International Patent Rights under the TRIPs Agreement

The Road to a More Equitable International Regime of Patent Rights

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Abstract

The International protection of Intellectual property has become an issue of major importance over the past century. This has led to the signing of Agreement on Trade Related Aspects of International Property Rights (hereinafter TRIPs), on April 15, 1994, at the conclusion of the WTO Uruguay Round of negotiations.

The practical effect of TRIPs is the harmonization of world patent laws. This harmonization has resulted in an over-arching umbrella framework used to apply legal standards to two expansive areas of human development. The first is a legal application to International social and economic conditions, which pit developed nations against developing nations. The second is a legal application to the forefront of controversial scientific conditions as humankind continues to push the envelope on bio-scientific progress.

The International issues that the incredibly broad application of the TRIPs Agreement attempts to address is doing nothing but making the interpretation of the vague language a confusing and onerous task for all the parties involved. This is primarily due to the large range of smaller, yet complex issues that the TRIPs agreement attempts to address and the large number of issues that various parties have tried to apply the TRIPS agreement too.

In this thesis, it is shown that the attempt to use an all encompassing umbrella treaty to solve problems which deal with topics that range from patent protection for essential medicines in developing nations to the moral issues that are involved in patenting life is an unrealistic goal.

The literature review consists of a critique of the current regime's ability to accomplish its intended goals. After the literature review, the following two chapters each cover a broad issue that the TRIPs Agreement attempts to address or that various parties have tried to apply the TRIPs Agreement to. Chapter Three is a discussion of the International social and economic impacts that the TRIPs Agreement may have on developing nations. Chapter Four explores how the TRIPs Agreement attempts to deal with the patenting of emerging life science products and the criteria for patentable subject matter. The final Chapter presents six prominent recommendations for change.

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Preface

There is an intense debate underway regarding the global harmonization of patent law, and involving a conundrum of complex legal issues.

In today's society, the lines that separate the humanities, economics and science are becoming blurred. Preconceived notions that these disciplines should remain separate and distinct are being challenged as we develop a system of human organization that intertwines different fields of knowledge. These events will raise issues not yet conceptually conceived by humankind. Whether practitioners dedicate themselves to fields of science or law, the social questions that arise will test our collective notions of humanity and what it means to be human. This thesis explores the role that the *Trade Related Aspects of Intellectual Property Rights Agreement* is having on international patent protection standards and the resulting effect on different circles of debate. It particularly focuses on the debate between the developed and developing nations as they attempt to achieve their, respective goals and, protect their respective interests.

Ultimately, we must take care not to stifle the benefits of scientific achievement by reducing the incentive to innovate and failing to protect the rights of innovators. Nevertheless, we must ensure that collective human rights are not placed in jeopardy by scientific advancement run wild. The question that arises is what place does law have in the regulation of science? I am a strong proponent for the advancement of scientific discovery and believe the law should interfere as minimally as possible in scientific research and development. However, we are arriving at a new social, economic and

scientific frontier where an intense examination of implications of certain developments is necessary for the preservation of our own dignity and integrity. In the final analysis, science is the world we live in, but law is how we live in that world. Therefore, an interdisciplinary approach is the only way for us to properly analyze the topics discussed in this thesis and, hopefully, to determine what course of action will derive the maximum human benefit.

In a utopian framework, legal rights would always coincide perfectly with one another regardless of changes in social and economic structures. Unfortunately, due to our natural imperfections we seem unable to create such a framework. Nevertheless, we should still strive to have our laws seek to resolve conflicts of rights in the most equitable manner possible.

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Seven Social Sins

Politics without Principles

Pleasure without Conscience

Wealth without Work

Knowledge without Character

Commerce without Morality

Science without Humanity

Worship without Sacrifice

♦Gandhi

CHAPTER I: OVERVIEW AND SUMMARY

In this chapter, I provide an introduction to the topic which is the focus of this thesis as well as a review of the fundamentals of patent law. I go on to review the basics of the TRIPs Agreement and the issues it addresses. Finally, I provide an overview of the structure and intent of this thesis.

