectual Property Rights at the Crossroad between Monopolization and the Abuse of Dominant Position: American and European Approaches Compared*, 25 J MARSHALL J. COMPUTER & INFO. L. (2007) *available at* http://ssrn.com/abstract=935047
[316] Case 95/04 P, British Airways v. Commission, 2007 E.C.R. I-2331.

In most developing countries, the application of compulsory licensing provisions as set out under the TRIPS Agreement may be resorted to in countering a patent owner's refusal to deal. However owing to the political reluctance to exploit compulsory licensing, many developing countries resort to utilizing those technologies where the patent rights are already exhausted or alternatively enter into costly licensing agreements with the patent owners. A refusal to deal where the patent is not worked in the country wishing to exploit the patent rights may result in the patent being nullified on the basis that it is not being worked in that particular country after which the country can freely exploit the patent rights. This option however is viewed in an anti-competitive angle as well as running counter the basic principles of nondiscrimination of patent rights. The EU requires that firms holding essential patents should license their patents under FRAND terms which mean the terms should be fair, reasonable and nondiscriminatory. The requirement to comply with this principle however is limited to within the territory of the EU.

### 3.5.5 Exhaustion of Patent Rights and Parallel Trade

Under patent law, there exists the doctrine of first sale under which once a patented product is sold, then the patent owner has no rights in it. However the patentee can impose contractual restrictions which can only be enforced against the other contracting party through breach of contract actions in a court of law. When the patent owner exploits the patent rights by granting licences with conditions, the breach of conditions by the licensee is patent infringement for which the licensee is likely held liable in court. No claim can however be enforced against any third party that acquires the patented product and relies on the exhaustion. Exhaustion doctrine is only applicable where the sale or licence of the patented invention is unconditional.

The issue of exhaustion of patent rights is controversial to the extent that even under the TRIPS Agreement exhaustion is not properly addressed.[317] Under Article 6 of TRIPS, each WTO member reserves the right to adopt its own rules regarding exhaustion of rights and parallel importation.[318] Article 28 dealing with exclusive rights a patent confers on the patent owner states that, "A patent shall confer on its owner [. . .] exclusive rights [to exploit the patent rights] by offering for sale or importing, preventing third parties from using a patented process, assign, or transfer by succession, and to conclude licensing contracts."[319]

The footnote to Article 28(1), clarifies that an explicit import exclusion right need not apply to goods originally placed in the market originating from other states.[320] There are however some arguments contradicting this interpretation, specifically the US which asserts that the import exclusion right mandated by TRIPS under Article 28(1)(a) means that patent holders have the right to block parallel trade.[321]

It follows from analysing the provisions that the drafters of TRIPS failed to reach a consensus as to the treatment of exhaustion and in addition to this they did not accept to have the issue resolved through the dispute settlement body of the WTO.

The subject of exhaustion of patent rights is important because rules on parallel importation directly impact pricing strategies of industries and affect the prices that will be charged in national and regional markets. In the pharmaceutical industry, parallel imports and rules on exhaustion are crucial in that restrictions on parallel imports permit low cost pharmaceuticals to be sold in developing countries without the pharmaceutical companies being threatened by export of these cheap drugs to high priced developed country markets.[322]



[317] Art. 6 dealing with the exhaustion principle resulted from lack of consensus during the drafting of TRIPS Agreement where the members agreed to disagree.
[318] *See* GERVAIS, *supra* note 125.
[319] TRIPS Agreement art. 28.
[320] *See* GERVAIS, *supra* note 125 at 372.
[321] 35 USC § 271(a) (2000) grants US patent holders the right to block imports infringing their patents.
[322] *See* FREDERICK ABBOTT ET AL., THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM: COMMENTARY AND MATERIALS 1819 (1999) (Abbott proposes that a general rule of international exhaustion should be put in place,

A recurring opinion with respect to developing countries interests is that a general rule of international exhaustion permitting parallel importation is beneficial to developing countries as it will not constrain export opportunities for producers in developing countries and will enhance economic growth.[323] Another opinion contrary to the general international exhaustion principle is that a general international exhaustion principle would mean that exhaustion occurs when the rights-holder puts his product on the market anywhere in the world but this would nevertheless not increase availability of essential products in developing countries.[324] The logic behind this assertion is that under international exhaustion, if low priced medicines are available in developing countries they are likely to be exported to developed countries where a higher price can be obtained. This would pre-empt developing countries of their needs and render the provisions for ensuring access to medicines for developing countries fruitless. Therefore differential pricing and the isolation of developed country markets from developing country markets is deemed necessary.

Restraints on parallel trade are justifiable for purposes of encouraging innovation. A justifiable restraint on parallel trade is the restraint from re importation of pharmaceutical products produced under compulsory licence as allowed by Article 31*bis* of TRIPS. This is because allowing re importation of these cheap medicines will result in loss of revenue for pharmaceutical companies and therefore be a disincentive for investing in research and development of needed medicines for developing countries. However circumstances may arise where firms attempt to restrain parallel trade and cause anti-competitive effects. The case of Astra Zeneca in the EU highlights this point where the European Commission determined that there was a negative effect on competition resulting from the blocking of generic drugs and parallel imports by Astra Zeneca. This was through Astra Zeneca providing



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however in the case of pharmaceutical companies to ensure their continued supply of low priced essential medicines to developing countries an exception to this rule should be made).

[323] *Id* at 1780.

[324] *Id.*

misleading information in its patent application for extra protection in an application for supplementary protection certificates for its *Losec* product.[325]

### *3.5.5.1 Parallel Trade in the EU and US*

Under EU law, once a product has been lawfully put in the market anywhere in the European Community, then the product is subject to free circulation with any national intellectual property rights being extinguished. The case law has established that national rights in intellectual property cannot be used to discriminate or restrict trade in the single market. In *Centrafarm v. Sterling Drug Inc.,*[326] the European Court held the exercise of a national intellectual property to be incompatible with the provisions of European Economic Community Treaty dealing with free movement of goods within the common market once the patent holder's product has been marketed in another Member State by the patent holder, with or without his consent. The European Community has a system of regional exhaustion of intellectual property rights. This principle of regional exhaustion has been consistently confined to internal application by the ECJ (in trademark cases) when the question of international exhaustion arose.[327]

Under European Community law, an original manufacturer can charge a different price in the EU and another price in a developing country. The only condition imposed is that the



[325] Case COMP/A.37.507/F3-Astrazeneca, O.J. (L 332). In 1999, Generics (UK) Limited and Scandinavian Pharmaceuticals instituted proceedings against AstraZeneca for abuse of dominant position. The EC concluded that AstraZeneca had abused its dominant position within the meaning of Article 82 EC by making misleading representations to national patent offices in order to obtain supplementary patent protection certificates. AstraZeneca also switched the formulation of the Losec drug from capsules to tablets for the express reason of hindering generic trade and parallel trade. The impact on parallel trade was that parallel trade was restricted. In Denmark, parallel trade in capsules was completely eliminated while in Sweden, the parallel trade licenses for omeprazole capsules were revoked. In Norway, parallel imports dropped sharply.

[326] Case 15-74, Centrafarm v. Sterling Drug Inc., 1974 E.C.R. I-1147.

[327] Case C-355/96, Silhouette International Schmied GmbH v. Hartlauer Handelsgesellschaft GmbH, 1998 E.C.R. I-4799, I-4818, (which held that Member States are precluded from adopting the principle of international exhaustion).

producer must be guaranteed that there will be no re-importation of the low priced drugs into the high priced region.

The EU option for regional exhaustion allows a patent holder to prevent importation of patented products that have first been put in a developing country market, thus allowing pharmaceutical companies to price differentiate. This option of regional exhaustion is reinforced by Council Regulation 935/2003 which is intended to restrict the flow of parallel imports of certain key medicines into the EU.[328] Under Article 11 of Regulation 953/2003, volumes of exports from Europe are continuously monitored where they are tiered priced products.

In the EU like other regions, restraints on parallel trade as has been stated previously may give rise to some anti-competitive effects, as illustrated in the *Astra Zeneca Case.*

Under US legislation, a patentee has a right "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States."[329] In the US, "the first sale doctrine" corresponds to the exhaustion rule. The first sale doctrine is a creature of the judiciary and is not incorporated in legislation.[330]

There is uncertainty as to whether US applies an international or national exhaustion principle. The Second Circuit has held that a US patent holder could not impede the importation of airplanes produced in Canada by the assignee of Canadian patent rights, thus upholding the international exhaustion principle.[331] This view however was somewhat rejected by the Federal Circuit in *Jazz Photo Corp. v. International Trade Commission*,[332] where the court clarified that exhaustion applies to goods first sold in the US only. Goods sold outside the US are still subject to the patent holder's right to exclude as illustrated in the



[328] Council Regulation 953/2003 to Avoid Trade Diversion into the European Union of Certain Key Medicines, 2003 O.J. (L135) 5.
[329] 35 U.S.C. § 154 (2000).
[330] *See* United States v. Univis Lens Co., 316 U.S. 241 (1942).
[331] *See* Adams v. Burke, 84 U.S. 17 Wall 453 (1873) (where the Court held that a purchaser of a patented item takes possession of the item without any territorial limits of the patent monopoly).
[332] Jazz Photo Corp. v. International Trade Commission, 264 F. 3d. 1094 (Fed. Cir. 2001).

courts decision in stating that, **"**United States patent rights are not exhausted by products of foreign provenance. To invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent."[333]

#### *3.5.5.2 Parallel Trade in Developing Countries*

In India, Kenya and South Africa, legislation governing intellectual property rights provides for parallel importation. In India, the Patent (Amendment) Act of 2005 provides for parallel imports under Section 107A(b) which provides that the importation of patented products by a person duly authorised under the law to produce and sell the patented product is not deemed as infringement of the patent rights.[334] The provision allowing for parallel imports has been found to conflict with the provision granting the patentee exclusive rights to import the patented product for which a patent is in force in India. The question arises whether the parallel importation provision under Section 107A in essence means that a generic version of a drug manufactured abroad can only be imported into India with the authorisation of the patentee. The provision also conflicts with the mandate granted to the Controller not to authorise a licensee to import a patented product or Article made by a patented process from abroad where such a product or process will constitute an infringement of the rights of the patentee.

### 3.5.6 General Analysis of Patent Licensing in Developing Countries

Patent licences in developing countries are necessary for the transfer of technology. In developing countries it facilitates movement of new technologies from the research phase to the commercialisation phase for the benefit of small or medium sized enterprises lacking the

[333] *See Jazz Photo Corp.*, at 1105
[334] *See* Verma, *supra* note 237, at 365.

capacity to manufacture but having carried out the research can license out their product or process for commercialisation.

Patent licences are also a means to negotiate patent thickets and overcome obstacles to incremental innovation especially for standard setting innovations where there is need to share patented technologies so as to maintain competitive markets. Although developing countries rarely participate as members of standard setting organisations, there is a slow change with developing countries such as India making their mark in the information technology industry both with regard to hardware and software development.

Patent licensing in developing countries plays a role in facilitating joint research and development thus accelerating technology development and spreading risk, especially where the country stands to gain assistance with regard to facilities and human resources for research. This is well illustrated the situation where Oxford University (UK) and the University of Nairobi (Kenya), entered into joint research in the continuing AIDS vaccine drug research.

Developing countries address anti-competitive patent licensing through regulation and court decisions. An illustration of this is the South African case against pharmaceutical companies, where proceedings were instituted against pharmaceutical companies for violating the Competition Act of South Africa. Following this case pharmaceutical companies issued voluntary licences to companies in South Africa and India as well as Brazil allowing them to produce patented drugs.

However the solution of issuing voluntary licenses does not eliminate the anti-competitive practices that may result from patent protection in developing countries, as illustrated by the complaint against Gilead by the Knowledge Ecology International (KEI) in 2007, where KEI wrote a complaint to the FTC regarding the anti-competitive practices of Gilead. Gilead signed voluntary non-exclusive licences with companies in South Africa and notably eleven

generic manufacturers in India for the production and sale of HIV/AIDS drug, 'Tenofovir disoproxil fumarate' as well as product patents on Emtricitabine, and combinations of the two. The terms of these licences were generally standard with royalty payments of 5%, meeting quality standards of the WHO and USFDA and grant-back licenses on improvements, modifications and derivatives. However, there were certain anti-competitive conditions of the license including a requirement of royalty payment where Gilead does not hold a patent, prohibition of supply of active pharmaceutical ingredients (APIs) to firms or markets not approved by Gilead and lastly, that licensed sellers were required to purchase the APIs from Gilead affiliated licensed suppliers. The KEI request to the FTC included suggested measures the FTC could take to stop the anti-competitive practices by Gilead. These included offering of separate patents for products and know how. The separate patents are relevant since know how and API licenses are bundled as one which is somewhat restrictive for a country with immense reverse engineering capabilities. This is because they are forced to incur extra costs for knowhow licenses they do not need. However where a country lacks reverse engineering capabilities, they can be able to acquire both know how and product. A second solution would involve removing obligations to pay royalties even where no patent is held by the company and allowing for the freedom to purchase from all suppliers who comply with the recommended quality standards. A third suggestion was that Gilead remove restrictions on sale in the concentrated API market since the cost of the API may account for a large percentage of the total cost of production which could raise the prices of the finished product. The final suggestion was that the FTC look into possible options of exerting pressure on Gilead by the government since all patents in question are government funded and subject to the Bayh Dole Act. Following the formal complaints Gilead announced that it had made amendments in relation to its licensing agreement with the generic manufacturer Ranbaxy. The license which deals with Tenofovir has been amended to delete

the specific clause that could be interpreted as preventing the licensee (here the generic manufacturer Ranbaxy) in mounting an opposition to Gilead's Tenofovir patents.[335]

Regulation of anti-competitive practices related to patent rights in developing countries is generally incorporated in legislation such as the competition statutes, intellectual property statutes and price control as well as anti-counterfeit statutes. Other regulations of a more comprehensive nature such as the EU Guidelines on competition and US Guidelines on Licensing may exist although not as detailed as those of the US and EU. The result is that developing countries are dependent on piecemeal legislations which consequently means that licensing of patent rights are not exploited as they should be due to weak regulations and guidelines.

It is evident that like industrialized countries, the developing countries strive to protect and enforce patent rights but as a result of weak regulation of licensing practices and lack of capacity in both human resources and infrastructure, legally granted patent rights can be exploited in a manner prejudicial to competition and to the detriment of the consumer.

***Summary***

Interaction between patent rights and competition policy is likely to be found in the interpretation and determination of substantive and procedural standards of patentability and in licensing agreement terms and conditions. It is in the patentability standards of obviousness and disclosure that the interaction is likely to be seen. Obviousness standard of patentability ensures that the invention represents a measurable technological advancement beyond what has already been done. An insignificant advancement if patented prohibits follow on innovation. Trivial patents as illustrated may if issued broaden the scope of patent protection therefore discouraging innovation from the competitors for fear of infringing the patents.

[335] *See* http://spicyipindia.blogspot.com/2008/07/kei-cracking-open-anti-competitive.html (last visited Aug. 3, 2010).

Disclosure also defines patent breadth and scope of the patent. Where patent breadth tends to be broadly defined, the products free to compete with the patent will infringe the patent. Where defined too narrowly, it may result in numerous patents ultimately resulting in the problem of patent thickets.

The interpretation of the claim in event of uncertainty also has an effect on the scope of the patent. The doctrine of equivalents under the US courts has been held to result in uncertainty of patent scope. Licensing provides a means to access technologies and products for developing countries as supported by the TRIPS provisions under Articles 7 and 40, which call for promotion of technological development, transfer and dissemination of technology for the mutual benefit of both developed and developing countries. The US with its licensing guidelines and the EU with its TTBER provide a comprehensive framework under which technology transfer through licensing can take place. These guidelines are applicable in correcting patent licensing abuses that have anti-competitive effects and ultimately have implications on technological access for developing countries.

Exhaustion of rights and parallel trade are important issues for developing countries because the doctrine of exhaustion adopted determines whether parallel importation is permissible or not. Developing countries benefit from parallel importation which may sometimes present a threat to developed countries due to fear of cheap products destined for developing countries, specifically pharmaceuticals being re imported into their countries. The decision as to whether a country should adopt regional, national or international exhaustion rests with how the particular country chooses to interpret article 6 of the TRIPS Agreement, under which every country is left to determine its own rules regarding exhaustion of rights.

Developing countries apply a mix, in sub Saharan Africa, some countries have no indication of preference, while some 16 member countries of OAPI apply the regional exhaustion regime and other countries specify in their legislation an international exhaustion regime,

where a patent owner may not exercise his rights once they have been put in the market anywhere else in the world. The international exhaustion regime allows for comparison shopping among the markets where the patent owner sells to different markets at different prices. However the US applies this doctrine as "national exhaustion" meaning that the patent owner can no longer exercise control of the product once placed in the US market but can exercise his patent rights with regard to products placed outside of the US.

In the EU, countries apply a "regional exhaustion," regime, which essentially means patent rights are exhausted only where products are placed on the market in EU countries but retained outside the EU.

With regard to pharmaceutical patents which are a hindrance to accessing medicines in the developing countries, the maintenance of patent rights outside the regions such as the US and the EU have contributed to the high prices of medicines needed to combat diseases such as HIV/AIDS, malaria and tuberculosis. The patent rights being national or territorial in scope means that such governments may apply their own regimes. Secondly, the higher costs result from the threat of products being shipped from lower priced countries to higher priced countries, as this has reduced the enthusiasm of rights holders to supply the needed medicines at low cost.

Patent licensing provisions in developing countries are governed by national legislation and guidelines. Although not as elaborate as those of the EU and US, they are primarily geared towards facilitating access to technologies from industrialized countries. There are some situations where patent licensing terms have had anti-competitive effects in developing countries with serious implications on health and socio-economic development. This is illustrated by the Gilead case in South Africa where the licensing agreement contained anti-competitive terms which had implications on the cost of the HIV/AIDS drugs and ultimately the consumer.

# 4 PHARMACEUTICAL PATENTS AND COMPETITION POLICY IN DEVELOPING COUNTRIES

## *4.1 Introduction*

In addition to having in place intellectual property rights, developing countries also need effective competition laws and policies so as to enable proper enforcement and acquisition of patent rights without detrimental effects on local industries which will enable the countries achieve their developmental goals. To do so, developing countries may opt to adopt a modified version of a competition regime already in place in a developed country or region such as the EU. Alternatively, developing countries may put into place custom made regulatory systems based on the basic principles governing intellectual property and competition policy. The solution varies depending on the goals and political will of the individual countries. The interaction between patent rights and competition policy in developing countries has implications in the fields of pharmaceutical patents, plant patents, biotechnology patents, technology transfer and traditional knowledge.

The pharmaceutical industry is characterized by its dependence on intellectual property rights, especially patents. The last thirty years of drug discovery have produced numerous important pharmaceutical treatments that have saved lives and increased the quality of life for millions of people in both developed and developing countries. Patent protection in the pharmaceutical industry is indispensable in promoting innovation. The US FTC in its report on the role of pharmaceuticals in promoting innovation emphasises that pharmaceutical patents promote innovation by creating incentives for brand name companies to innovate and through disclosure encourages the generic companies to innovate.[336] Patenting standards, notably the inventive step or the non-obviousness criteria have been lowered over the last 10-20 years,

[336] *See* FTC REPORT ch. 3.2.

making it easier to obtain patents, with more inventions being patentable, ranging from living organisms to software programs.[337]

Patents are an important factor in motivating firms to invest in research and development in only a handful of industries, such as the chemical and pharmaceutical industries. The industry is characterised by a long time frame for development of its products, major investments, involvement of the State in pricing issues and competition from rivals which is likely to raise difficulties with competition law.[338]

The minimum mandatory period for patent protection is 20 years as from the date of filing as stated under the TRIPS Agreement.[339] Pharmaceutical patents receive some special treatment which allows for protection to extend beyond the minimum 20years required by TRIPS. The argument for this special treatment results from the fact that in pharmaceutical patents the effective period of protection is shortened due to developmental delays. The developmental delays result from mandatory clinical trials and time consuming filing and granting of marketing approvals necessary before pharmaceutical companies can begin recouping their investments.[340] It has been suggested that it can "take twelve to fifteen years or more, from the first research steps through to the proven pharmaceutical product on the market".[341] The extension of patent protection for pharmaceuticals thus does not so much ask for more favourable treatment than that enjoyed by other patent holders rather it seeks to restore the



[337] *See* Sandra Schmeider, *Scope of Biotechnology Inventions in the United States and Europe-Compulsory licensing, Experimental Use and Arbitration: A Study of Patentability of DNA Related Inventions with Special Emphasis on the Establishment of an Arbitration Based Compulsory Licensing System*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 163 (2004); *Diamond v. Chakrabarty* 477 U.S. 303 (1980).

[338] The pharmaceutical research and development process is long, risky, and expensive. It typically takes from ten to fifteen years from drug discovery to approval by the Food and Drug Administration (FDA). Of every five thousand medicines tested, only one ultimately receives FDA approval. The average cost of developing a new drug has been estimated at $802 million. Only three out of every ten marketed drugs generate revenues that match or exceed average research and development costs.

[339] TRIPS Agreement art. 33.

[340] *See* Steven Ang, *Patent Term Extensions in Singapore for Pharmaceutical Products*, 27 EUR. INTELL. PROP. REV. 349 (2005).

[341] MICHAEL JACKSON, IPR AND THE PHARMACEUTICAL INDUSTRY: HOPES BASED ON HOPES, IN INNOVATION AND THE INTELLECTUAL PROPERTY SYSTEM 66 (Andrew Webster et al. eds., 1996); *see also* Robin Whaite & Nigel Jones, *Pharmaceutical Patent Term Restoration -the European Commission's Proposed Regulation*, 5 EUR. INTELL. PROP. RTS. 179 (1990).

protection of pharmaceutical patents to the level enjoyed by other patent holders. The restoration of such patent period protection can be evidenced in various jurisdictions. In the US, the Hatch-Waxman Act of 1984 through offering extensions for certain drugs and medical devices so as to make up for the time lost as a result of federal regulatory review requirements. In the EU, this extension is given through the passing of Regulation 1768/92[342] which introduced Supplementary Protection Certificates (SPC) covering medicines for all its member states. In 1996 such Supplementary Protection Certificates were mandated for plant protection products by Regulation 1610/96.[343] These SPC extend the right of the patent with the term of extension being linked to the date on which the product received marketing authorisation in Europe.

In developing countries such as Kenya, extensive regulatory testing is carried out only on some specific drugs due to lack of capacity to undertake such extensive regulatory testing prior to marketing approval. As a result, there is a blind acceptance that drugs approved for marketing in developed countries are safe and therefore patents can be issued.[344] In Kenya as well as other developing countries and least developed countries, that lack comprehensive drug testing regulations comparable to those of the US and EU, there is assistance from the WHO which assumes the role of a quality and standard assurance organisation, for the welfare of the consumers in developing countries.



[342] Council Regulation 1768/92 Concerning the Creation of a Supplementary Protection Certificates for Medicinal Products, 1992 O.J. (L 182)1. This was extended to agro chemicals by Regulation 1610/96 Concerning the Creation of a Supplementary Protection Certificate for Plant Protection Production, 1996 O.J. (L 198) 30.

[343] Council Regulation 1610/96 O.J. (L 198) 30.

[344] Robert Lewis- Lettington & Peter Munyi, *Willingness and Ability to use TRIPS Flexibility: A Kenya Case Study*, DFID Health Systems Resource Centre (2004), http://www.dfidhealthrc.org/publications/atm/Lettington2.pdf.

### *4.2 Impact of Generic Medicines on Competition in the Pharmaceutical Industry*

Generics are medicines produced and distributed without patent protection.[345] For generic medicines to be available, the brand name or originator drug patent must have expired thus bringing the information regarding the patented drug into the public domain and available for exploitation by generic manufacturers. The emergence of generic medicines into the market usually has an effect on increasing competition and therefore lowering prices of drugs. Generic medicines are available at lower prices since the manufacturers incur lower production cost. The generic manufacturers do not incur the high costs of drug discovery, nor do they incur the high costs of proving efficacy and safety through time consuming State regulated clinical trials. The generic manufacturer may only need to prove that they manufacture bioequivalent drugs to the brand name drugs so as to get regulatory approval.

The fact that the generic drugs are known in the market already as they have been there during the duration of the patent means that they are well known to both the retailers and sellers hence the need for marketing the drug is eliminated, this translates to lower production costs and lower prices for the consumer.

Before the expiration of the patent, the brand name company has an exclusive market in which they are able to set drug prices at levels which enable them to receive maximum profits. These prices are excessive and usually exceed the production costs of the drug so that the brand name company can recover the production costs as well as their investment in research and development. Competition resulting from generic pharmaceutical manufacturers is therefore beneficial to the consumer since it acts as a check on the price to ensure the brand name companies do not continue reaping excessive profits due to high prices. In regions such



[345] Generics must contain the same active ingredients as the original formulation according to the US FDA.

as the EU, there is strong effort to encourage physicians to prescribe generic medicines as first line therapies due to the economic value of generics.[346].

With regard to pricing, the US does not regulate drug prices unlike the EU where drug prices are regulated by the Member States.

Generic medicines in developing countries play the role of extending access to affordable quality, safe and effective medicines. Common chronic diseases such as colds, coughs are usually treated with generic medicines that are affordable. Under programs for production of generics, the State is able to save money on public health spending. This allows the State to allocate more funds for research and development of pharmaceutical products thus fostering innovation. Generic medicines encourage development of medicines with newer formulations and methods of delivery, which provide incremental innovation for patients.

The market for generic medicines in developing countries is highly competitive, with countries like India, Malaysia and Brazil leading in generic medicine production. The competition is intensified through dependency on generic medicines for the treatment of HIV/AIDS in developing countries.

### 4.2.1 Generic Pharmaceutical Industry and Medicines in the EU

Pharmaceutical companies in the EU are rated the third largest in the world, after US and Japan. The UK according to the House of Commons Health Committee in 2004 sells 7 percent of the world's pharmaceuticals and accounts for 10 percent of world pharmaceutical research and development expenditure.[347] European generic pharmaceutical companies are now expanding into new areas of pharmaceutical development, such as new formulations and

[346] Elke Grooten, Challenges and Opportunities for Generic Medicines Companies, 20th Annual Euro Meeting Barcelona, Spain (2008), http://www.egagenerics.com/doc/EGA_DIA_08_ElkeGrooten_FutureGenerics.pdf (last visited Aug. 3, 2010).

[347] HEALTH COMMITTEE, THE INFLUENCE OF THE PHARMACEUTICAL INDUSTRY, 2004-5, H. C. 42-I *available at* http://www.parliament.the-stationery-office.co.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf (last visited Mar. 30, 2010).

bio similar medicines and are moving into new and fast growing pharmaceutical markets such as China, Russia and the Middle East.

Accordingly, the generic pharmaceutical industry has been increasing in strength and is in a strong competitive position having 50 percent of the market in volume with the potential to rise up to 70 percent in the European market.[348]

There has been recognition of the advantages of generic drugs among the policy makers, players and patients in the EU, especially following the accession of the new member countries. In addition to this, generic medicines are now regarded as being a key to sustainable, affordable and quality healthcare. However, according to the Drug Information Association, there are shortcomings of the generic medicine industry that have been identified. Among these shortcomings is the view that the industry has no influence in the structure and application of patent law in the EU. In addition to this the countries of the EU all have different generic medicines policies. This lack of a single market environment for generic companies in the European market is disadvantageous for European generic pharmaceutical companies.

There has been increasing intellectual property protection for pharmaceuticals in Europe although despite the increased protection a decline in the rate of innovation has been experienced. This increase in intellectual property protection is evidenced by the 1992 regulation which aimed at restoring the patent term for pharmaceutical products by allowing the extension of rights by a single patent for certain pharmaceutical by 5 years through Supplementary Protection Certificates (SPC). This amounted to extending the patent term post patent expiry thus granting up to 25 years in patent life for pharmaceuticals. The objective of extending the patent term was to encourage investment in research and development through restoring the patent term where patent life is eroded in the lengthy procedures undertaken in conducting safety and efficacy trials on new medicines. Because

[348] *See* Grooten, *supra* note 346.

patents are usually applied for at the beginning of the life of a potential new product, the pharmaceutical products patents 20 years exclusivity was being reduced by the period required to obtain regulatory approval from the State. By 2007, over 8500 patent extensions were granted through Supplementary Protection Certificates regulation

Other indications of increased patent protection in Europe are seen in the period 1992 to 1994 during which product patents for pharmaceuticals in central and eastern European countries as well as south Europe countries were introduced. In 1994 the TRIPS Agreement with minimum standards for patenting was introduced and in 2004 data exclusivity increased from 8 to 11 years.[349]

Data exclusivity in addition to the issuing of SPC serve to extend the patent protection period for originator drug manufacturers who have invested time and finances in rigorous testing aimed at efficacy establishment before the drugs can be placed into the market. Data exclusivity means that marketing authorisation authorities are barred from processing an application for the marketing of generic drugs only after a certain number of years. The current legislation provides for 8 years to have passed from the date of authorisation of that drug.

The EU data exclusivity regime is governed by Directives 2001/83 which was amended by Directive 2004/27 although they are both applicable with the 2004 Directive being applicable to marketing authorisation submitted on or after October 30, 2005. Market exclusivity has also been introduced in addition to data exclusivity to prevent the marketing of the generic drug during 2 years following the expiry of the data exclusivity period. In the case of a new therapeutic indication considered to be of significant clinical benefit, the originator drug manufacturer is likely to obtain a one year extension in addition to the 2 year marketing



[349] Council Regulation 469/2009, Creation Of Supplementary Protection Certificates For Medicinal Products(codified version), 2009 O. J. (L 152) 1 (a codified version after the original Regulation 1768/92, 1992 O.J. (L 182) (EEC) underwent several amendments)

exclusivity.[350] In Europe on price linkage between reference product and generic alternatives, when a medicine is off patent, the price of its equivalent generic medicines should be set independent from the off patent reference product and from other genetic formulations. Price linking is considered anti-competitive as it enables brand name companies to force generic medicine competitors off the market by lowering prices to the point where generic medicines can no longer afford to enter into or stay on the market.

The presence of generic pharmaceutical companies in the market therefore serves to stimulate innovation through competition. Savings from the use of competitive generic equivalents can also be used to finance new innovative products.[351]

### 4.2.2 Generic Pharmaceutical Industry and Medicines in the US

Pharmaceutical generics in the US are mainly protected by the Patent Term and Restoration Act of 1984 also known as Hatch-Waxman Act of 1984. The Hatch-Waxman Act is particularly important because it provides incentives for innovation by research based companies including both public sector and private sector based research companies. More importantly the Hatch-Waxman Act allows for market entry by generic manufacturing companies.

There has been resistance to generic medicines in the US mainly due to the high costs of developing and marketing of pioneer drugs by the pharmaceutical research companies. Despite the conception that the industry receives massive profits, it is clear that the cost of developing drugs is extremely high and the shortened patent cover does not allow for recouping of investments. On the other hand, generic drug manufacturers do not incur high



[350] Paul Garlan & H, Kristjan Larusson, *Data Exclusivity, Bolar Exemption and Generic Drugs in the EU*, 29 EUR. INTELL. PROP. REV. 128 (2007).

[351] In the last 20 years with regard to major innovative breakthroughs, very few new drugs have been developed; most new drugs have actually been variants of already existing drugs.

research and development costs and are able to enter the market at dramatically reduced prices as they take advantage of prior marketing done for the patented pioneer drug.

The Hatch-Waxman Act protects the intellectual property rights of the pioneer drugs that have been patented by establishing a set of procedures to promote the resolution of patent infringement claims prior to the market entry of potentially infringing products. This protects innovators from unrecoverable losses and also generic drug manufacturing companies are shielded from overwhelming liability. The Hatch-Waxman Act provides these procedures which allow innovators instituting a patent claim learn in a timely manner whether the product they wish to market is claimed by an existing patent thus preventing the infringing of potential products. Due to the lengthy drug development and approval process of drugs, pioneer drugs receive far less patent life than innovators in other industries. The solution to this is patent restoration, thus the Hatch Waxman Act was enacted.

With regard to the question of how patent protection in the pharmaceutical industry has impacted investment in research and development, the FTC has determined that an increase in the protection of intellectual property rights corresponds to an increased investment in research and development.[352]

A comparative analysis of treatment and protection of generic medicines in the US and EU shows that the US generic medicines comprise of 63 percent of the pharmaceutical market volume as compared to 43 percent in the EU. In the US patent extensions are allowed for a maximum period of 14 years unlike the EU which allows for patent extensions e.g. through the supplementary protection certificates for a period limited to 5 years.

Both the EU and the US have bolar exemptions which allow for the performing of generic research and development before expiration of the patent. In the EU however there is no immediate generic competition due to the fact that there are many pricing and reimbursement procedures to be followed in different Member States. The US does not have any fees for

[352] *See* www.ftc.gov/os/comments/intelpropertycomments/phrma020422.pdf (last visited 12th July 2009)

generic drug registration which is advantageous and an incentive for generic companies while in the EU high fees for generic registration must be paid which range from €80,000 to 120,000.

### 4.2.3 Generic Pharmaceutical Industry and Medicines in Developing Countries

#### *4.2.3.1 Analysis of Generic Medicines in Kenya*

In developing countries, intellectual property legislation based on the provisions of the TRIPS Agreement generally governs generic medicines and pharmaceutical patents. In Kenya the adoption of the Industrial Property Act of 2001 paved the way for access to generic medicines under its provisions for parallel importation[353] and Government use.[354] The generic medicines debate in Kenya has been merged in controversy and attempts at amending the Industrial Property Act following lobbying from the pharmaceutical industry. In 2007 the Kenyan Parliament rejected a proposed amendment to the Industrial Property Act which would have deleted Section 80 allowing for compulsory licensing. The rejection of this proposed amendment meant that the government of Kenya was able to retain the right to issue compulsory licenses that authorise the importation, manufacture and supply of generic copies of patented products. The attempted changes were clearly TRIPS plus and the campaign for these changes backed by pharmaceutical companies sought to prevent generic medicines from flooding the Kenyan market. The protest against generic medicines in Kenya has somewhat achieved its intended goal with generic medicines now being limited by the Anti-Counterfeit Bill of 2008, which was adopted to prevent counterfeit goods from flooding the Kenyan market. The Anti-Counterfeit legislation blocks most generics through defining counterfeit goods in such a way that generic medicines amount to counterfeit goods. The law allows

[353] Industrial Property Act § 58(2).
[354] Industrial Property Act § 80.

pharmaceutical companies to charge patent infringement in Kenya even if the patent allegedly infringed is not registered in Kenya. The failure to distinguish medicines which are essential goods from other non-essential goods in the Act has had the effect of not only limiting access to essential drugs and affecting the right to health but has also seriously eroded those gains made by the Industrial Property Act of 2001 in procuring and protecting pharmaceutical patents while ensuring access to essential drugs for the treatment of HIV/AIDS, Tuberculosis and Malaria. The Anti-Counterfeit Bill of 2008, has a negative impact on competition in two ways in that first, it provides more avenues for the pharmaceutical companies to curb competition from smaller competitors since they have the resources to institute infringement proceedings even where their patents are not registered and in so doing removing opportunities for licensing and ultimately limiting transfer of technology.[355]

#### *4.2.3.2 Analysis of Generic Medicines in India*

India having one of the largest generics industry in the world supplies majority of developing countries with cheap medicines as provided for under Article 31*bis* of TRIPS Agreement which allows compulsory licensing of drugs for export to countries having no or insufficient manufacturing capacity. India implemented the TRIPS Agreement through amending its patent legislation. The Patent Amendment Act of 2005 provides incentives and encourages research and development in the domestic pharmaceutical industry. The generics manufacturers were granted protection through the innovative provision of Section 3(d) of the Act as well as the amended compulsory licensing provisions which allow compulsory licensing on various grounds ranging from non-working to where a refusal to license is prejudicial to the economic interests of India or does not serve the public policies adequately. With the pharmaceutical industry being composed of a mixture of multinational corporations

[355] *See* Effect of the Anti-Counterfeit Bill (2008) *available at* http://www.haiafrica.org/downloads/anti_counterfeit_bill_factsheet.pdf (last visited 6 August 2009).

and domestic owned corporations, the legislation governing pharmaceutical patents is also aimed at promoting research and development and innovation in the industry to ensure that the domestic owned manufacturing companies have a fair and competitive playing field to compete on.

### *4.3 Pharmaceutical Patents in Developing Countries: Compulsory Licensing after Doha Declaration*

Prior to the TRIPS Agreement, many developing countries did not offer patent protection for pharmaceutical products and agricultural chemicals for the simple reason that they needed to be accessible to ensure adequate access to medicines and sufficient food production. Therefore prior to TRIPS Agreement coming into force there is limited information on competition practices relating to pharmaceutical patents. Presently, there are in place competition provisions relevant to pharmaceutical patents which include and are not limited to pricing issues, compulsory licensing, trademark infringements and unfair competition through imitation. Developing countries such as India which is a large producer of generic drugs experience the anti-competitive effects of patent rights. These anti-competitive practices usually occur in practice where voluntary licences are issued and there are some restrictive terms within the licensing agreement. The pharmaceutical companies are able to employ practices which are anti-competitive through a legal framework. The TRIPS Agreement allows contracting members to resort to compulsory licenses in an effort to correct anti-competitive patent practices.

The December 31, 2002 deadline of the Doha Declaration to address the difficulties that WTO Members with insufficient or no manufacturing capacities could face passed without the Contracting Parties reaching an agreement. The WTO on August 30$^{th}$ 2003 decided to implement paragraph 6 of Doha Declaration which had an effect of resulting in a waiver of

Article 31(f) requirement restricting compulsory licences to use in domestic markets only. This decision was a solution for countries lacking manufacturing capacity.[356] The decision in essence allows any Member Country export medicines produced under compulsory license on condition that certain requirements are met by the eligible Member Country.

On the face of the Implementation Decision, it seems as if the humanitarian objectives that were defined in the Doha Declaration are being achieved. Upon further analysis, it becomes apparent that the developing countries lacking manufacturing capacity have to go through a lot of red tape to purchase drugs from those countries with manufacturing capacity, which goes against the main goal of the Doha Declaration to provide easy, affordable access to pharmaceuticals for developing and least developed countries.

Under the Implementation Decision, the countries seeking to procure drugs under compulsory licence must undergo a series of steps.[357] The first step involves the seeking of a voluntary license on reasonable terms by the country where the drug is patented but the country seeks to import the drug through compulsory licence. If unsuccessful in obtaining a voluntary license, the eligible country has to make an application to the WTO for a compulsory license.[358] The third condition requires that where the compulsory license is to produce drugs for importation into a developing or least developed country lacking manufacturing capacity, then the importing country must assess its generic industry and determine if it is able to produce the medicine locally. For the developing and least developed countries, this is usually not possible hence the need to import the medicines. The fourth step involves notifying the WTO of its decision regarding its insufficient capacity to produce the medicine locally. The fifth step involves identifying and notifying a potential exporter. Once an exporter is identified, the



[356] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Aug. 30, 2003), *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (last visited Aug. 3, 2010).

[357] Importing countries that have no manufacturing capacity would have to go through more steps than those countries with the ability to produce the drug in question generically.

[358] *See* GERVAIS, *supra* note 125, at 54,58; *see also* Brook Baker, *Vows of Poverty, Shrunken Markets, Burdensome Manufacturing and Other Nonsense at the WTO*. (Sept. 27, 2003) http://www.healthgap.org/press_releases/03/092703_HGAP_BP_WTO_Cancun.html (last visited Aug. 3, 2010).

exporter must seek a voluntary license on reasonable terms for a reasonable period of time before engaging in compulsory license production. Following refusal, the exporter must seek a compulsory license from its government and a royalty set based on reasonable and fair standards. If a compulsory license is granted by the exporter's government, the exporter manufacturing company must then undertake to comply with requirements relating to investigating pill size, shape, colour, labelling and packaging of the drugs so as to differentiate the compulsory licensed product from the original brand name product in the market. The exporting company would also have to seek product registration and undertake a process to prove bio equivalence due to changes regarding pill size and shape. This process must be done regardless of cost. This process is complicated further because each step must be followed each time a drug is exported, even if the same drug is being exported to another country. This procedure is cumbersome and complicated for countries seeking to access cheap lifesaving medicines for their citizens.

There are five parties are involved in fulfilling developing or least developed country's pharmaceutical needs via compulsory licenses, which renders the process complicated and time consuming. These parties are the importing country; the exporter; the exporting country; the patent-holder in the importing country; and the WTO. The exporting country is in a very influential position in terms of affecting the global marketplace for pharmaceuticals of all varieties, especially the generic market. If an importing country specifically targets exporters who concentrate on the generic market, an exporting country that believes in strong patent rights may decline to grant compulsory license to such parties and instead insist that any request to export pharmaceuticals via a compulsory license from a developing or least developed country be fulfilled by the actual patent-holder. If the exporting country were to grant licenses to the patent-holder of the drug that is the subject of a compulsory license from a developing country, this would drive drug prices high because there would be little or no

incentive for these parties to lower prices without the outside threat to its stronghold on the market for the particular drug. If the exporting country were to grant the compulsory license to a generic manufacturer, raising competition by making generics more available, the patent-holder would lower prices. This decision appears to rest with the exporting country, but the implications of their decision will affect the worldwide market for pharmaceuticals.

A more positive outcome results if countries with the ability to manufacture drugs recognize and respond to the needs of developing and developed countries by encouraging voluntary licences for generic manufacturers thus shortening the time consuming and burdensome procurement process for developing and least developed countries in accessing cheap affordable drugs.

### 4.3.1 The Case of Canada and Medicins Sans Frontiėres

The Case of Canada and the attempt to procure generics by the NGO *medicines sans Frontieres* illustrates the problems undertaken in procuring pharmaceuticals under compulsory licensing using the Implementation Decision Regime. The implementation of paragraph 6 of Doha Declaration on Public Health as stated has proved to be problematic in solving the problems of access to necessary pharmaceutical products for eligible developing countries. The reason for adopting this view is that, in theory, under the Implementation Decision regime, developing and least developed countries would be able to utilise compulsory licences to ensure the availability of vital drugs but in practice there are certain hindrances that have been identified.[359] The compulsory license known to have been issued under the Implementation Decision Regime was issued by Canada under the Canadian Access to Medicines Regime (CAMR) legislation.[360] Following Canada's adoption and

[359] Katri Paas, *Compulsory Licensing Under the TRIPS Agreement*, 13 EUR. INTELL. PROP. REV. 613 (2009).
[360] Bill C- 9: An Act amending the Patent Act & Food & Drugs Act (2004) (the Jean Chrėtien Pledge to Africa). Referred to also as the Canadian Access to Medicines Regime (CAMR).

implementation of this legislation, *Medicins Sans Frontiers* (MSF) made an attempt at publicly testing the legislation by making a drug order. It identified the needed drugs and solicited for manufacturers in this case the largest generic manufacturer in Canada, Apotex Inc., to produce antiretroviral drugs destined for Rwanda, which is a least developed country lacking manufacturing capacity. There was months of testing and lobbying and negotiations in attempting to fulfil the requisite formalities set out in the Implementation Decision before any production could take place. Compulsory licences in reality are rare and exceptional as seen in the South African cases and there are political barriers that prevent them from being exploited as an option in provision of cheap medicines. There is the general government resistance to the use of compulsory licences for the production of medicines in their own countries, not to mention the production of medicines under compulsory licences for export to other countries. Taking this into consideration, it is evident why negotiations in attempting to procure generic medicines for Rwanda were time consuming. According to MSF the first exports took more than 4 years to happen. Given that Canada was presented with all the necessary conditions having already in its national legislation the regulation adopting the Implementing Decision and having a non-governmental organisation like MSF ready to place an order and pay for it; there were still barriers to providing cheap medicines in a timely manner.

The post Doha changes despite good intentions have been cumbersome and not so much a straightforward solution as had been anticipated during the Doha negotiations and subsequent Implementation Decision.

### 4.3.2 Problems Identified in the WTO Implementation Decision

Compulsory licensing process is time consuming and costly under the procedures described in the Implementation Decision. The generic manufacturer once identified in compliance with the requirements, must begin by engaging in negotiations with the patent holding pharmaceutical company for a voluntary licence. Although there is a fast track method where in urgent situations the requirement to seek a voluntary license may be waived, this requirement is provided for under the national laws and not under the Implementation Decision. Thus where the national laws do not provide for this fast track method then negotiation for a voluntary license must be made. The result of this is that the generic manufacturers are discouraged from participating in compulsory licensing for the benefit of developing and least developed countries lacking manufacturing capacity since they are likely to incur huge financial and human resources costs without any guarantee of success.

The second shortcoming of the Implementation Decision is its requirement that the drugs to be exported under the Implementation Decision regime should be clearly labelled and marketed so as to ensure they are exported to the intended destination. This has proved to be cumbersome and an extra expense to the generic manufacturing companies, when they consider the costs of manufacturer and the selling prices. It ultimately seems not attractive enough for the generic manufacturing companies to easily undertake production of necessary medicines of developing and least developed countries under the Implementation Decision.

The third problem of the Implementation Decision regime of compulsory licensing is that it requires the importing country to notify the WTO TRIPS Council of its intention to import drugs under the regime. The effect of such notification is that it brings the importing country in the limelight, putting their governments under pressure from those countries whose policy is to discourage the granting of compulsory licensing. Those countries that discourage

granting of compulsory licensing are usually industrialized countries, which are likely to subject a developing country to pressure so as to cease from issuing compulsory licenses.

Other shortcomings of the Implementation decision include the fact that it does not take into consideration economies of scale are needed to attract manufacturers of the medicines and also the stipulations that the application for compulsory licenses must contain precise information relating to quantity and destination. Where there is a slight variation or change in quantity and destination, then the procedure and application process must begin afresh. In light of the above, it is evident that compulsory licensing under the Implementation Decision is not as straight forward as had been thought. It is not so much a flexibility of TRIPS in practice as opposed to one in theory. Recent developments in relation to exploiting compulsory licensing following the Implementation Decision involve the seizure of drugs produced under compulsory licensing in transit through the EU region.[361]

### 4.3.3 Compulsory Licensing in Developing Countries

#### *4.3.3.1 Analysis of Compulsory Licensing in Kenya*

The Kenya Industrial Property Act 2001 provides for the granting of compulsory licenses under Sections 72 through to Section 78. Section 72(1) and Section 73(1) set out the grounds under which a compulsory license may be granted. Compulsory licences may be granted where there is market for a patented invention and the market is not being supplied under reasonable terms. Secondly, under Section 73(1) a compulsory license may be granted where the patented invention constitutes an important technological component of a previously patented invention such that the previously patented invention cannot be worked without the



[361] *See* Frederick Abbott, *Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare*, 1 WIPO. J. 43 (2009) *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1535521

new patented invention.[362] Section 72(1) also serves to prohibit anti-competitive practices by requiring that a product be both supplied to meet market demands and the product must be supplied on reasonable terms. Among the conditions imposed by Section 72(2), the compulsory licence may not be granted where the patent owner demonstrates that there are existing circumstances justifying the market for the patented invention not being supplied at all or not being supplied on reasonable terms. A compulsory license can also be granted in two specified conditions set out under Sections 74(1) and 74(2) of the Act, namely where an applicant for a license for a patented invention has been refused a license on reasonable terms and where the applicant has not received a response from the patent owner within a reasonable time. In event of national emergency however the applicant for compulsory license need not demonstrate these conditions. The Industrial Property Act provides for the issuing of compulsory licenses on terms similar to those set out under the TRIPS Agreement. Of particular interest to the patent competition interaction in Kenya are government use orders, under which the government may issue compulsory licenses for patented inventions on grounds of general public interest and anti-competitive practices.

The government use provision in the Industrial Property Act 2001 under Section 80 grants the minister for trade and industry the power to assert the governments' right to take and use protected technology in the public interest. Here, the public interest covers national security, nutrition, health, environmental conservation or the development of other vital sectors of the national economy as required. Under this provision, where the managing director of KIPI determines that the manner of exploitation of an invention by the owner of a patent or his licensee is not competitive, he may recommend that the Minister issue a government use order on terms similar to those under which the Minister may issue an order on public interest grounds. The Minister is granted extremely wide powers and discretion under this provision

[362] Industrial Property Act, § 73(1) (2001) which provides that the invention constitutes an important technical advance of economic significance compared to the earlier claimed patented invention.

which states that the Minister need not necessarily follow the specified procedures in determining whether to issue a compulsory license on grounds of government use.[363] The managing director of KIPI despite having powers to determine whether the exploitation of an invention is competitive or not, is not guided by established guidelines or legislation to assist in making such determinations.

The developments undertaken by the government of Kenya in exploiting the Doha Declaration on Public Health are chaotic in the sense that the legislature persists in attempting to pass TRIPS plus legislation that would in effect render the Doha Declaration inapplicable. A Bill was tabled in parliament where provisions relating to compulsory licensing and changes to the Industrial Property Act were proposed. The proposed legislation sought to seek the consent of the patent holder before granting of compulsory licences which went against even TRIPS provisions relating to compulsory licenses and would have had the effect of rendering inapplicable the Doha Declaration on Public Health in Kenya. The proposed legislation would have been anti-competitive to the extent that where patent holders must consent to the production of generic drugs an increase in affordable drug prices and consequently limiting the options for importation of much needed generic drugs for the treatment of HIV/AIDS, malaria and tuberculosis and granting the brand name pharmaceutical companies monopoly power over drug manufacturing and production past the period of patent grant. The persistence and vigilance of NGOs' have been successful in investigating and lobbying against such legislation as well as educating the public on the effects of legislations to be passed. However an anti-counterfeit legislation that blocks off parallel imports of generic medicines from India and other generic medicine producing countries has sailed through and will present a tremendous setback for access to cheap medicines for HIV/AIDS and other common diseases.

[363] Industrial Property Act, § 80(1) Cap 509 (2001). The government use provision lays out procedures to be followed for the issuance, variation, cancellation and appeal for Ministers decisions to issue a government use order but these provisions are unclear.

### *4.4 Parallel Importation and Access to Affordable Drugs*

Parallel importation refers to the situation whereby a pharmaceutical company sells its product in the international market, after which the product is imported back into the country of origin without any profits to the original seller as he has already exhausted his rights. Parallel importation is closely linked to the issue of exhaustion and has implications on access of affordable medicines generally for both developed and developing countries.

With regard to pharmaceutical patents the motivation to supply much needed drugs to combat HIV/AIDS, malaria and tuberculosis has significantly decreased for two reasons. The first being that it is costly to maintain patent rights outside regions lacking strong intellectual property protection, The cost of maintaining the patent rights and monitoring against infringement through imitation raises costs of medicines. A second reason would be that the pharmaceutical companies rely heavily on the national legislations of countries where their drugs are patented. Thus different territories apply different legislation which have to be complied with, this results in higher costs hence the lack of motivation.

There are a number of reasons why pricing may not favour low income nations. This is because when the prices are higher in one nation than in others, there is a likelihood of parallel trade in that supplies are diverted from the low priced countries through the international market back to the high priced countries.

In seeking to create a true common market in the European Union, there has been a discouragement of impediments to parallel trade within the European Community. In pharmaceuticals this is illustrated by the 1996 incident during which Bayer AG was fined for attempting to restrict reshipment of cardiovascular drug “Adalat” by wholesalers in Spain and France where the wholesale price was low, to the United Kingdom, where prices were 53-94% higher. However, EC rules prevent unauthorised parties from importing drugs enjoying patent protection within the Community from nations outside the Community. Many nations

share the same opinion as the EC in the ban on parallel imports of patented goods outside their borders but some developing nations have enacted laws permitting parallel imports.

Pharmaceutical manufacturers may also choose not to offer much lower prices in less-developed nations when the richer nations subject drugs to price controls, as many nations do, and when the controls ensure that prices in the home market are set at a level not exceeding the prices charged for the same drug in other countries. When the prices include those in least developed countries and developing countries, the drug manufacturers' have no incentive to offer lower prices. Drug manufacturers may also engage in "niche pricing", selling their drugs at high prices to the wealthiest consumers in a low-income nation and ignoring the possibility of making broader sales at low prices to poor consumers.

The international community has placed a lot of emphasis on the need to have strong and predictable intellectual property rights for the encouragement of pharmaceutical innovation, with developing countries benefiting from generic manufacturing following the Doha Declaration on Public Health and the Implementation Decision.[364]

In the US, there has been a vigorous campaign to reduce intensive antitrust scrutiny of patents in the pharmaceutical industry as this will undermine the legitimate intellectual property rights that the industry relies on.

There are some common aspects evident following an analysis of compulsory licensing and parallel importation in the US, EU and developing countries. The first common issue is that in all these jurisdictions, the legislation encourages competition where it is not detrimental to production of adequate medicines. All the jurisdictions are especially pro generic medicine production on a domestic level due to the effect that manufacture of generic medicines has on domestic competition and reduction of healthcare costs. The US has encouraged promotion of generic medicines through the Hatch-Waxman Act and the FTC guidelines on antitrust and

[364] Following the example of Canada as an industrialized country and the implementation of Bill C- 9: An Act amending the Patent Act and Food and Drugs Act (the Jean Chrètien Pledge to Africa). The legislation is also referred to as the Canadian Access to Medicines Regime (CAMR).

competition which also address parallel importation and compulsory licensing. The EU has support for parallel imports and compulsory licensing through relevant Regulations and developing countries are reliant on compulsory licensing provisions and parallel importation provisions under the TRIPS Agreement as implemented in their intellectual property legislation.

Developing countries realise the importance of pharmaceutical patents and are aware of the implications of pharmaceutical patents on access to essential medicines and as incentives for investment in research and development.[365] Prior to implementation of TRIPS, many developing countries did not grant patents for pharmaceutical products, and were under no obligation to do so. The reason for this may be because there was no heightened alert on the relevance of patents in the developing countries and pharmaceutical companies did not at that time consider developing countries to be relevant markets large enough to realise profits. The end of colonialism and subsidised medicines from the colonial authorities meant that the newly independent States had to procure medicines and other pharmaceutical products on their own from pharmaceutical companies in industrialised countries.

A reason for the dependence on foreign pharmaceutical patents by developing countries is the lack of adequate resources both facilities and financing to engage in research and development. A look at the treatment of pharmaceutical patents in India illustrates the situation of pharmaceutical patents in developing countries pre TRIPS Agreement.[366]

The patent legislation fulfils the need to allow and promote access to foreign technologies which was previously unavailable due to the high costs associated with patented rights. Thus previously patents were only issued for methods of production.[367] This meant that a drug with

[365] Many developing countries today are not reluctant to issue pharmaceutical patents since they can rely on compulsory licensing and the Doha Declaration on Public Health should a situation arise where patents rights are overridden or suspended to avert a national disaster.
[366] The case of India is unique to the extent that India became TRIPS compliant in 2005.
[367] The 1970 Patent Act did not offer patent protection for imported products but protected the means of producing the product.

a similar composition to another drug could be produced as long as the method of production was not similar. In India the patent term for expiration of a patent was 7 years for chemicals, food and drugs and not the minimum 20 years from the date of filing as under the TRIPS Agreement. In a developing country such as Kenya, the former industrial property law provided for some form of patent protection for pharmaceutical patents, however patent issuance was a lengthy procedure. Many pharmaceutical companies wanting pharmaceutical patents to be granted from developing countries in Africa could opt to do so through regional intellectual property organisation such as ARIPO and OAPI.

A different approach towards patenting of pharmaceutical products should be considered by developing countries. This can be an approach which prevents patenting for new uses those medicines that are known or previously patented. This has been done by the Andean Community as described under the Andean Community Decision 486 which brought the Andean Community intellectual property rights systems in line with the TRIPS Agreement while doing so with direct reference to the Convention on Biological Diversity.[368]

***Summary***

With the implementation of the TRIPS Agreement, pharmaceutical products fell within the products requiring patents, as illustrated by the case of India which previously did not issue patent rights for pharmaceuticals. One of the implications of TRIPS for developing countries was that pharmaceutical products were no longer affordable by the State therefore a large percentage of the population was forced to go without the medicines or resort to other sources such as traditional medicines. The interaction of patent rights and pharmaceutical products is seen in the anti-competitive effects patent rights can have caused by high prices and unfair licensing terms as illustrated by the cases instituted in South Africa and the failed case against Brazil by the US and multinational pharmaceutical companies. The feasible option for

[368] Andean Community Decision, http://www.grain.org/briefings_files/andean.pdf (last visited Mar. 30, 2010).

developing countries in countering the anti-competition abuses and accessing affordable medicines lies in utilising the flexibilities in the TIRPS Agreement especially the use of compulsory licences in correcting anti-competitive abuses of patent rights.

# 5 PATENTS IN PLANTS, GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE INTERACTION WITH COMPETITION POLICY

## *5.1 Introduction*

This Chapter analyses the legal frameworks relating to plants, genetic resources and traditional knowledge and examines the rights related to patents in plants, genetic resources and traditional knowledge from the perspective of the relationship these rights have with competition policy. Plant rights in the form of plant variety rights and patents, protection of genetic resources and traditional knowledge in fields of agriculture and pharmaceuticals are important and affect all countries developed and developing equally because they influence production of food and medicines. Genetic engineering is a part of biotechnology, addressing the technical use of biological processes; it is also relevant in the development of plant varieties and exploitation of traditional knowledge resources. The three issues cannot be addressed exclusively and are closely intertwined in relation to governing frameworks and their general exploitation. As will be demonstrated by case law, issues of plant varieties and their protection today involve biotechnology either through biotechnology processes in development of new plant varieties or through genetic engineering in the attempt to develop new plant varieties. Biotechnology encompasses various aspects and is defined under the CBD as "[M]erely any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." This definition will be used in this paper, as it appears to be the most comprehensive definition of biotechnology.[369] Article 2 of the CBD defines "genetic resources" as "genetic material of actual or potential value" although it does not clarify the meaning of value.



[369] *See* Convention on Biological Diversity, Dec. 29, 1993, 143 U.N.T.S. 1994 [hereinafter CBD]

Genetic resources therefore comprise "genetic material of actual or potential value of plant, animal, microbial or another origin."[370]

Intellectual property rights relating to plants, both plant varieties and plant breeders are of importance to developing and least developing countries because of the reliance of these countries on agriculture for local food production and foreign exchange. Biotechnology relating to plants is of crucial importance to all countries since it has revolutionized how plants are cultivated, affecting not only quantities of harvests but quality, seeds, vulnerability to disease, weeds and influences food production generally.

The way in which intellectual property rights in plants are exploited may have implications on competition through anti-competitive licensing terms and conditions attached to plant patent licenses. Plant patent licenses involving patented processes and genetic material can include terms and conditions with exceed the scope of patent protection granted. What makes the issue of such licenses containing anti-competitive terms and conditions of interest to the discussion on developing countries is that the seed and plant industry is largely private owned and run with the objectives of profit maximization which is sometimes detrimental to food security for developing countries.

An analysis of the intellectual property frameworks governing patents in plants and biotechnology is therefore important. The international framework governing these rights in the developed and developing countries shows the differing objectives of the countries depending on the level of development. In the developed countries protection of plant rights through plant variety rights, patents and the plant breeders' rights are geared towards maximizing profits to the right holders through ensuring their rights are protected.

The effect of this is the broadening scope of intellectual property protection relating to plants which ultimately when applied to developing and least developed countries is detrimental to

[370] Philippe. Cullet et al., *IPR, PGR and Traditional Knowledge*, *in* RIGHTS TO PLANT GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE: BASIC ISSUES AND PERSPECTIVES 117 (T. Cottier, et al. eds., 2006)

their food security. This broad scope of patent rights has been exploited by multinational corporations to gain monopoly rights over plant genetic resources ultimately compromising farmers control over their genetic resources.[371]

### *5.2 Intellectual Property Rights in Plants*

Plant variety protection is a form of industrial property right. Like other forms of industrial property, the objective of granting protection to plant varieties is to create an incentive for research and development into the creation of further varieties in plants. Lacking such protection competitors may free ride on the investment. Plant variety protection like patent rights are territorially limited to the extent that the protection extends within designated States where application is made for protection.

Intellectual property rights were historically applied to inventions or artistic creations and not living organisms. In the US, plants that had been vegetative propagated were patentable first in 1930. Patents and plant breeders' rights have implications on food security worldwide in that they affect agriculture and food production through creating a market for plant breeders and by imposing restrictions on the farmer's ability to sell or reuse seeds. This restriction has implications in developing countries, because majority of the farmers are small scale subsistence farmers who traditionally reuse and exchange seed with other farmers within the same community.

In addition to having in place legislation governing plants through plant variety rights and patent rights, the campaign advocating for genetically modified foods to meet the food needs of developing countries warrants examination.[372] Plant variety and plant breeder's rights also



[371] *See* Diamond v. Chakrabarty, 477 U.S. 303 (1980); Monsanto also instituted cases relating to control over seeds and institutions of lawsuits against farmers for keeping and using seeds over which Monsanto has patent rights.

[372] The debate as to whether or not genetically modified foods are hazardous to health is beyond the scope of this thesis. The interest here is in the ability of cultivating genetically modified foods so as to meet the food needs

have an aspect of traditional knowledge in that in many developing countries the farmers utilize seeds to create plant varieties and improve their food crops. Farmers in developing countries are small scale farmers who depend on subsistence farming for their livelihood therefore an increase in the costs of patented seeds ultimately makes access to seeds beyond their means resulting in loss of livelihood, inadequate food production and increase in poverty.

### 5.2.1 International Regulatory Framework Governing Rights in Plants

In analyzing the regulatory framework governing the patenting of plants and biotechnology, notice must be taken of the various forms of intellectual property protection that can be conferred on plant material. These include plant patents which differ from normal utility patents, patenting of plants or parts of the plant such as the cells, patenting of plant varieties, *sui generis* plant variety protection, patenting of DNA sequences, and gene constructs.[373]

The protection of plant variety rights has undergone some changes due to genetic engineering and biotechnology, such that the legal protection of varieties based on phenomena of plants is insufficient where plant varieties have undergone genetic changes. Some commentators have undertaken a discussion as to whether plant variety rights have become obsolete as a form of protection, with this view based on the technological advances that have taken place since the UPOV Conventions came into being.[374] Another issue highlighted by commentators concerns the overlap of protection relating to plants with the availability of plant patents and plant



since they can be resistant to common plant diseases and weeds as well as grow under special conditions not requiring too much water, in light of the long droughts that have been experienced in the past years especially in sub Saharan Africa.

[373] Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (2002), http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf (last visited Jan 07, 2010).

[374] Laurence R. Helfer, *The Demise and Rebirth of Plant Variety Protection: A Comment on Technological Change and the Design of Plant Variety Protection Regimes*, 82 CHI. KENT. L. REV. 1619 (2007) *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=954000.

variety rights being utilized.[375] Intellectual property protection governing plants exists in the form of international conventions regarding protection and sustainable development as well as in national legislation.

The UPOV (International Convention for the Protection of New Varieties of Plants) system is comprised of two Conventions. The first Convention being was set up in 1961 and underwent various amendments in 1978 commonly referred to as UPOV 1978. The second Convention is the 1991 Convention. The UPOV Convention was established with the aim of introducing property rights in plants.[376] Under the UPOV Convention, Member States undertake to establish a system for protection of plant breeders' rights under their national legislation following uniform internationally agreed principles. The rights granted are legally enforceable and national in nature only in the territory of the Member State. According to Vandana Shiva,[377] the UPOV Convention having originally members from industrialised countries and not developing countries indicates that the Convention was aimed at developed countries and their socio economic status. The objective of UPOV was to grant exclusive rights to plant breeders so as to enable them develop new plant varieties. Shiva in analysing the UPOV Convention finds that it is rigid in its requirements for standards of protection for plant varieties which the member states are obligated to adopt as national law. This rigidity is illustrated by the requirements to be met before plant breeders rights can be granted under the Convention, which has been found not to enhance diversity and sustainability due to the fact that it excludes plant varieties created by farmers but is aimed at "creating uniform and hence ecologically vulnerable agricultural systems."[378] Note that this rigidity of ruling out farmers'



[375] Markus Lenssen, *The Overlap between Patents and Plant Variety Protection for Transgenic Plants: Problems and a Solution*, University of Bonn, Institute of Commercial and Economic Law, May 2006 *at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=924343.

[376] International Convention for the Protection of New Varieties of Plants, Paris December. 2, 1961, as revised Geneva, Nov. 10, 1972, Oct. 23, 1978, [hereinafter UPOV 1978] and Mar 19, 1991, 815 U.N.T.S. 89 [hereinafter UPOV 1991]. UPOV 1978 is the establishing Convention (Article 2 of UPOV 1991 provides that each State Party to the Convention has an obligation to grant and protect breeders rights)

[377] VANDANA SHIVA, PATENTS: MYTH & REALITY 99 (2001).

[378] *Id.*at 100.

innovations with regard to plant varieties breeding is found in the 1991 Convention. The 1978 Convention contains a farmer's exemption granting the right to save seeds of protected varieties. The 1991 Convention did away with these exemptions and instead provided that a royalty to be determined by the legitimate breeders is payable. A notable difference between the 1978 Convention and the 1991 Convention is that the 1978 Convention provided for an exclusive protection in that it prohibited Member States from allowing dual forms of protection for plant varieties. A member had to choose either *sui generis* plant variety protection under national legislation or patents and not both. This ban on dual protection was eliminated in the 1991 Convention. This difference between the Conventions concerning duality of protection is emphasised by the legislation governing plant variety rights in the EU which has been determined by some commentators to have misinterpreted the requirement prohibiting dual protection for plant rights to mean an absolute prohibition of patenting of plants. This interpretation in the EC was incorporated into the Strasbourg Convention which was a basis for the European Patent Convention and ultimately formed part of Article 53 (b) of the EPC which places limits to patentability of plants and animals.

It has been argued by critics that developing countries entering into the UPOV Convention 1978 would be entering into "[a] political and policy treadmill leading inevitably to UPOV 1991 and then onward until UPOV is indistinguishable from the most monopolistic elements of the utility patent system."[379] This contention is based on the reasoning that UPOV 1991 strengthened the rights of commercial plant breeders and provided protection for all plant genera and species in addition to other rights which essentially amounted to weaker monopoly rights than patents.[380]

In analyzing the relationship between plant variety rights and plant breeders' rights, a breeder is described under the 1991 UPOV Convention as the person who bred, or discovered and

[379] *See* Crucible Group, http://www.cidse.org/pubs/tglpppt2.htm.
[380] Philippe Cullet, *Plant Variety Protection in Africa: Towards Compliance with the TRIPS Agreement*, 45 J. AFR. L. 100 (2001).

developed a variety. The protection afforded under the Convention covers the production of varieties through processes of cross planting and selective propagation as well as discoveries of mutate or chance seedlings which are then converted into cultivated varieties.

#### *5.2.1.1 Statutory Requirements for Plant Variety Protection*

The 1978 UPOV Convention in Article 6 sets out the criteria that member states should adopt as minimum requirements for protection of plant varieties. The requirement that must be fulfilled for the grant of plant breeders' rights under plant variety protection includes the requirements of novelty, distinctness, uniformity, stability and appropriate denomination. The requirements with regard to plant breeders' rights take on a slightly different meaning from patentability requirements. Novelty requirement for plant breeders rights mandates that the requirement not have been offered for sale prior to the application for protection with the permitted selling period before the application is made being one year in the country where the application is made or six years in other countries. Distinctness for the purposes of plant breeders' rights is basically a requirement that the variety be distinguishable from other varieties known at the time of application. Uniformity requires that a variety be uniform in its characteristics and is closely linked with the requirement of stability. A variety is stable when its relevant characteristics are uniform and remain unchanged following repeated propagation. The generic designation is the denomination which refers to the name the species will be given. The denomination must be registered and once allocated cannot be used by another species or variety. The period of protection for UPOV Member States is 25 years for vines and trees and 20 years for plants which is counted from the date when the rights were granted. Following the adoption of TRIPS, many countries have resorted to granting patent protection for plant varieties. The granting of protection through patent rights serves the role of

providing incentives for breeders to engage in research and development. The protection granted may take the form of patents or other means of *sui generis* protection.

#### *5.2.1.2 Plant Variety Rights under TRIPS Agreement*

Plant variety rights are provided for under the TRIPS Agreement in Article 27.3(b). Article 27.3(b) allows for protection of plant variety rights under either a *sui generis* system or through grant of patent rights. In this respect it is similar to the UPOV Convention of 1991 since it does not emphasize an exclusive form of protection for plant varieties neither does it prohibit a dual protection. The flexible option for protection of plant varieties is beneficial for developing countries since it allows the countries to choose a suitable option given the differing perspectives many developing countries have with regard to patenting of plant and animal varieties. Under Article 27.3(b) of TRIPS, countries must provide for the protection of plant varieties either by patents or by an effective *sui generis* system or any combination thereof. Such a *sui generis* system would be based upon an internationally recognized system of plant breeders' rights or plant variety protection measures. A clause is incorporated under Article 27.2 which makes allowances for patent exclusions where necessary to protect human, animal or plant life or health or to avoid serious prejudice to the environment. The interpretation of Article 27[381] has been addressed by the Doha Declaration paragraph 19, which instructs the TRIPS Council to continue the review of Article 27.3(b) TRIPS and to examine the relationship between TRIPS, CBD and protection of traditional knowledge.



[381] *See* Doha Declaration para 19.

### 5.2.2 Plant Patents and Plant Variety Rights in the EU

Before exclusive rights in plants and plant varieties were established, farmers had an established tradition of seed saving for the following season's crop. Using the saved seed is cheaper than buying seed hence more economical. The hostility of farmers to the system of paying for seeds every planting season is therefore understandable. On the other hand there is a need to have improved varieties of plants which produce high yields and are resistant to weeds. These improved seed varieties are obtained after extensive and costly research and development by plant breeders. The EC thus had to strike a balance between the interests of the farmers and the need to ensure an adequate return for breeders, whose efforts bring about substantial improvements on the quality of plant varieties.

Intellectual property protection relating to plants in the EC is characterized by the exclusion from patentability of plants and animal varieties and essential biological processes for the production of plants and animals as specified under Article 53(b) of the EPC. Under the EPC, the definition of plant variety has been determined following case law to be the definition adopted from the viewpoint of a skilled person as, "[a] multiplicity of plants which are largely the same in their characteristics and remain the same within specific tolerances after every propagation or every propagation cycle."[382] In addition to the EPC provisions, the Directive 98/44 of the EU commonly known as the Biotechnology Directive also excludes plant varieties from patentability.[383]

The Community Regulation 2100/94 establishes the Community plant variety system as the exclusive form of community industrial property rights for plant varieties.[384] The Community Plant Varieties Rights Regulation is described as being the exclusive EC form of protection for plant varieties.

[382] *See* Plant Genetic Systems, Case T 356/93 [1995] EPOR 357; Case T 49/83 Ciba Geigy [1979-85] EPOR 758; Case T 320/87 Lubrizol [1990] EPOR 173.
[383] Biotechnology Directive, 1998 O.J (L 213) 13.
[384] Council Regulation 2100/94, 1994 O.J. (L 227) 1 amended by Council Regulation 873/2004, 2004 O.J (L 162) 38.

The issue of plant variety protection and plant patents in the EC seems uncertain in that there is an overlap of intellectual property rights relating to plants. This is more so with the advances in biotechnology which allow genetic modifications of plants and result in patenting of these genetic modifications. In this respect, an analysis of the practice of the EPO in cases relating to intellectual property rights in plants is undertaken to illustrate the overlapping nature and the implied patenting of plants in the EC, despite the explicit exclusion provisions set out in the legislation.

### 5.2.3 Plant Patents and Plant Variety Rights in the US

Intellectual property rights in plants in the US have been in existence as early as 1930 when the Plant Patent Act was enacted.[385] The Plant Patent Act grants protection to asexually produced plants, with the Act specifying that protection through patents is granted that prohibits others from "asexually reproducing the plant or selling the plant so reproduced."[386] Under the Plant Patent Act, for a patent to be granted the conditions to be fulfilled by the plant variety are set out that the plant variety must be distinct, novel, and not obvious. The plant variety protection system in the US is also comprised of the Plant Variety Protection Act (PVPA).[387] The PVPA grants protection for those plant varieties that are sexually produced in that they are seed bearing plants. The protection under the PVPA is the *sui generis* form of protection under which the statutory requirements for protection are set out as novelty, distinctness, uniformity and stability.[388] The PVPA like other plant variety legislation prohibits others from selling, importing or exporting the protected varieties.

The US also provided plant variety protection through utility patents specifically providing protection to plant cultivars and hybrids. The requirements to be met prior to receiving a

[385] 35 U.S.C. § 161 (1994):
[386] 35 U.S.C. § 163 (1994).
[387] 7 U.S.C. §§ 2321-2583 (1994).
[388] 7 USC §§ 2402a (1994).

utility patent include that the invention be new, useful and non-obvious.[389] An analysis of the US framework governing plant varieties shows some overlapping protection which is aimed at filling the gap in protection that previously existed because plant varieties were found to lack inventiveness. In the age of biotechnology, plant varieties have been determined to involve inventive step in some genetic modifications hence requiring different protection.

### 5.2.4 Plant Patents and Plant Variety Rights in Developing Countries

Plant variety rights in developing countries generally are afforded protection under the TRIPS Agreement, the CBD and the UPOV Conventions. Developing countries have been slow in drafting and implementing plant variety protection as compared to industrialized countries which have had protection for plant varieties as early as the 1930's as in the case of the US. The developing countries on the issue of plant variety protection have been subjected to intense pressure to put into place plant variety rights legislation in order to be in compliance with the TRIPS Agreement, which has resulted in inconsistent legislations and adoption of unsuitable legislation following models of plant variety rights intended for industrialized countries.[390]

Following the adoption and implementation of TRIPS Agreement, developing countries continue to express concern over the implications Article 27.3(b) has on food security, especially for small scale subsistence farmers. The limitations placed on seed savings and exchange and fear of prosecution for patent infringement is a real issue that will have widespread implications once intellectual property rights enforcement in developing countries improves to match that of developed countries and multinational seed companies can be able to institute proceedings against developing country farmers successfully.

For developing countries especially sub Saharan Africa, in an effort to comply with TRIPS provisions the countries opted to adopt UPOV 1991 as opposed to devising their own

[389] 35 USC § 112 (1994).
[390] *See* Cullet, *supra* note 380.

legislation. This was mainly due to pressure from developed countries such as the US which made a campaign for adoption of UPOV to secure protection for multinational US based plant breeder organizations. In the African continent, the two regional intellectual property organizations namely OAPI and ARIPO provide intellectual property protection. While OAPI provides protection for plant variety rights, ARIPO has not dealt specifically with plant variety rights but leaves the issue to be governed by domestic law. Thus member states of ARIPO have the choice of adopting or rejecting patent protection for plant varieties. On the other hand OAPI has specifically dealt with plant variety rights through revising the Bangui Agreement in 1999 to include new text obligating member states to adhere to the UPOV 1991 Convention.[391] Within the African continent there exists model legislation aimed at protecting rights of local communities, plant breeders and farmers which is relevant for plant variety rights protection. The model legislation was drafted under the auspices of the Organization of African States (OAU).[392] It deals with defining rights of communities in relation to plant breeders farming access to biological resources among other rights related to the communities. The model legislation is of interest because it specifically rejects patents on life or the appropriation of any form of life as well as derivates of life form.[393] Farmers' rights within the model legislation are provided for with broad rights which include the protection of traditional knowledge relevant to plant and animal genetic resources as well as the right to save, use, exchange and sell farm saved seeds and use commercial breeders' variety to develop other varieties as also provided for in the UPOV Conventions. In addition this, there are exemptions to breeders rights which include the rights to sell plant or propagating material



[391] *See* Annex 1 of the Banjul Agreement *supra* note 239.
[392] *See* African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (2000) [hereinafter African Model Legislation].
[393] *See* Cullet, *supra* note 381, at 103.

as food as well as to use the propagating material for other purposes not necessarily commercial in nature.[394]

#### *5.2.4.1 Plant Variety Rights in Kenya*

Kenya introduced plant variety protection prior to its adoption of TRIPS. The Industrial Property Act specifically rejects patenting of plant varieties in its Section 26 although it provides for the patenting of biotechnological processes and products. Plant variety protection was incorporated in the Seeds and Plant Varieties Act of 1972.[395] The plant variety rights under the Act are modeled following the UPOV Convention including requirements for granting of protection specified in Section 20 of the Seeds and Plant Varieties Act, following the UPOV requirements of distinctness, uniformity and stability and providing protection for 25 years. A Plant Breeders Office was established in 1994 following amendments to the Act. Because the Act followed UPOV Convention as drafted in 1961, the decision to ratify the UPOV Convention 1978 only resulted in minor changes to the legislation.

#### *5.2.4.2 Plant Variety Rights in India*

In the period prior to implementation of the TRIPS Agreement and amending of the Patent Act of 1970, India did not grant patents for any method of agriculture or horticulture.[396] The reasoning behind such prohibitions was to protect public interest from exploitation in areas of industry which was concerned with basic needs such as food and medicines. The Protection of Plant Varieties and Farmers Rights Act of 2001 grants protection to plant breeders rights,



[394] *Id.* at 104.
[395] Seeds and Plant Varieties Act, Cap 326 (1972).
[396] Patent Act, § 3 (1970) Ind.

farmers varieties and varieties of plants held by NGOs and public sector institutions.[397] The objective of the Act is to ensure fair distribution of rights and providing a means to assign multiple rights for the efficient utilization of resources. The Act incorporates farmers' rights as a chapter and provides a mechanism for farmers to register their plant varieties. Thus three aspects of farmers rights are covered by the act namely, the privilege of farmers to save, exchange, reuse and sell seed. The second aspect is the provision of a mechanism where framers can make claims for compensation in event of their plant varieties being utilized by breeders for commercial purposes. This benefit sharing aspect is available for farmers and communities. The third is the allocation of farmers rights as ownership in that they can be able to register their own varieties. It is however unclear as to whether the criteria for protection are to be based on the requirements of distinctness, uniformity and stability.

The Indian Patent Amendment Act 2005 with regard to plant patents under Section 3(j) explicitly excludes from patentability all indigenous forms of medicines, inventions based on traditional knowledge, plants and animals in whole or part thereof except microorganisms.

#### *5.2.4.3 Plant Variety Rights in South Africa*

In South Africa, plant variety rights are protected under the Plant Breeders Rights Act No 15 of 1976 which following amendments is known as Plant Breeders Rights Amendment Act, No 15 of 1996. In addition to the Act, South Africa is also a signatory to the UPOV Convention 1978. The Act provides protection for varieties of any prescribed kind of plant that meets the requirements of new, distinct, uniform and stable as set out in Section 2(1) of the Act. The rights of the plant breeder as prescribed in Section 23 include the right of production, reproduction, conditioning for propagation, sale, export and import. The circumstances provided under Section 23(6) where use of protected plant variety propagation material is not

[397] *See* Anitha Ramanna, *India's Plant Variety and Farmers' Rights Legislation: Potential Impact on Stakeholders Access to Genetic Resources, at* http.

considered infringement include where the propagating material is legitimately obtained and resold, where the propagating material is obtained for *bona fide* research purposes, used for private and non-commercial purposes, or where the farmer uses the harvested material from the propagating material for propagation purposes under Section 23(6) f. This is the farmers' rights provision contained in the Act. The duration for protection granted under the Act is 25 years in case of vines and trees and 20 years in all other cases.

Where the owner of plant breeders' rights unreasonably refuses to grant a license or imposes an unreasonable condition for the issue of a license, a person may apply to the Registrar for a compulsory license following a prescribed procedure set out in Section 26 and 27 of the Act. Before a propagating material relating to specific plants mainly agricultural, vegetable and fruits can be granted protection and sold in South Africa, the variety must be contained in variety listing which is provided for under the Plant Improvement Act No 53 of 1976. The objective of the Act is to ensure that a listing of agricultural, vegetable and fruit varieties in South Africa is maintained thus controlling and monitoring quality of propagating material in the market. In addition to this, the variety listing enables South Africa to comply with seed certification schemes of the Organization of Economic Cooperation and Development (OECD) which increases trade in seed markets with EC countries and internationally. Thus the variety listing assists in lowering the barriers to trade in agricultural products experienced by developing countries trading with the EU countries.

The common aspect of plant variety protection in developing countries is the existence of plant variety protection legislation following either of the UPOV Conventions with some minimum variations in the different countries.

### 5.2.5 Anti-Competition and "Monopoly Rights" in Plant Varieties

Agriculture is a crucial sector in the economy, not only because it is profitable but that it provides food needed by all human beings. In the developing world, agriculture occupies a special place in the economy because it has the dual role of providing food needs as well as forming the largest percentage of exports and being the foreign exchange earner for the countries. In addition to being the main products for international trade, agriculture is the main form of livelihood for individuals in developing countries who rely heavily on subsistence farming. Taking this into consideration plant varieties and innovations relating to plant varieties can be highly beneficial for developing countries. There is need to encourage innovations relating to plant varieties while at the same time ensuring that these rights in plants, be they patents or plant variety rights do not conflict with the rights of small farmers and unfairly infringe on their rights through granting overly broad rights to breeders at the expense of small scale farmers.

With technological changes and genetic engineering, the scope of plant variety rights has somewhat broadened. This could explain why patents have in some instances been considered better forms of protection for plant varieties. In light of technological advances, there has been an emerging trend of anti-competition practices relating to plant varieties. This can be illustrated by the *Maize Seed Case* in the EU.[398]

The *Maize Seed Case* illustrates a situation where plant breeder rights can be exploited by the rights owner through licensing agreement terms and conditions giving rise to anti-competitive implications and effects. Like patent rights, intellectual property rights in plants through plant variety rights can be exploited by rights owner such that anti-competitive implications arise. In the *Maize Seed Case*, the court undertook an analysis as to whether an open exclusive licensing contract concerning plant breeders rights where the owner undertook not to grant

[398] Case 258/78, Nungesser & Eisele v. Comm'n E.C.R. 02015 (1982)

other licenses in the same territory and not to compete with the licensee in the same territory was contrary to Article 101(1) TFEU (ex Article 81(1) EU Treaty). The court found that where the exclusive license is necessary for the purpose of facilitating dissemination of new technology within the European Community then the absolute territorial protection would not amount to anti-competitive behavior. Under normal circumstances however such territorial protection would be contrary to Article 101(1). In another case before the ECJ, *SPRL Louis Erauw Jacquery v. La Hesbiognonne SC* which concerned plant breeders rights and violation of competition policy within the Community, an exclusive license had been granted with gave absolute territorial protection to the licensee on the grounds that it would allow the licensee to propagate seed was held not to be in violation of Article 101 as such because it dealt with basic seed.[399]

The granting of intellectual property protection for plant varieties is premised on the need to provide incentives for further research and development and allowing the plant breeders and farmers to recoup on their investment. The agricultural industry is highly competitive with multiple players involved ranging from small scale subsistence farmers in developing countries to large multinational seed companies. The legislation governing plant varieties should ideally seek to protect the various interests of these key players while taking into consideration principles of trade that are fair and reasonable. In an attempt to do this, international agreements such as TRIPS have in requiring some form of intellectual property protection for plant varieties, provided the Member Countries with the option of adopting a patent system, a *sui generis* system or a combination of both. This is evident in the analyzed jurisdictions of US and India which have adopted a combination of protection systems for plant variety rights.

The controversy surrounding the patenting of plant varieties and opposition to granting plant patents today seems somewhat displaced. In the age of technological developments where

[399] Case 27/87, SPRL Louis Erauw-Jacquery v. La Hesbignonne SC. 1988 E. C. R. 01919.

plant varieties are invented through genetic engineering, patent protection is the only adequate means of protecting varieties from exploitation by free riders. In the EU, it can be seen that although plant patents are explicitly forbidden, patent claims can be phrased in such a way that the patent is granted. The resistance to plant patents in the EU and some developing countries based on the reasoning that plants are living matter and should not be patented today seems weak and is further weakened by case law relating to patenting of living matter as far back as 1969 in the *Red Dove Decision* (*Rote Taube*) where the German Federal Court held that the living character of an invention is irrelevant as regards the issue of patentability.[400] This reasoning however was not taken into consideration when determining legislation relating to patentability of plants and plant materials.

### *5.3 Biotechnology Patents and Competition Policy Interaction*

Biotechnology is important for developing countries because of its relevance to food production and most importantly in relation to exploitation of traditional knowledge and genetic resources. Biotechnology is intricately linked with plant varieties, pharmaceutical patents, traditional knowledge and transfer of technology. For developing countries biotechnology is important not only for increasing food production but also for industrial development. The type of intellectual property protection offered to biotechnology which is patent protection has resulted in a lot of controversy between developed and developing countries.[401] An analysis of the legislation governing biotechnology allows for an examination of the approach taken by developed countries to address the above mentioned biotechnology controversy as well as the reactions of developing countries. The biotechnology industry due to its importance in the agricultural and food sector as well as pharmaceutical, traditional

[400] *See* Entschidungen des Bundesgerichtshofes [BGHZ] [Federal Supreme Court] 52, 74 (1969)(F. R. G) *translated in* 1 INT'L. REV. INTELL. PROP. & COMPETITION L. 136 (1970).
[401] *See* LI WESTERLUND, BIOTECH PATENTS: EQUIVALENCE AND EXCLUSIONS UNDER EUROPEAN AND US PATENT LAW, 2 (2002).

knowledge and genetic resources sectors is a billion dollar industry and extremely competitive today. Soya bean and corn ranked first and second, making up 57 percent and 22 percent of the total cereals planted as genetically modified foods.[402]

In some industrialized countries such as the US, transgenic crops were adopted fairly quickly due to the high yields the seeds resulted in, most notably the farmers in the US were saving on herbicide costs.

In developing countries, especially those suffering from droughts and food scarcity resulting from civil wars and other social and economic factors, biotechnology has begun to play an important role in providing a solution to food shortages and ensuring adequate food production to cater for the population.[403] South Africa, Kenya and India have all accepted genetically modified crops and implemented legislation aimed at regulating these crops which are produced for consumption and industrial purposes. An example of genetically modified crops is the genetically modified cotton grown in South Africa, rice in India and sweet potatoes and bananas grown in Kenya.

There are generally two classes of invention in the biotechnology industry, the first one being newly discovered and isolated genes and proteins or pharmaceutical inventions based on those genes or proteins. The second class of biotechnology invention relates to the discovery of a new method to use the gene or protein, in this case the researcher may patent the method. Biotechnology for developing countries is a tool for acquiring knowledge and allowing the direct intervention in plant and animal breeding by transferring genetic information from one sort of organism to a particular crop, or to a farm animal to make it transgenetic. A naturally occurring gene or protein in a living organism be it plant, animal or human cannot be patented



[402] *See generally* http://ec.europa.eu/food/food/biotechnology/index_en.htm The DNA molecule is read in the same way in all organisms in order to make proteins; it is possible to take any single gene from any organism and transfer it to into any other organism so that the recipient produces a protein normally only made in the donor. This resulting organism is called the transgenic.

[403] Developing countries could benefit from transgenic crops such as virus resistant cassava, sweet potatoes, papaya, rice and diverse crops that are drought resistant than the usual varieties.

however, once it has been isolated and is determined useful in a different application it can be patented.[404]

Biotechnology is useful for following genetic markers in plant and animal breeding hence allowing for the cross breeding and the prediction of some phenotypic properties which will show up later in life. Biotechnology legislation in many developing countries is fairly recent and can be analyzed under the TRIPS Agreement and CBD in relation to protection granted to biotechnology inventions and preventing the unethical use of biotechnological inventions.

### 5.3.1 TRIPS Agreement and Biotechnology

Article 27.3(b) of the TRIPS Agreement outlines patentable subject matter. The provision describes the subject matter that Members may exclude from patentability while at the same time specifically obliges members to protect microorganisms and certain biotechnological processes. The provision is also commonly referred to as the biotechnology clause. Article 27.3(b) brought about the biotechnology controversy because some developing countries chose to exclude from patentability all plants and animals, while most developed countries chose to interpret the provision loosely. Biotechnology like plant varieties are also excluded from patent protection in most developing countries, Kenya being one of them which excludes patenting of plant varieties under the Seeds and Plants Varieties Act.[405].

The resultant broadening of scope of patentability results in differing consequences with developing countries bearing the brunt of the problems. Kenya together with other developing



[404] Biotechnology involves reading of information in the DNA (deoxyribonucleic acid) which is the genetic material of all living organisms; it can be isolated, modified, and transformed into other organisms to carry out a desired function. A protein made by one specific organism can be produced in another contained in all genes, through biotechnology. DNA was discovered by Oswald T. Avery in 1944 where he discovered that they represented the building blocks of life. Following this discovery, there was further groundbreaking invention in 1974 when two scientists named Stanley Cohen and Frederick Boyer successfully modified genes systematically.

[405] *See* Seeds and Plant Varieties Regulations, 1994 giving effect to the Seeds and Plant Varieties Act which is modeled on UPOV; *see* UPOV Convention *supra* note 377.

countries has argued that Article 27.3(b) should be reviewed to clarify the patenting of microorganisms and micro biological processes.

The implication of Article 27.3(b) is that it forced the introduction of intellectual property rights in an area where most developing countries granted no intellectual property rights and this raised concerns in these countries as it touched on issues related to cultural and farming practices, genetic diversity and food security.

#### *5.3.1.1 The Ethical Debate Surrounding Biotechnology Patents*

The controversy surrounding biotechnology stems from the question concerning what is patentable. After adoption of the TRIPS Agreement, developing countries maintained that living matter is not patentable, while developed countries advocated to some extent for the patenting of living matter. The objective of biotechnology for developing countries differs from that of developed countries. Developed countries utilize biotechnology as a means of reducing costs and making profits in food production by promoting efficient food production and achieving having high yields, basically an economic and profit making objective. Developing countries are skeptical and resistant to biotechnology, considering it in many ways immoral and amounting to patenting of life forms and a threat to life forms while also recognizing that biotechnology could help solve the problem of acute food shortages due to climatic changes and poor farming practices.

The ethical debate also centers on other issues of biotechnology such as food safety through genetically modified foods, environmental degradation and other adverse effects of bio fuels and the biotech research involving stem cells which is an ethical and moral issue for many developing countries. Bio safety in food production and the unethical corporate control of basic needs for profits such as control of the seed industry through genetic modification has not endeared biotechnology to developing countries. In addition to this, there is fear that with

the widespread use of bio fuels, there will be an increasing need for land resources currently used for food production in developing countries. This competition for land use will then result in extensive deforestation followed by other adverse environmental effects.

The approach towards the ethical debate regarding biotechnology and plant rights in the EU has weakened following failed oppositions of patent grants on genetically engineered plants. In response to the claim in the *Plant Genetic Systems case*, that it was immoral to patent life forms and plants on the basis that they are the common heritage of mankind and therefore in breach of Article 53(a) of the EPC, the Appeal Board found that it was not the appropriate institution to discuss the morality issues. The EPO Extended Board of Appeal in the *Norvatis Case* also found the issue of morality raised as a point in opposition of a patent to be too controversial to amount to a successful challenge of the patent granted. It follows also that with the enactment of the Biotechnology Directive, the EU legislators acknowledged genetic engineering to be beneficial in many ways to the consumers in the region.

### 5.3.2 Legal Framework for Biotechnology Patents: US, EU and Developing Countries

In the US, as aforementioned, the criteria to be met before a patent is granted is that an invention be new, useful, non-obvious, sufficiently enabled and described such that a person having ordinary skill in the art can be able to reproduce it.[406] Biotechnology patents have been granted in the US since the 1980's when the Supreme Court decided that a strain of bacteria genetically engineered to break down and consume oil was patentable in the case of *Diamond v. Chakrabarty*.[407] Following the *Chakrabarty case* and other decisions relating to biotechnology inventions and their patentability, in 1987 the USPTO formally announced that

[406] *See* Schmeider, *supra* note 306.
[407] 447 U. S. 303 (1980).

non-human multi cellular organisms that were plant or animal and were not naturally occurring were patentable.[408]

The EU allows for the grant of biotechnology patents as governed by the Biotechnology Directive. In Europe, the biotechnology patents have been granted as far back as 1969 in Germany where the court in deciding the *Red Dove Case* found that patentability of living organisms is allowable, the question of whether an organism is patentable or not is not based on the issue of whether it is a living organism.[409] An analysis of EU legislation governing patents in biotechnology illustrates that principles governing the patenting of living organisms as contained in the EPC did not take into consideration the developments of biotechnology.

Biotechnology patents are relatively recent for a majority of developing countries due to the low level of innovations. In some developing countries such as India and South Africa, biotechnology patents have been identified to play a crucial role in innovation of pharmaceutical and agricultural industries and are therefore granted protection with legislation aimed at encouraging research and development in various fields of biotechnology. An analysis of the regulatory frameworks governing biotechnology in these countries illustrates the importance placed on biotechnology patents.

***India***

India has multiple regulatory agencies dealing with biotechnology products and processes. These agencies are involved in granting protection and rights related to biotechnology as well as ensuring biotechnology products and processes are not harmful to the consumers and environment. The regulatory regime governing biotechnology in India is comprised of a group of legislations namely, the Plant Varieties and Farmers Rights Act of 2002, Seeds Act



[408] *See* LI WESTERLUND, BIOTECH PATENTS: EQUIVALENCE AND EXCLUSIONS UNDER EUROPEAN AND US PATENT LAW 3 (2002); *see also* Ex parte Hibberd, 227 USPQ 447, (PTO Bd. Of App. & Inter. 1985) (held that plant patents to be generally allowed); Ex Parte Allen, 2 USPQ 2d 1425 (PTO Bd. of App. & Inter. 1987) (multicellular organisms found to be patentable subject matter).

[409] Entschidungen des Bundesgerichtshofes [BGHZ] [Federal Supreme Court] 52, 74 (1969) (F. R. G) *translated in* 1 INT'L. REV. INTELL. PROP. & COMPETITION L. 136 (1970).

of 1966, the Plants, Fruits and Seeds (Regulation of Import into India) Order, 2003, the Prevention of Food Adulteration Act, the National Biodiversity Legislation of 2002, Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms and Genetically Engineered Organisms or Cells contained in the Environmental Protection Act of 1986.[410]

The developing countries have to examine their approach to biotechnology legislation, whether to adopt the European approach as in the EPC and Biotechnology Directive or to adopt the broader approach as in the US. The approach adopted, will have implications on innovations in food production and agriculture, pharmaceuticals and other fields related to biotechnology as well as implications related to ethical and moral reasons. The experience of the EU on patenting of biotechnology shows the scope of patentability of living organisms ultimately widening without much control.

Under the TRIPS Agreement, the exceptions in Article 27 are modeled closely on Article 53 of the EPC. The exclusion provisions of the EPC are set out in Article 53 (a) and (b), they provide that inventions and publications contrary to *ordre public* and morality are not patentable, and that plant and animal varieties or biological processes for the production of plants and animals are not patentable.[411] In addition to these provisions of the EPC, is the Biotechnology Directive Article 4 which allows for patenting of plants and animals under some circumstances.[412]



[410] *See* A. Damodaran, *Implications of Competition Policy on Biotechnology Industry in India*, *in* TOWARDS A FUNCTIONAL COMPETITION POLICY FOR INDIA: AN OVERVIEW 244 (Pradeep S. Mehta ed., 2005)

[411] Article 53(a) and (b) of the EPC provides that European patents shall not be granted for plant and animal varieties or essentially biological processes for the production of plants or animals.

[412] Biotechnology Directive, 1998 O.J (L 213) 13, 21 (EC) art. 4 states that plant and animal varieties shall not be patentable but contains some exclusion in those inventions which concern plants and animals are patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

The ECJ has interpreted the Directive and the Convention to mean that patent protection is allowed for transgenic plants where the claim is drafted in a form that it covers more than one plant variety.[413]

The lack of definition of key terms under Article 27 provides a possible solution to the problem of scope of patentability. This leaves the developing countries free to interpret Article 27 narrowly, such that the scope of patentability is not widened to the extent it is in the US and EU. However this may work against developmental goals of the developing countries since they will not be able to utilize patent rights in biotechnology optimally to enable them compete internationally by incorporating the latest technologies. The balance as to the scope of patenting rights in biotechnology is yet to be achieved.

Despite the narrow interpretation of Article 27(3) of TRIPS by developing countries so as not to allow for patenting of microorganism to the extent allowed in the US and EU, they have to a limited extent as allowed by financial and technological capabilities, embarked on biotechnology and exploitation of biotechnological inventions especially related to food production. A large number of developing countries have legislated on biotechnology for the purposes of meeting the requirements of the Cartagena Protocol on Bio safety. An illustration of such legislation is the South Africa Bio safety regulation regime through the Genetically Modified Organisms Act passed in 1997 which became effective in 1999. The Act regulates genetically modified organisms and looks into conditions the GMO and utility as well as the effect of GMO on the socio-economic situation of the community.

The effect of the biotechnology controversy and patent rights is seen in different fields of development and more importantly the agricultural field. The link between patent rights in plants and development is seen in the use of plant patents to limit farmers' free use of patented seeds. The licensing rights that are restrictive and the centralization of agribusiness

[413] *See* Case C-377/98, The Netherlands v. European Parliament and EU Council, 2001 E.C.R. I-7079, (the Netherlands and Italy instituted proceedings in the ECJ challenging the Directive).

as well as the increasing and widespread dependence on monoculture seed has a huge impact on development, including the fear that genetically modified strains will result in out crossing of the native strains. In addition to this there exists the fear of innocent infringers of patented seeds having to pay damages for use of the seeds unknowingly.

Many farmers in developing countries unknowingly using patented seed are forced to pay up technology fees to avoid being sued and going to court.[414] In addition to the problems developing countries will encounter due to loss of small farms and businesses, there will also be the problem of agricultural imports being restricted especially to the EU which has strict rules regarding genetically modified organisms. The major importers of agricultural produce for many developing countries are European countries and as it stands there is resistance to genetically modified foods in Europe.

### 5.3.3 Anti-Competitive Abuses of Biotechnology Patents

In addition to the controversy surrounding genetic engineering of plants centering on ethical arguments, a problem concerning the anti-competitive abuses of biotechnology patent rights has emerged following the advances in biotechnology. Anti-competitive abuses of biotechnology patent rights usually arise out of uncertainty as to the scope of the patent rights granted. In that the scope of rights may be too broad such that it limits innovation downstream or alternatively the scope of protection may be too broad such that it grants in some instances *per se* monopoly power such as in the case of patents on seeds. An example of the two instances can be illustrated in a case before the ECJ which deals with whether the patent rights granted on DNA incorporated in a plant or organism which has performed its function and remains present in the plant or organism is protected by patent rights by virtue of the fact that it is present in the plant or organism even though it is not performing the intended

[414] *See* Stephanie M. Bernhardt, *High Plains Drifting: Windblown Seeds and Intellectual Property Implications of the GMO Revolution*, 4 NW. J. TECH. & INTELL. PROP. 1 (2005).

purpose for which the patent is granted. The issue has arisen before the EU Courts in the case of *Monsanto Technology LLC v. Cefetra BV and Others.*[415] In this case, Monsanto instituted proceedings against the defendants who were importers of soy bean containing DNA patented in the EU belonging to Monsanto. The soy beans were from Argentina which did not grant a patent to Monsanto for the particular DNA that had been introduced into the soy bean for the purpose of making the bean resistant to the Glyphosphate herbicide. The DNA having performed its purpose remains present in the plant. Monsanto instituted claims against the importers for violating their patent by importing the soy bean from Argentina. The court in the Netherlands where the suit was instituted then presented questions to the ECJ relating to the case, the three questions presented were centered on whether infringement of patent has occurred in the Monsanto situation where the patented DNA incorporated in a seed although not performing its function or having already performed its function is commercially exploited, in such a situation is the national legislation under an obligation to provide patent protection or precluded from providing protection and thirdly the question as to whether the court in deciding the controversy should take consideration of TRIPS Agreement Articles 27 and 30. The questions illustrate that biotechnology presents an opportunity for anti-competitive practices, the only question being whether anti competition is initiated by parties taking advantage of the unclear parameters of scope of protection offered by biotechnology patents or those parties taking advantage of this unclear scope of protection to infringe on legitimately granted patent rights. For developing countries the aspect of anti-competition presents itself in the terms of licensing agreements and not through innovations in biotechnology or research. The decision of the court in the Monsanto Soya bean case will have implications for developing countries to the extent that if the defendants are found liable for patent infringement, developing countries will be forced to stop importing products

[415] Monsanto Technology LLC v. Cefetra BV and Others Case C-428/08 Opinion of Advocate General Mengozzi delivered on 9 March 2010.

containing patented DNA irrespective of the fact that they do not wish to exploit the patent, merely because the product contains genetic material that is patented. On the other hand, where countries like Argentina fail to grant patent rights for products or processes based on national legislation, they will not be able to engage in commerce or trade outside their borders in products containing patented genetic material even where the genetic material is not performing any purpose in the product thus the trade implications are extensive.

Controversy surrounds the genetic engineering of plants first because of the major ethical issues raised due to the patenting of living organisms. Patenting of plants means that the seed of the plants become the exclusive property of seed firms. This raises concerns because in the recent years seed companies have seen a rash of mergers which sees a handful of multinational corporations such as Monsanto, AstraZeneca and Norvatis having an oligopoly in the seed industry.

About 80 years ago, seeds and more specifically germplasm was not legally viewed as property.[416] The commodification of seed germplasm has two components that have been realised since seeds began to be viewed as a valuable natural resource like land or water. The first component is the ability of seed germplasm to be manipulated through technological advances such that the seed characteristics are modified. The second is the major shift in legal treatment of seed resources that addressed the technological changes in molecular biology and genetic engineering ineffectively. The question as to whether plant genomes are merely products of nature raises different answers in that if they are understood as natural then they are likely to be treated as raw material awaiting for value to be added by human intervention. Consider the time and resources spent in selecting and growing common crops such as maize, potatoes, beans and peanuts which are traditionally considered the "common heritage of mankind."[417] Taking these efforts into consideration the research and development

[416] Germplasm refers to the complement of genes that determine organism's characteristics.
[417] UN Food & Agriculture Org. [FAO], Comm'n on Plant Genetic Resources, CPGR 89/5 (Aug. 23, 1983).

investments and resulting innovation in form of a new species will deserve intellectual property protection or the innovators will lose the incentive to produce more new plant species.[418] Aside from the ethical controversy, there is a positive aspect of biotechnology and advances in the seed industry for food production and security. The seed industry in an effort to increase its market has teamed up with research institutes in developing countries to research into ways of improving crop varieties in the developing countries. On one hand, a positive aspect of these transgenic seeds is that they do not generally involve inputs that are costly, hence are affordable for a majority of small scale farmers. Another positive aspect of the transgenic seeds is that due to their very nature they do not require farmers to change their cultural practices thus easily utilised by farmers in developing countries.[419]

Other anti-competitive practices relating to the exercise and exploitation of biotechnology patents involve collaborative agreements among patent holders such as patent pools and other licensing agreements. With regard to patent pools and competition analysis as to whether licensing agreements within the patent pool are anti-competitive in the US and EU, such collaborative agreements are generally accepted where the patents in the pool are valid patents and the technology covered by the patents are essential and complementary with fair, reasonable and nondiscriminatory licensing terms being offered for nonexclusive licenses.[420] Hanns Ullrich, on analysis of biotechnology and competition with regard to patent pooling contends that "requiring an open, non-discriminatory licensing policy to everyone in third party licensing via pooling as a matter of competition law tends to convert the exclusivity



[418] *See* Keith Aoki, *Weeds, Seeds and Deeds: Recent Skirmishes in the Seed Wars*, 11 CARDOZO J. INT'L & COMP. L. 247 (2003).
[419] MATIN QAIM ET AL., AGRICULTURAL BIOTECHNOLOGY IN DEVELOPING COUNTRIES: TOWARDS OPTIMIZING THE BENEFIT FOR THE POOR 94 (Matin Qaim et al. eds., 2000).
[420] Geertrui van Overwalle, A *Man of Flowers: A Reflection on Plant Patents*, *in* TECHNOLOGY AND COMPETITION CONTRIBUTIONS IN HONOUR OF HANNS ULLRICH 327 (2009)

principle of patent protection into a mere liability system, i.e. into a reward by compensation rule."[421]

Patent thickets are identified as a common problem in the biotechnology industry and are generally described as causing "ever greening" where sets of patent rights are acquired which require individuals seeking to commercialize new technology to obtain licenses from multiple patentees. Ever greening of patents limits innovation in the sense that it raises the costs of acquiring technology and presents a barrier to further innovative developments. In addition to this, companies may divert resources from research and development to fund patenting programs that are defensive to counter the effects of patent thickets and cover legal costs.

### *5.4 Traditional Knowledge and Competition Policy*

The area of traditional knowledge and the associated rights poses to be problematic to both the right owners and the transferees or licensees of the rights, partly due to the uncertainty as to what kind of property rights traditional knowledge possesses and how such rights can be allocated to benefit the owners of the traditional knowledge. The benefit of traditional knowledge should be experienced not just by an individual who appropriates and exploits the traditional knowledge but by the community from which the knowledge is derived. This is especially where traditional knowledge is specific to a particular community or people.

The discussion of traditional knowledge will be limited to biological resources for medicinal and cosmetic purposes, agriculture, as well as production processes because traditional knowledge generally covers a wide range of issues. Traditional knowledge for developing countries is closely related to genetic resources and plant rights. The discussion of traditional knowledge and genetic resources from developing countries is usually related to medicinal

[421] Michael Blakey, *Biotechnological Patenting and Innovation*, *in* PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALISED WORLD 243 (Josef Drexl et al. eds., 2009)

and food products. The scope of traditional knowledge addressed is that for which patent protection may be possibly obtained as a form of protection.

Where traditional knowledge rights are granted patent protection there may be competition issues which are likely to arise, especially with regard to any licensing agreements and terms that may be anti-competitive, especially territorial restrictions. Other competition concerns that may arise may relate to issuing of overly broad patents which deter competition and innovation in certain areas especially in traditional knowledge related to medicines.

Traditional knowledge is important for developing countries especially since it can be described as a new form of intellectual property and therefore a source of revenue for developing countries. Many people in developing countries depend on traditional knowledge for provision of traditional medicine where due to financial and cultural reasons there is limited access to modern medical facilities.

Another important role played by traditional knowledge is in the provision of seeds. Food production is guaranteed through the continuous use and improvement of seed varieties using traditional methods. Traditional knowledge exists in many forms including biological resources and plant genetic resources.[422]

Different forms of protection may be used to protect traditional knowledge, these include, various forms of intellectual property protection, the development of a *sui generis* form of protection, and a combination of both *sui generis* and intellectual property protection. The form of protection of traditional knowledge is based on the rationale for protection. Two rationales exist, the first being to exclude unauthorized persons from accessing and appropriating the traditional knowledge while ensuring equitable redistribution of profits accrued from the traditional knowledge and the second rationale for protection can be said to

[422] The definition of traditional knowledge has an effect on the scope and kind of protection given to traditional knowledge. According to the WIPO, traditional knowledge includes information on biological resources, used for medical treatment and agriculture, production processes, literature, designs, music, rituals and other techniques and arts.

be for the purpose of preservation of the traditional knowledge from uses that may erode it or uses that are harmful to the life and culture of the communities that have nurtured and preserved the traditional knowledge.[423] The existing protection strategies have been defined as the defensive protection strategy and positive protection strategies. Defensive protection strategies seek to protect the traditional knowledge from unfair appropriation of the rights of indigenous peoples knowledge and this form of protection ranges from the establishment of databases, registers to enable searches for prior art, requirements of prior informed consent and bilateral licensing contracts as well as benefit sharing agreements, *sui generic* forms of protection. The positive protection strategies are those suggested forms of protection that aim at establishing positive property rights over traditional knowledge. These include contracts where the State enters into contractual agreements with the users of traditional knowledge allowing use of the knowledge for a limited time period in return for royalties or fees. Also included under positive protection strategies are patents and utility patents, where the traditional knowledge meets the requirements for conventional patents. There is a fear of traditional knowledge if subjected to stringent legislation in an attempt to curb misappropriation will result in the commonly referred to anti commons tragedy where many parties having the right to exclude ultimately gives rise to under utilizations and the diminishing of economic value. Developing countries in seeking to protect traditional knowledge based on its value and utility should take consideration of this perspective.



### 5.4.1 Models for Structuring Rights in Traditional Knowledge

Models for structuring rights in traditional knowledge are still under discussion and have been an emerging issue for discussion in the WIPO for 10 years. In July 2009, the 14th session of

[423] See Organization of African Unity Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources. The Model Legislation covers community rights in detail and recognizes community rights in its preamble.

the WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore finalized with the conclusion that "the parties have failed to reach a decision on this Agenda item." This proves to be a disappointment especially for the developing countries that had hopes of securing legislation governing traditional knowledge; genetic resources and folklore so as to enable them utilize the resources for the benefit of the developing world population. The apparent reason for the failure to successfully conclude the intergovernmental negotiations was according to reports, the irreconcilable differences on three issues namely, the demands for one or more internationally binding legal instruments, text based negotiations and a clear time frame.[424]

An international legally binding instrument is important to entitle indigenous communities with rights over their resources and traditional knowledge. As has been stated in the previous section, traditional knowledge poses a problem when it comes to affording it protection that ensures all parties benefit and in event of infringement the granted rights can be enforced. Professor Shuba Ghosh has come up with a comprehensive model suggesting how rights in traditional knowledge could be structured.[425]

a. Public Domain Model

Under the public domain model, the traditional knowledge and other genetic resources are available for use by the public. The public domain model allows for the appropriation of the resources for free. Many developed countries have been pushing the adoption of this model of rights in traditional knowledge mainly due to the fact that the majority of biological resources and traditional knowledge resources can be found in developing countries.[426] Were the appropriators of traditional knowledge to pay for the resources they take, wealth distribution

[424] India, China, Brazil and other developing countries held the belief that text based negotiations on a timetable and the introduction of legally binding instruments was the only means to guarantee the effective protection of local and indigenous rights in developing and developed countries, http://spicyipindia.blogspot.com/search/label/Traditional%20Knowledge.

[425] *See* Shuba Ghosh, *The Traditional Terms of the Traditional Knowledge Debate*, 11 CARDOZO J. INT'L & COMP. L. 497 (2003).

[426] *See* Aoki, *supra* note 419.

would be fairer today than what is evident. Despite the developed countries advocating for the public domain model for structuring rights in traditional knowledge as belonging under "common heritage of mankind", they are clear about distinguishing these rights from the biological resources that have been genetically engineered and hybrid lines as being "common heritage". This distinction is evident in the US case of *Diamond v. Chakrabarty*.[427]

b. Commercial Use Model

Under the commercial use model, the exclusive rights to the traditional knowledge would go to the first person who made successful commercial use of the knowledge. The shortcoming of this model is the measure of what amounts to successful commercial use of the knowledge since even small scale farmers who cultivate wild crops and produce seed for commercial cultivation can claim successful commercial usage. This ambiguity as to what amounts to successful commercial usage is a shortcoming thus rendering this model virtually unfeasible.

Another shortcoming of this model is that it will be a disadvantage for developing countries from a competition perspective. This is because developing countries suffer from limited availability of investment funds to enable individuals engage in research and development to fully exploit the traditional knowledge resources, while developed countries have firms willing to loan funds or invest in projects exploiting traditional knowledge that can be a successful commercial venture. The commercial use model has been in use and has been challenged severally by the communities owning the traditional knowledge. This is evidenced in the case of the Turmeric patent, where a patent was issued to the Mississippi Medical Center conferring on it exclusive rights to some specific formulations of Turmeric while Turmeric has been used for centuries as food and as a cosmetic in India.[428]

c. Trust Model

[427] Diamond v. Chakrabarty, 477 U.S. 303 (1980).
[428] VANDANA SHIVA ET AL., THE ENCLOSURE OF AND RECOVERY OF THE COMMONS: BIODIVERSITY, INDIGENOUS KNOWLEDGE AND INTELLECTUAL PROPERTY RIGHTS 41 (1997).

The trust model as explained by Professor Ghosh requires the rights in traditional knowledge be assigned to a third party other than the community from which the traditional knowledge originated.[429] This according to Professor Ghosh is the model advocated for under the CBD, where the CBD gives the state power to grant or deny access to the genetic material or traditional knowledge and the state will administer a royalty scheme distributing the royalty income to the appropriate traditional knowledge communities. The trust model presents problems in that using this model may result in failure to meet the requirements for patentability in that individual ownership requirement is not fulfilled. The trust model has been used in India and South Africa but has been somewhat unsuccessful.

d. Ownership Model

The ownership model confers proprietary rights of the traditional knowledge on the community or individual. The ownership model is advantageous because there is an identifiable legal entity owning the traditional knowledge. However for purposes of intellectual property rights, the community cannot be allocated patent rights in that it does not meet the requirements required for issuing of patents. Other forms of protection may be applicable. From the forgoing suggested models of protection for traditional knowledge it is evident that traditional knowledge will only in limited circumstances fulfill the requirements for patenting.



### 5.4.2 Traditional Knowledge Interaction with Competition policy

There are difficulties encountered in the commodification of traditional knowledge, which due to its very nature that may give rise to competition issues. The problems of traditional knowledge commodification are related to the nature of traditional knowledge and the issue that it is communal therefore has cultural connotations. Developing countries are a rich source

[429] *See* Aoki, *supra* note 419.

of the traditional knowledge resources and rarely engage in converting traditional knowledge into new products that are marketable. An observation has been made that part of the problem is the developing countries tend to have more interest in traditional knowledge resources transfer as opposed to encouraging innovation because they lack scientific and financial infrastructure to create patent induced innovations from their traditional knowledge resources.[430]

Traditional knowledge due to its very nature encounters various problems in the attempt to commodify it. These include problems relating to disclosure, lack of consent, identification of the traditional knowledge used in the invention, evidence of benefit sharing with the owners of the traditional knowledge.

There may be circumstances where the traditional knowledge resources are used in making an invention but there occurs a problem in disclosing the source since no one individual owns the traditional knowledge. Traditional knowledge resources are cultural in nature hence "owned" by all individuals who embrace the particular culture. Some situations arise where an inventor may fail to disclose the source of traditional knowledge purely for purposes of misappropriating the resource.

An important aspect of patenting inventions where traditional knowledge has been used is the identification of the traditional knowledge used in the invention. A traditional knowledge resource may fail to be identified so as to evade the payment of license fees or royalties.

Evidence of prior informed consent by the owners of the source of genetic resource used in the invention must also be shown so as to ensure that the inventors obtained prior informed consent from the owners of the resource, through legal and transparent means.

Evidence of benefit sharing with the owners of the genetic resource and related traditional knowledge should be available and included in the patent application for perusal by patent

[430] Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights*, 28 WAKE FOREST L. REV. 89, 121 (1993); *see also* Reto M. Hilty, *Rationales for the Legal Protection of Intangible Goods and Cultural Knowledge*, 8 INT'L REV. INTELL. PROP. & COMPETITION. L. 898 (2009).

officers. This is because in many instances the owners of the genetic resources do not benefit from the licensing and royalty fees collected on their behalf by trustees gauged with the responsibility of ensuring the funds are collected and disseminated to the community which owns the traditional knowledge.

Many patent offices especially in the developed countries fail to understand what amounts to traditional knowledge falling under the public domain as distinguished from traditional knowledge which is private. In such circumstances the patent office grants patents for those inventions made utilizing traditional knowledge in the public domain. This is detrimental to development and use especially in the developing countries. It is for this reason that developing countries have now undertaken projects to create databases which list traditional knowledge in their communities. Maintaining such databases is an onerous task since traditional knowledge is dynamic in nature. The databases although not exhaustive are made available to the patent granting agencies in the developed countries to assist while analyzing patent applications and in their determination whether a patent application fulfills the requirements for patent grant before granting the patent. An example of this is India's Traditional Knowledge Digital Library which is currently accessible to the EPO during examination of patent applications after India and EU signed an agreement allowing access to the Digital Library.[431]

Traditional Knowledge is misappropriated mostly in technological and biotechnology fields where the traditional knowledge is used as part of the research and development process and ultimately becomes part of the protected invention.[432]



[431] Under this arrangement the EPO accesses the digital Library in order to determine whether the patent application amounts to prior art.

[432] A good example of this is the Turmeric Patent (US Patent No. 5,401,504), the "Neem" (Azadirachta indica) Patents (over 40 in the US alone and more than 150 throughout the world including Europe) and the "Ayahuasca" (Banisteriopsis caapi) Patent (US Plant Patent No. 5,751) failure to recognize the products as prior art resulted in questionable patents being granted. These so called "inventions" were based on biological resources and traditional knowledge and practices of indigenous communities in India and the Amazon respectively, which have been used for centuries in these parts of the world and which were obtained without any due respect to indigenous peoples' rights over their resources, intellectual efforts and developments.

Therefore, although it is difficult to counter the anti-competitive effects of misappropriation of traditional knowledge, the creation of databases listing the available traditional technology such that the information is available during prior art searches in patent applications is a beginning. India and the US signed an agreement in 2009 allowing the USPTO to access India's Traditional Knowledge Digital Library and in so doing patent examiners will deny claims to known plants listed in the digital library even though they have been used and sold only in India.[433] The practice in the US is to allow patents for claims where the plant has not been used in the US. There has been a protest that the rejection of patents involving plants listed in the library basically amounts to the rejection of US law in favor of a non-binding agreement.[434] The proponents of patenting traditional knowledge opine that the granting a US patent on traditional knowledge does not affect the indigenous people from using the knowledge but merely bars them from using the knowledge in the US to make sell or import products that affect the issued patents. Their contention is that the owners of the traditional knowledge being "indigenous" they lack the capability to sell in the US thus they have nothing to lose.[435] Given the nature of trade today where the global market place is accessible from any part of the world through e–commerce, the argument is not convincing. However the contention that there is disregard of domestic legislation in favor of a trade bilateral agreement is strong. Following the contention and the change in practice of the USPTO, a case is yet to be decided before the courts on the issue of traditional knowledge and the use of the databases.



[433] Harold C. Wegner, *Patents on Traditional Knowledge*, 29 BIOTECH. L. REP 21 (2010).
[434] *Id.*
[435] *Id.*

### 5.4.3 Protection of Traditional Knowledge under CBD and TRIPS Agreement

The relationship between TRIPS Agreement, the CBD and the protection of traditional knowledge has so far been dealt with under review of the Article 27.3(b) of TRIPS in the WTO. The 1992 CBD recognizes the sovereign rights of States over their biological and genetic resources and it requires signatories to protect and promote the rights of farming communities and indigenous peoples vis-à-vis their customary use of biological resources and knowledge systems. The CBD signatories have added a Bio safety Protocol to the CBD which would regulate genetic modification internationally. This Protocol helps to protect the rights of countries to decide for themselves how they wish to develop their agriculture in a sustainable fashion. The Bio safety Protocol is relevant for all those countries reluctant to introduce genetically modified foods and adopt diverse agricultural practices which may have implications on the ecosystem.

The principles of the CBD state that,

> States have in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or of areas beyond the limits of national jurisdiction.[436]

The biodiversity convention applies to *in situ* and *ex situ* genetic resources acquired in accordance with the Convention but those taken and deposited in gene banks before the Convention came into force are not covered.

This implies that those resources are the common heritage of mankind and anyone can access them. Article 12 which deals with research and training, Article 17 dealing with the exchange or sharing of information, Article 18 on technical and scientific cooperation, and Article 19 on handling of biotechnology and distribution of its benefits are all provisions that can be

[436] CBD *supra* note 369

applicable to traditional knowledge, in that these provisions can be used under any model to enable an individual or group gain access to traditional knowledge for purposes of research or exploitation.

The reliance on the CBD is however limited by the fact that, access must be by agreement with the owners of the technology in this case the traditional knowledge. According to some authors, the pivotal provision of the CBD dealing with traditional knowledge is Article 8(j). Intellectual property rights are explicitly mentioned in the second, third and fifth paragraphs of Article 16.

The interpretation of Article 27 has been addressed by the Doha Declaration paragraph 19, which instructs the TRIPS Council to continue the review of Article 27.3(b) TRIPS, and to examine the relationship between TRIPS, CBD and protection of traditional knowledge.

Another point of view with regard to application of intellectual property rights to traditional knowledge is the view that for developing countries to apply intellectual property rights to protect against exploitation and misappropriation of traditional knowledge may prove detrimental to the developing countries in the long run.[437] This is because intellectual property rights protecting traditional knowledge where the developing countries lack innovative capabilities will result in the traditional knowledge being unexploited and therefore not beneficial. The solution possibly lies in having in place not only protective legislation empowering the developing countries to sell their traditional knowledge to industries that are able to exploit the knowledge but also legislation geared towards enabling the communities owning the traditional knowledge to be able to possess the relevant knowledge and resources to enable them exploit these assets on the international markets themselves. It therefore follows that, having in place strong legislation prohibiting exploitation of traditional knowledge will be self-defeating since it will not encourage and stimulate innovation and new inventions.

[437] *See* Hilty, *supra* note 432.

An analysis of traditional knowledge protection in developing countries indicates that reference is made to traditional knowledge in connection with legislations dealing with Biodiversity and the protection of indigenous communities. In India, the Biological Diversity Act acknowledges that patent rights may be granted on resources forming part of traditional knowledge when these are appropriated by foreign parties. There is therefore a need to regulate the access to these resources through national legislation which requires a person applying for patent protection to obtain permission from the National Biodiversity Board that is mandated to grant joint ownership of the patent rights to itself or an identifiable actor having contributed to the invention. The Act also contains provisions on how the benefits derived from the exploitation of the patent rights may be allocated.

In many developing countries, the debate as to how the traditional knowledge can be afforded protection still exists. The countries are yet to devise specific legislation centered on governing traditional knowledge and its appropriation.

***Summary***

The legal framework governing patents in plants, plant variety rights, biotechnology patents and traditional knowledge should be an elaborate and effective framework which would be a means through which developing countries can narrow the wealth gap between the north and the south. The US and EU provide effective and detailed legislation to govern plant and genetic resources through patents, plant variety rights legislation, plant breeders' rights and other related legislation. Although unlike the US the EU does not provide broad patent rights to living organisms, these are strictly regulated. Developing countries are plagued by the dilemma of deciding which form of protection should be granted to plant and genetic resources, whether under the TRIPS Agreement, CBD or either of the two UPOV Conventions. The TRIPS Agreement allows for protection through patents or an effective *sui*

*generis* system or any combination thereof. The anti-competitive implications relating to plant patents and patenting of plant varieties are evident in the licensing terms of large seed multinationals such as Monsanto which criminalize seed saving, which has implications on food production and food security in developing countries.

Biotechnology is intricately related to plants and plant variety rights as well as traditional knowledge since biotechnology is applied in the manipulation of genetic resources related to living matter. Although in the biotechnology industry, patents are crucial in that they provide incentives to innovate and outline the scope of protection to allow for competitors to innovate on new products, there is an ethical and moral debate as to what is patentable and what is not patentable. The exclusion of living matter from patentability is an issue that has been left to the individual States to decide. The patentability of living matter has the effect of broadening the scope of patentability which can have anti-competitive effects, by deterring innovation where competitors fear innovating and infringing on an existing patent.

Where the patent owner is in a dominant position relating to a process or product, then anti-competitive issues arise where the patent owner can set prices as they wish. This is best illustrated in the seed industry where Monsanto and a few other seed companies are gaining monopoly rights over food production through owning genetically modified foods. Licensing agreements entered into by farmers with these companies usually contain unfair terms and these have serious implications on food production and food security worldwide. The developing countries are therefore deeply impacted by the trade and ownership of seed germplasm.

Traditional knowledge is a resource largely held by developing countries. The attempts to legislate on traditional knowledge, genetic resources and folklore under the WIPO have failed miserably due to the inability to come to agreement on key issues relating to the codification of the traditional knowledge. This is because the traditional knowledge exploitation once

codified will render inaccessible numerous resources used by developed countries in research and development of new products. The communal nature of traditional knowledge plays a key role in the difficulty to commodify traditional knowledge and find a suitable model under which traditional knowledge rights may be structured. The applicability of patent rights to traditional knowledge is in many circumstances not feasible mainly due to its communal nature, having no individual owner, determining its novelty, and inventive step requirements. In many circumstance the traditional knowledge must be modified to fulfill the inventive step requirements. Developing countries unfortunately in many circumstances lack the financial resources and technological capability to engage in such modifications. The only viable option for those countries lacking such technological capability is to appropriate the traditional knowledge to firms in industrialized countries in exchange for reasonable returns.

# 6 TECHNOLOGY TRANSFER AND COMPETITION POLICY INTERACTION

## *6.1 Introduction*

Technology transfer for developing countries focuses on two aspects which are firstly the acquisition of technology[438] and diffusion of the technology. The issue of transfer of technology to developing countries culminated into a debate as early as the 1970s, leading to the unsuccessful launching of negotiations on a draft International Code of Conduct on the Transfer of Technology.[439]

Developing countries rely on imported technologies to foster productivity and development as well as enable their integration into the global economy.[440] Licensing is an important source of technology transfer to developing countries. The presence of intellectual property protection is crucial since firms will refuse to license their technology where it will be subject to imitation and where the payment of license fees is not guaranteed.

The reluctance to license due to fear of imitation has been a problem in developing countries which have poor enforcement of intellectual property rights and weak competition policies. The consequences are that the owners of technology refuse to license or offer lagging technology for licensing. The technology owners may also opt for foreign direct investment (FDI), where they retain control of the know-how as opposed to licensing as a method of technology transfer. In such a situation, developing countries cannot effectively compete in the international market.



[438] In developing countries the acquiring of technology usually means adapting the technology to local circumstances. *See* Bernard M. Hoekman et al., *Transfer of Technology to Developing Countries: Unilateral and Multilateral Policy Options* (World Bank Policy Research Working Paper No. 3332 2004), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=610377.

[439] These negotiations ended in 1985 and were not successful. *See* PATEL, ROFFE, YUSUF, INTERNATIONAL TECHNOLOGY TRANSFER: THE ORIGINS AND AFTERMATH OF THE UNITED NATIONS NEGOTIATIONS ON A DRAFT CODE OF CONDUCT (2001).

[440] *See* Hoekman et al., *supra* note 479.

This Chapter discusses limitations on technology transfer through unreasonable licensing terms and conditions which present anti-competitive effects with implications for developing countries which are generally licensees of technology. Anti-competitive licensing terms and conditions that have negative effects on transfer of technology include territorial and field of use restrictions, royalty requirements which exceed the patent grant period, tying arrangements and price restrictions.

### *6.2 Role of Patents in Technology Transfer*

Patents play an important role in the transfer of technology since the patent documents contain a detailed description of the invention and the technology patented in fulfillment of the disclosure requirement that can allow others to reproduce the technology. The disclosure requirement when fulfilled gives a full description of the prior art thereby providing a broad outline of the technology.

Most importantly patents play a role in facilitating transfer of technology in that the patent documents identify the inventor and applicant which enable third parties interested in licensing the technology to do so directly without going through intermediaries which increases transaction costs.

Broad statements with regard to technology transfer for developing countries have been made in the TRIPS Agreement, although the agreement does not establish a direct link between enforcing intellectual property rights and promoting domestic transfer of technology. The TRIPS Agreement highlights the importance of transfer of technology in technological innovation in Article 7, which states that,

> [P]rotection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and

> users of the technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[441]

Article 67 of TRIPS also deals with technology transfer in that it calls for technical cooperation, where developed countries are invited to provide technical and financial cooperation in favor of developing and least-developed countries. In the case of least-developed countries the agreement calls on developed countries to provide incentives to enterprises and institutions for the purpose of promoting and encouraging technology transfer so as to assist least-developed countries develop a sound and viable technological base.

### *6.3 Transfer of Technology Obligations under TRIPS Agreement*

The obligation on developed countries to facilitate the transfer of technology to the least developed countries under the TRIPS Agreement is set out under Article 66(2). The provision is interesting in the sense that it is a positive obligation on developed countries to provide incentives for their institutions and enterprises encouraging them to engage in technology transfer to developing countries. A crucial question which is yet to be satisfactorily answered is whether this positive obligation on developed countries may give rise to competition issues in the sense that Article 66(2) could be relied on in event that a technology transfer arrangement proves to be anti-competitive in nature.

Under Article 67 developed countries are obliged to provide technical and financial cooperation on mutually agreed terms in order to facilitate implementation of the TRIPS Agreement. The provision specifies a wide range of assistance developed countries are obliged to render which range from the assisting in the establishment of intellectual property agencies and training of personnel as well as in assistance in drafting of suitable intellectual property laws and enforcement regulations. Unfortunately the conditions for assistance mostly

[441] TRIPS Agreement art. 7.

tend to seek to strengthen the intellectual property rights and ensure enforcement rather than dealing specifically with facilitating transfer of technology. Developing countries should utilize this provision to advocate for specific obligations in future negotiations under the TRIPS Agreement especially with regard to the technologies that can be transferred and the definition of what amounts to a developed country to which the provision is applicable.

### *6.4 Transfer of Technology under CBD*

The CBD, in Article 1 explicitly refers to transfer of technology as a means to implement its third objective which is to ensure the fair and equitable sharing of benefits arising out of utilization of genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies and by appropriate funding.[442]

Articles 16 to 19 of the CBD are concerned with technology transfer and patent rights. Article 16 recognizes that both access to and transfer of technology among the contracting parties is crucial to attainment of the objectives of CBD.[443] Article 16 goes further to provide guidance on environmentally sound management of biotechnology as well as establishing mechanisms for the development as well as sound application of biotechnology.

Article 16(2) states that where a technology is subject to patents and other intellectual property rights, access and transfer of that technology shall be provided on terms that are consistent with adequate and effective protection of intellectual property rights.

Article 16(3) requires Parties to the CBD to take legislative, policy and administrative measures which will allow parties providing genetic resources be given access to technologies that will enable them make use of their resources. These measures should be provided on mutually agreed terms. A good illustration of this is the agreement between the University of

[442] *See* CBD, art. 1, *supra* note 369.

[443] *Id.*, art 16 (providing that each Contracting Party "undertakes ….to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.").

California and the Government of Samoa on the use of the *mamala* bark for developing AIDS treatments, in exchange for preferential access to resulting technologies.[444]

Article 16(4) requires parties to take legislative, administrative and policy measures aimed at the private sector that facilitate access to joint development and transfer of technology for the benefit of both governmental institutions and private sector of developing countries. Article 16(5), recognizes that patents and other intellectual property rights may have an influence on implementation of the Convention and goes further to stress that subject to national and international law, parties should cooperate to ensure that these intellectual property rights are supportive of the CBD and do not run counter to its objectives.[445]

Article 17 of CBD is important in that it requires the parties to facilitate the exchange of information relevant to the conservation and sustainable use of biological resources, taking into account the special needs of developing countries. This provision is interesting in the sense that its reference to special needs of developing countries is not specific as to what exactly entails special needs. The provision however goes further to state that this information exchange shall include, "results of technical, scientific and socio-economic research, as well as information on training and surveying programs, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16 paragraph 1."[446]

Article 18 of CBD requires parties to promote international technical and scientific cooperation in the conservation and sustainable use of biodiversity while giving special attention to the need to strengthen national capabilities through human resource development and institution building. In addition to this, cooperation is required for the development and use of technologies, including indigenous and traditional technologies.



[444] *See* Conference of the Parties to the Convention on Biological Diversity, March 20-31, 2006, *Technology Transfer and Cooperation* UNEP/CBD/COP/8/INF/32 (Feb. 15, 2006) *available at* http://www.cbd.int/doc/meetings/cop/cop-08/information/cop-08-inf-32-en.pdf (last visited Aug. 11, 2009).
[445] *See* CBD *supra* note 392.
[446] *Id.* art. 17.

Technology transfer can be addressed under both CBD and TRIPS Agreement. There is however confusion over which legal system supersedes the other. The problem here occurs when developed countries rely solely on the protectionist provisions of the TRIPS Agreement with the intention of protecting their patent rights to the exclusion and disregard of the obligations under the CBD. When this happens, developing countries on failing to reach an agreement with the technology owners have no option but to abandon their efforts of acquiring the technology. Under such circumstances the developing countries cannot rely on the available flexibilities under the TRIPS Agreement unless the technology needed fulfils the requirements for compulsory licensing.[447]

### *6.5 Developments in Technology Transfer to Developing Countries*

Access to technology is still a major problem for many developing countries, which is further heightened by their adoption of strengthened national intellectual property regimes presenting barriers to cheaper means of accessing the technology. In addition to this, there has been no sustained and consistent effort to facilitate and promote access to technology by the developing countries themselves.

The debate on transfer of technology prompted the WTO Ministers in Doha to adopt a Ministerial Declaration which provided for the establishment of a working group on trade and transfer of technology.[448] Under paragraph 37 of the Doha Declaration, the Ministers agreed to establish a working group under the General Council, which was to examine the relationship between trade and transfer of technology and come up with recommendations



[447] TRIPS Agreement art. 30 providing the requirements to be fulfilled prior to the issuing of a compulsory license as previously outlined are under Article 30 of the TRIPS Agreement. The provision sets out three substantive requirements that must be fulfilled for there to be an allowed exception to patent exclusivity. (1) Must be a limited one; (2) cannot "unreasonably conflict with a normal exploitation of the patent;" and (3) cannot "unreasonably prejudice the legitimate interests of the patent owner, taking into account of the legitimate interests of third parties."

[448] Doha Declaration para 37.

that may increase flow of technology to developing countries. This resulted in developing countries writing proposals and recommendation papers for possible changes.[449] The issues addressed covered the extent to which the developed world has fulfilled the promises of transfer of technology in exchange for strengthened intellectual property laws in developing countries.

Technology transfer requires the cooperation of both the technology owners and the technology users. The developing countries should ensure they have created a sound technological base that will allow them access the appropriate technology to meet their needs. On the other hand, industrialized countries should strive to provide technology on fair and reasonable terms to developing countries which will be mutually beneficial to both parties.

### 6.5.1 Licensing and Technology Transfer to Developing Countries

Licensing of technology is crucial for developing countries in their efforts to acquire new technologies and compete effectively in today's markets. In addition to the role played by patents, other mechanisms that facilitate technology transfer include putting into place clear legal remedies against abusive licensing practices as well as engaging in capacity development and training. The attempts at licensing of technologies are severely limited by the high licensing transaction costs. The consequences of these limitations are that developing countries are not able to effectively compete with developed countries, especially taking into considerations that they are mainly users of technology and not innovators.



[449] Non Paper submitted to the Council for Trade Related Aspects of Intellectual Property Rights by South Africa WTO Ref: Job (02)/156.

#### *6.5.1.1 Limitations to efficient Technology Transfer*

Developing countries encounter limitations to technology transfer mostly stemming from failure to plan for the technology, have in place a technological base and identify the needed technology. The limitations to technology transfer include inadequate national capabilities such as human resources and institutions required to use the technologies available. Those limitations encountered as a result of patent protection usually stem from resource and capacity constraints of the patent offices, specifically prior art searches and granting of overly broad patents.

Weak intellectual property protection and enforcement procedures also pose a barrier to technology transfer in that owners of technology fear they will be subject to imitation and little compensation in event of infringement of their rights. In response to the lack of strong protection, there is limited voluntary technology transfer.

Another limitation of technology transfer for developing countries is evident with failure to acquire and use environmentally friendly technology. The importance of this is that when it comes to exports, developed countries which are the target market for developing countries products usually adopt standards at national level that ban imports not complying with certain environmental requirements. Here, the lack of access to alternative technology that complies with these environmental requirements poses a problem for exports from developing countries.[450]

Weak intellectual property protection and enforcement procedures also pose a barrier to technology transfer in that owners of technology fear they will be subject to imitation and little compensation in event of infringement of their rights. In response to the lack of strong protection, there is limited voluntary technology transfer.

[450]A good example is provided by the case of a substitute to chlorofluorocarbons (CFCs). India found difficulties to get access to technology for HFC 134 A, which is considered the best available replacement for certain CFCs. That technology is covered by patents and trade secrets, and the companies that possess them are unwilling to transfer it without majority control over the ownership of the Indian company.

Anti-competitive practices relating to patent protection may also limit technology transfer. These anti-competitive practices aimed at pushing the competition out of the market through registering overly broad patents, tying patents, imposing crippling territorial and field of use restrictions as well as prohibiting dual use of the acquired technology present barriers to technology transfer. In addition to these, there are usually high royalty fees and licensing transaction costs incurred by developing countries seeking to acquire technology.

Due to poor capacity for registration and granting of patents, patent office's such as KIPO in Kenya resort to registering patents without investigating whether they comply satisfactorily with all patenting requirements simply because the patents have been registered previously in developed countries. This blind acceptance paves way for anti-competitive practices such as the fraudulent extension of a patent past the required 20 years, further blocking out competition. This also has implications on blocking out domestic competition which cannot engage in imitation of technology whose patent has in reality expired.

For technology transfer to be beneficial for developing countries there must be in place qualified and experienced human resource to manage, maintain and improve on the technology. In addition to this, there must be in place adequate infrastructure to operate and utilise the acquired technology. Lacking these two factors simply results in the acquired technology being wasted. There exists a serious problem of lack of human resource and this is compounded by failure of Universities and research institutions to cooperate in research and development endeavours. A problem of brain drain also exists with qualified persons from developing countries migrating to developed countries where better remuneration and living standards are offered. The problem of lack of adequate infrastructure is compounded by poor governance, lack of accountability in management of resources and rampant corruption.

### *6.6 Anti-Competitive Patent Practices Affecting Technology Transfer*

Technology transfer takes place in the pharmaceutical industry, research on plant varieties and plant breeders, biotechnology, traditional knowledge and genetic resources. The main method by which technology transfer takes place is by licensing of technology by owners of technology. In the various areas of interest for developing countries, it is fair to say that a standard requirement for fair competition exists. However, there may be anti-competitive practices in the bid to acquire technology.[451] To curb such anti-competitive practices, it is necessary to have in place clear legislation and guidelines governing technology transfer in addition to legislation governing intellectual property.[452] Legislation and guidelines governing transfer of technology will play a dual role of protecting the technology owner's rights by ensuring returns on the invention and providing certainty that the rights are protected from infringement thus encouraging more technology transfer agreements. In an effort to encourage the equitable transfer of technology and benefit from the technology transfer obligations of developed countries that are outlined in the TRIPS Agreement and CBD, developing countries should set up specialized Commissions addressing technology transfer issues. The Commissions should be mandated to address issues such as highlighting the areas where technology is needed and ensuring that the needed infrastructure to support and utilize the technology is present. The Commission should also be able to address the issue of human resource, through the provision of skills and knowledge and offering opportunities for further acquisition of skills and knowledge with the guarantee that the knowledge and skills will be utilized in the developing countries. The monitoring and provision of opportunities to



[451] The anti-competitive practices may be through licensing restrictions in the terms relating to field of use restrictions and territorial restrictions, broad patent applications, tying patents and fraudulent extensions of patent periods so as to receive more royalty payments.

[452] An example of good guidelines and legislation governing technology transfer is the EU Technology Transfer Block Exemptions. In a Kenya the technology transfer guidelines are limited to the licensing agreement terms set out in the Industrial Property Act (2001).

improve on transferred technology through providing incentives to innovate and encouraging local investment in research and development will also result in efficient technology transfer.

***Summary***

The enforcement of competition policies and patent rights influence whether for not a developing country will benefit from technology transfer. This is because a patent owner is reluctant to license its technology under circumstances where patent rights are not protected nor are competition policies enforced due to the fact that their technology may be subjected to imitation with translates to loss of revenue for the patent owner.

Developing countries unlike the US and EU lack elaborate legislation and case law covering transfer of technology, with provisions being contained in intellectual property legislations.

Under TRIPS and CBD, industrialised countries are under an obligation to transfer technology to developing countries under fair and reasonable terms. Technology transfer to developing countries however faces certain barriers originating from within the developing countries themselves which include lack of institutional and human resource capabilities to use the technology effectively. This coupled with poor governance and procedures for procurement of technology do not help developing countries benefit from technology transfer.

On the other hand, there are barriers to technology transfer which originate from the industrialised countries through licensing restrictions that have anti-competitive effects. Territorial and field of use restrictions, tying practices and unfair terms resulting in extending the patent period beyond 20 years. Tying practices may force developing countries to purchase technologies they do not need, and territorial and field of use restrictions may prevent technologies from being put to other uses where it would be most valuable for developing countries. The implications of these practices is that developing countries are

forced to adopt lagging technologies for which patent rights have expired but these are not efficient enough to allow them effectively compete in the global market.

## 7 CONCLUSION

The basic proposition of this paper has been that when patent rights and competition policy interact, the interaction may give rise to an anti-competitive effect which may have negative implications for developing countries. The interaction may take place in the course of trade where developing countries are party such as in licensing agreements between technology owners and licensees in developing countries. The interaction may also take place where the exercise of patent rights by a patentee in circumstances where there is market dominance hinders competition giving rise to detrimental effects for consumers in developing countries.

The paper has examined the interaction in several fields of relevance to developing countries and has suggested the possibility of resolving or minimising these anti-competitive effects being found both in the implementation and enforcement of the TRIPS Agreement provisions, and competition policies.

Developing countries attach great importance to the provisions of the TRIPS Agreement dealing with competition since they are under the impression that intellectual property rights are a stimulus to investment and innovation and contain pro-competitive elements. This is partly true although the benefits regarding investment, innovation and pro competition are largely being enjoyed by the developed countries.

The TRIPS Agreement recognises the possibility of intellectual property rights having anti-competitive effects and thus grants Member States the authority to implement rules on anti-competitive practices without violating their obligations under the agreement. TRIPS also recognises that some licensing practices or conditions pertaining to intellectual property rights have anti-competitive effects which restrain and adversely affect trade, acting as barriers to technology transfer which is important for developing countries.

Following the overview of competition legislation in developed and developing countries undertaken in this study, it is evident that the developed country jurisdictions of the US and

EU have a history of applying competition law and having in place competition policies aimed at supporting intellectual property rights with the objective of encouraging innovation through fostering an environment of fair competition. The US provides a good illustration of the different approaches adopted by the courts in dealing with patent rights and the abuse of patent rights through monopolistic practices. The enactment of guidelines relating to licensing and exercising of patent rights that were developed in the US indicates the necessity for rules and guidelines in addition to legislation to ensure a balance between the exercise of patent rights and the encouraging of competition is maintained without one regime infringing on the other. The developing countries while recognising the need for adequate competition policies have to a large extent not made similar efforts. The developing countries have gone as far as recognising the need to find a balance but have not put in place the relevant rules and regulations. The interaction between patent protection and competition policy in developing countries is therefore largely unregulated and relies on respective legislations relating to intellectual property and competition law.

### *7.1 Implications for Developing Countries*

The implications of the anti-competitive effects resulting from the interaction between patent rights and competition policy are mainly associated with pharmaceutical products, food production and agriculture, bio piracy and transfer of technology.



1. *Implications of Pharmaceutical Patents and Competition Policy Interaction*

The interaction may in circumstances where dominant position is held by the patent owner in the pharmaceutical industry, have anti-competitive effects with consequences on the consumer in the developing countries. This is evident where pharmaceutical patents result in high prices for medicines necessary in the treatment of HIV/AIDS, malaria and tuberculosis.

As a consequence of these high prices, essential drugs are inaccessible to a large portion of the population needing them. The numbers speak for themselves with more than 21 million people having died of AIDS since 1981 according to the WHO. Today, there is an estimated 33.4 million people living with HIV/AIDS, in developing and transitional countries there are 9.5 million people in immediate need of life saving drugs and of these only 4 million are receiving the necessary drugs.

In addition to the numerous deaths resulting from inaccessibility to costly medicines, there are socio-economic implications since majority of the deaths tend to be adults who are the labour force in developing countries. This results in the economy stagnating and slow economic development. The economic consequences of the HIV/AIDS crisis to a large extent have contributed to the developing countries declaring the HIV/AIDS catastrophe a national disaster.

2. *Implications of the Interaction on Plants, Genetic Resources, Traditional Knowledge and Biotechnology*

In the fields of plants, plant variety rights, traditional knowledge and biotechnology, the anti-competitive implications for developing countries mainly concern food production and food security for both the present and future generations. The anti-competitive effects of patent and competition policy in this regard have implications evident in the declining levels of food production and lack of guarantee for food security. These implications have been largely felt due to the issuing of plant patents and patenting of living organisms. The patent rights and competition policy interaction is also evident in the seed industry where monopolies such as Monsanto are legally able to thrive and expand. In developing countries companies such as Monsanto have affected agriculture and food production through owning seed germplasm and forcing farmers to buy seeds. In addition to this, there is the threat of rendering extinct local

seed races and replacing them with seeds incorporating hazardous technology such as the terminator technology. The prohibition of seed saving and licensing agreements relating to seed use from the seed companies such as Monsanto have made farmers liable to costly law suits for using seeds which were previously free of charge. The inapplicability of the Bio safety protocol of the Convention on Biological Diversity due to lack of sufficient financial resources and manpower presents a problem in that the harm likely caused by genetically modified organisms may not be minimised or stopped thereby having negative effects in the future. The practices of corporations such as Monsanto illustrate how the exercise of patent rights in certain situations where access to substitutes is limited can give rise to anti competition practices that are detrimental to the consumers in developing countries on a wide scale.

Bio piracy and misappropriation of traditional knowledge through patenting has implications on the local communities and countries from which the genetic resources and traditional knowledge comes from because once patented, the resources are rendered inaccessible by these communities for the duration of the patent. In some cases, the community may be forced to pay for resources that were previously utilised freely.

*3. Implications for Transfer of Technology*

With regard to transfer of technology, it is recognised by developing countries that transfer of technology contributes greatly to economic development. Where there is a barrier to technology transfer the developing countries stand to lose on economic development and progress. Under the TRIPS Agreement, developed countries are mandated to promote and encourage transfer of technology by offering incentives to their own industries and firms so as to encourage investment in developing countries and transfer of technology thereof. It is therefore the responsibility of developing countries to build adequate capacity and have a

viable technological base for technology transfer to be effective. Where there is a barrier due to unfair terms of technology transfer licensing agreements. Solutions through sound competition policies should be applicable.

### *7.2 Recommendations and Proposals for Developing Countries*

The interaction between patent rights and competition policy has demonstrated that a purely legalistic approach to resolving the effects of the interaction is not feasible. Legislation should be coupled with an economic analysis and sound policies being implemented in circumstances where the interaction takes place and is likely to produce anti-competitive effects. Notice should be taken of the field of patent rights in event of the interaction and consequences thereof, taking into consideration that there are different paces at which different fields of patent rights develop. A good example is the biotechnology field which is fast changing therefore uncertainty exists as to the anti-competitive effects and implications of these effects. In such fast changing fields of patent rights, the implications on developing countries are only realised at a much later stage, sometimes after the harm has taken place. It is therefore in adopting a flexible approach in analysing the interaction in the different fields of patent rights that a suitable solution can be applied.

Developing countries also need to endeavour to meet their obligations under regional and international agreements they are party to. There is concern that developing countries make formal commitments but do not implement these agreements. Developing countries enter into unrealistic and unfeasible agreements which are difficult to implement due to resources among other factors. These agreements are usually not beneficial for promoting trade and development. This can be illustrated by the ambitious treaties and protocols entered into by East African Community countries which lack the resources to implement and enforce these

treaties and protocols. The effects are also realised in the sense that the countries lose credibility at international level.

### 7.2.1 TRIPS Related Proposals

*Provisions regulating licensing of patent rights:* A review of TRIPS incorporating detailed pro competition provisions aimed at regulating licensing practices would assist developing countries avoid the anti-competitive licensing terms they are forced to endure in the procurement of essential technology. These provisions regulating licensing practices should model their provisions borrowing from licensing guidelines of industrialized country jurisdictions such as the EU but modified to fit the licensing needs of the developing countries which usually need licensed technology for industrialisation.

*Patentability criteria and scope of patent rights:* Review of legislation specifying patentability criteria and resolving issues related to scope of patent rights in patenting of living organisms and plants. The review and adoption of uniform interpretation of TRIPS Agreement Article 27.3 will resolve numerous issues relating to patent rights and the effect on competition.

Review of the standards of patentability to include collective and communal property ownership will allow the patenting of traditional knowledge, which will make its commodification easier for the benefit of developing countries. The review of patentability standards should also be specific enough so as to curb the ever broadening scope of patent rights.

*Legislate on compulsory licensing and mandatory disclosure of origin:* Developing countries should in addition to incorporating the TRIPS Agreement in their intellectual property legislation, also legislate on compulsory licensing parallel import and bolar provisions through detailed and comprehensive provisions within the main IP legislation or in separate

Statutes. The advantage of having in place comprehensive legislation is that it will make it easier to exploit these flexibilities as well as create certainty which encourages investment from both domestic and foreign sources.

With regard to mandatory disclosure of origin requirement, an amendment of TRIPS Agreement to include a mandatory requirement for disclosure of origin of genetic resources and associated traditional knowledge that are subject of patent applications is a possible solution to the problems associated with bio piracy and misappropriation of genetic resources and traditional knowledge by developed countries. The proposal should incorporate the goals of the CBD on ensuring access to benefit sharing in genetic resources. The introduction of such an amendment to the TRIPS Agreement introducing the mandatory disclosure requirement will make the patent system more transparent and credible, especially if legal consequences are applied in event of non-compliance of the mandatory disclosure requirement.

International obligations regulating the issues of traditional knowledge and bio piracy should be adopted especially since the issue of bio piracy has international dimensions and alternative *sui generis* means of protection resorted to once patent rights produce anti-competitive effects that have detrimental implications for developing countries.

*Differential application of TRIPS based on level of development:* The international nature of the TRIPS Agreement with its uniform applicability should be reviewed since different countries have different levels of development. The countries should be allowed to apply the agreement based on their level of development, such that there is a differential application of the TRIPS Agreement. This differential application of TRIPS will allow for a situation where countries are under no obligation to patent products or processes that are essential for development or for national disaster purposes. The basis for determining the differential application of TRIPS should be purely economic level of development. This means that least

developed countries and developing countries can be allowed to suspend patents in a certain industry crucial for their development for a strictly limited period of time during which they can access the needed technology. The fields under which the differential option is application should also be specified due to the negative implications that the approach is likely to have on the incentive to innovate as evidenced when the pharmaceutical companies were forced to issue voluntary licenses for production of patented HIV/AIDS medicines for use in developing countries which resulted in drastic lowering of prices. The effect of issuing the voluntary licenses was that the amount invested in research and development for HIV/AIDS and other diseases prevalent in developing countries plummeted sharply. The difference between this differential application of TRIPS and compulsory licensing is that it will cover both products and processes, there will be no lengthy procedure to be followed before applying the option like that for compulsory licensing and it will involve technology transfer under compulsory basis.

### 7.2.2 Institutional Proposals

1. *General Recommendations.*

National institutions and competition bodies working in collaboration should encourage governments of developing countries to utilise their government use procurement legislation to procure patented products and processes having anti-competitive effects.

Developing countries should collaborate with developed countries and push for the creation of a global fund such as suggested by Norvatis for funding research and development for neglected diseases that are prevalent in developing countries. This will ensure cooperation between the private companies undertaking the research and the relevant governments which will be beneficial for the consumers in developing countries. The collaboration will also

eliminate the need for coercion and conflict with private companies thus allowing both trade rights and human rights to be upheld.

Encouraging innovation in developing countries should be undertaken through prize models and other incentives for research institutions that aim at increasing funding such that researchers can benefit through such prize models.

Regional intellectual property bodies such as ARIPO and OAPI should play an active role in assisting with provision of training for patent officers on intellectual property administration. In addition to this, they should reduce the resource burdens on national offices by streamlining the procedures of patent applications and providing information on patents granted in the respective countries, making the information easily available for investors.

2. *Proposals Relating to Plant Patents and Agriculture*

Developing countries should push for agricultural issues to be tabled once more before the WTO after having developed a proper and feasible proposal which will balance the needs for farmers in developed countries and those in developing countries so as to reduce the current trade disadvantages since the issue is of extreme importance to both parties.

3. *Transfer of Technology Proposals*

The establishment of contact offices dealing with technology transfer in research institutions, universities and other public organisations could make identifying technology needed for development easier. In so doing the developing countries are better able to engage in capacity building and identifying where the technology can be received from. This also facilitates building of the necessary base for the needed technology and accessing the technology. Such identifiable and centralised contact offices for technology transfer will allow setting of specific goals related to technology transfer making it easier to liaise with the developed

country partners from which the technology comes from. Emphasis should be placed also on transfer of knowledge and not only technical technology. Due to little industrial capacity and lack of finances and skilled manpower, developing countries should seek to build on these three issues mainly through education and promoting industrialisation geared at provision of the essentials for better living standards before embarking on more challenging technological advances.

A possible answer to technology transfer is the establishment of innovation centres in developing countries which are funded by key players in the particular industry from international development partners, national and international business and the government. The innovation centres should be for the primary purpose of building local capacity, encouraging enterprise and providing finance for developing technologies needed at that particular time and for the future. This is an ideal solution in that it is industry specific and dealing with the particular circumstances of a country therefore applicable in that particular developing country. The idea calls for a shift in focus from technology transfer to technology collaboration.

On the legal aspect of encouraging technology transfer, developing countries should endeavour to provide legislation governing technology transfer that ensures the rights of the patent owner are protected where technology is licensed and providing adequate enforcement of rights for the technology owners. This will encourage accessibility to licensed up to date technology for developing countries.

4. *Traditional Knowledge and Genetic Resources Proposals*

The protection of traditional knowledge from misappropriation through systematic disclosure through databases accessible to patent offices prevents the granting of patents on traditional knowledge resources. Where traditional knowledge can be unintentionally disclosed, strategies to prevent the unintentional disclosure through a registration mechanism can be

adopted where an informal innovation can be registered such as a petty patents system which allows registered traditional knowledge holders the right of precedence where issues relating to filing of applications for protection of traditional knowledge arise.

High costs of patent filing applications usually present a barrier to the filing of applications involving traditional knowledge since most times the communities are poor. To counter this problem, traditional knowledge owners can resort to collective filing of patent applications through local associations so as to share costs.

Emphasis on collaboration as opposed to selling of traditional knowledge should be encouraged where the local community wishes to sell to foreign companies which modify the traditional knowledge then acquire intellectual property protection for the modified traditional knowledge. The developing countries should be encouraged to instead seek means of exploiting the traditional knowledge themselves and making it marketable in the global markets. This will have long term benefits for developing countries as opposed to exchanging their resources for cash.

### 7.2.3 Competition Policy Proposals

1. *Consumer Welfare and Developmental Objectives.*

Sound predictable and enforceable intellectual property rights are essential for economic growth. Pro-competitive policies should be enacted which respect the freedom of licensing and encourage technology transfer for the benefit of the patent owner and the licensee in the developing country.

Competition policies in place in developing countries should be welfare based in that they should focus on the effect on consumer welfare such as those of the EU TTBER and the US 1995 Intellectual Property Licensing Guidelines which apply an effect based approach. This will ensure the consumer welfare of the developing country population is placed foremost in

determining competition disputes. A good example is South Africa which has the objectives of ensuring social benefits and equality as the basis for its legislations.

A suitable solution under competition policies is that which is based on balancing developmental goals of the developing country through making an analysis to determine which economic aspects should be encouraged whether patents, competition or both. This determination should take into consideration economic aspects and following this legislate accordingly. The ideal solution would be to attempt a balance that ensures competition policy while protecting consumer welfare also encourages innovation and in collaboration with patent rights provides an incentive for innovation. This approach therefore requires flexibility and recognition that patent rights should not be limited unfairly through competition policy. This has been illustrated by India which while seeking to build and expand its pharmaceutical generic industry, enacted legislations relevant to protect and guide the industry to the level it stands today, as the 4th largest generic manufacturer in the world.

Developing countries can rely on the jurisprudence and case law of the EU and US in this regard. The EU has already established the principle that a firm having dominant position and refuses to grant a license is under an obligation not to charge excessively high prices for its products. This principle as illustrated in the *Volvo Case* can be relied on by developing countries when faced with similar situations. The adoption of competition policies similar to those of the EU by these countries also implies that a similar interpretation is likely to be adopted by the courts.

2. *Tailor Made Competition Policies Based on Economic Goals*

The push by international institutions and developed countries to adopt a universal or model competition policy or any competition policy for the sake of having one should be ignored by developing countries. The countries should instead strive to enact a competition policy geared towards development.

Competition authorities while carrying out their duties should keep in mind situations may arise where the interest of the society supersedes the competition provisions and in such cases in the face of anti-competitive behavior then competition rules may be dispensed with. In case of intellectual property rights, they should be upheld where the benefits outweigh the harm in terms of consumer welfare and this translates to better living standards and access to basic necessities of food, health and shelter for the people in developing countries.

3. *Establishment of Specialized Institutions to Regulate and Adjudicate on Patents and Competition Policy.*

In dealing with cases relating to anti competition and intellectual property rights, the establishment of an international competition and intellectual property authority for developing countries operating together with the WTO Dispute Resolution Body would assist developing countries address their grievances originating from anti-competitive abuses by large multinational corporations, especially in cases where the government is helpless to act. This would assist the non-governmental organizations by providing a forum for their grievances aside from the public outcry endlessly directed towards the WTO by the non-governmental organizations where there are negative implications for developing countries resulting from the TRIPS Agreement.

Developing countries encounter an internal barrier within their judicial bodies through the archaic interpretation of legal provisions relating to the interaction between patent rights and

competition policy, where the judges are not informed on dynamic technical fields such as biotechnology patents.

Developing countries on the national front should aim to have in place specialized tribunals and courts to deal with matters relating to intellectual property rights such as those present in the US and EU. Having such specialized agencies tribunals and courts will mean that matters of dispute relating to intellectual property rights and competition policy will be tabled before experts knowledgeable in the field therefore able to adequately adjudicate the matters while taking into consideration all the relevant legal and economic aspects.

4. *The Barrier of TRIPS Plus Provisions for Developing Countries*

The implementation of strong TRIPS plus provisions by developing countries without proper examination of the effects of implementing these provisions has proved to be a barrier to development and minimizing the implications of the interaction between patents and competition policy. In addition to this, the reluctance by developing country governments to utilize the flexibilities inherent in TRIPS Agreement due to fear of repercussions by development partners or withdrawal of development assistance is a major barrier.

Legislation should be well drafted in a comprehensive manner so as to make it understandable to parties involved in agreements related to licensing and technology transfer. This is because poorly drafted legislation leaves lacunae for misrepresentations which may be detrimental in encouraging investment and transfer of technology to the developing countries.



### *7.3 Recommendations and Proposals for Developed Countries*

Recognition that there are different levels of development between developing and developed countries will have implications on patent rights and competition policy interaction. In recognizing that the effects will have a larger impact on developing countries, informed

decisions should be made regarding patent rights and competition policy which take into consideration not only trade and profitability aspects but social and human rights values. The recommendation for developed countries is to focus mainly on technology transfer that will enable developing countries become self-sufficient while also promoting trade and fair competition in developing countries. Where technology transfer takes place on fair and reasonable terms many anti-competitive practices will diminish in the sense that there will be available substitutes in the domestic markets of developing countries which will compete with products from the global market place. An illustration would be in the pharmaceutical industry where the brand companies issue licenses to domestic companies to manufacture medicines on reasonable fees, the need for compulsory licenses is eliminated and the drugs can be sold at competitive prices to be determined by market forces in the developing countries.

The industrialized countries should encourage collaborations with regard to technology transfer through offering more incentives to their own national firms in fields of importance to developing countries that aim at encouraging transfer of technology. This will translate to less finances being channeled to the developing countries in form of aid. The successful transfer of technology has lasting implications on the living standards in developing countries.

Education, and the transfer of knowledge should be a priority, encouraging education and knowledge transfer through offering teaching and training services in the developing countries is beneficial and does not present an opportunity for brain drain that the developing countries have been experiencing.

### *7.4 Areas of Further Study*

Developing countries having entered into regional trade agreements which undertake the role of promoting and ensuring fair competition present a new perspective to competition policies in developing countries. An analysis as to whether the harmonization of competition policy in the face of regional trade agreements that are currently in place could provide a feasible method of resolving the anti-competition issues and implications of the patent and competition interaction in developing countries. This can be also analyzed from the perspective that the developing countries have better chances of attempting to resolve these problems under a regional body as opposed to only nationally, especially when the solution may involve pressuring for changes from international bodies such as the WTO.

Another area requiring further study concerns the implications of anti-competitive practices related to standard setting organizations for developing countries. This is in light of the emerging technology industry in developing countries such as India and other developing countries of Asia which have well advanced technology industries that pose as strong competitors with developed countries technological industries. The dynamic nature of the industry makes the competition and patent interaction in this field an important area of study in relation to developing countries.

A study on the anti-competitive practices relating to plant varieties is lacking. In this field research needs to be conducted on how the developing countries can encourage innovation and protect investments relating to plant varieties while at the same time protecting small subsistence farmers who are highly dependent on exchange and sharing of plant varieties through established local farming practices.

Issues of traditional knowledge ranging from the patenting of traditional knowledge and whether it would be beneficial to legislate exclusively on traditional knowledge remain without comprehensive solutions. In addition to this, the current trend of entering bilateral

agreements allowing the access of digital libraries documenting a countries traditional knowledge so as to prevent the patenting of traditional knowledge in developed countries raises a number of issues. The first of which is the legality of these bilateral trade agreements where they contradict with the patent requirements as specified in national legislation. How developed countries can address this issue so as to be in compliance with the bilateral agreements relating to accessing the digital libraries warrants some study.

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