1. Introduction to the Topic

The international protection of intellectual property has become an issue of major importance over the past century. Most countries acknowledge a need to protect intellectual property, and that such protection is essential for the fair conduct of international trade.[1] The protection of a nation's intellectual property rights abroad can

be a critical issue in the development of the domestic economy.[2] However, it is an onerous task to persuade another country to alter its intellectual property laws in order to protect the assets of its international trading partners.[3] The desire to achieve this goal led the signatory nations[4] of the *General Agreement on Tariffs and Trade* **("GATT")** to sign the *Agreement on Trade Related Aspects of International Property Rights* **("TRIPs" or the "Agreement")** on April 15, 1994.[5]

TRIPs is viewed as the "most ambitious international intellectual property convention ever attempted."[6] By building upon the conventions of the past,[7] the Agreement sets forth an International baseline for patent, copyright, and trademark protection, in addition to providing enforcement and dispute resolution measures.[8]

This section is a precursor to a further analysis of the broad application of TRIPs in subsequent chapters. The Agreement has been used as a vehicle to address such a wide range of global, social, economic and scientific issues that its effectiveness must be questioned.

The practical effect of TRIPs is the harmonization of world patent laws. This harmonization is resulting in an over-arching umbrella framework used to apply legal standards to two expansive areas of human development. The first is a legal application to International social and economic conditions, which pits developed nations against developing nations. The second is a legal application to the forefront of controversial

scientific conditions as humankind continues to push the envelope on bio-scientific progress. The result is an ever-increasing array of moral and ethical questions.

The harmonization of world patent laws and its effect on both of these areas of human development is likely a beneficial direction for us to take as we head towards an integrated global community. However, the progress made during the negotiations that led to TRIPs seems to have only exposed legal scholars, economists, and scientists to the tip of an iceberg of issues requiring exploration. It is likely that further international treaties that have a significantly greater focus on new economic and scientific issues will be needed. It is also likely that alternative and more creative approaches to the current international regime will be required.

2. The Fundamentals of Patent Law

A patent is a government grant of a monopoly on an invention for a term of years, after which the technology enters into the public domain.[9] Patents protect the fundamental elements of inventions and emerging technologies and are available to protect either a product, machine, composition or process.[10] The patent not only describes the invention but also gives the owner the right to exclude others from producing, using or selling the invention without consent.[11] In order for an invention to be patentable, it must possess a minimum degree of non-obviousness, usefulness and novelty.[12]

In theory, domestic patent laws have two main functions. First, they stimulate scientific research by rewarding inventors with limited monopolies on their inventions. Second, they foster economic benefits for the inventors' nation.[13] The International security provided by TRIPs should protect the International revenues on products that are provided under patents. Without such an Agreement, this type of protection is more susceptible to frustration and the source nation's economy and trade may ultimately suffer.[14]

3. The TRIPs Agreement

The Uruguay Round, the most recent of several rounds of GATT negotiations, resulted in TRIPs, which was signed in 1994.[15] The Agreement was forged due to a concern among developed countries that their intellectual property rights were not being sufficiently protected in the marketplaces of developing nations.[16]

The Uruguay Round also established the World Trade Organization (**"WTO"**) to oversee GATT and TRIPs. Developed signatories support the WTO because it promotes enhanced enforcement of rights in developing countries by undertaking a proactive trade surveillance role.[17]

TRIPs formally recognizes the need to promote "effective and appropriate means for the enforcement" of Intellectual property rights, and provides for "expeditious procedures

for the multilateral prevention and settlement of disputes" relating to private intellectual property rights.[18]

In the attainment of such a lofty goal the Agreement attempts to set up an umbrella framework to addresses a number of patent laws issues. TRIPs has had the practical effect of movement towards the harmonization of the world's patent laws. This harmonization occurs through the domestic implementation of International obligations.

TRIPs requires that all signatories enact domestic legislation to implement the minimum levels of patent protection provided by the Agreement.[19] Thus, developed and non-developed signatories alike must adhere to an international baseline for patent protection[20] and ensure effective, expeditious and impartial application of patent rights.[21] The provisions that relate to this international baseline deal with legal rights and obligations, enforcement and dispute resolution.

The TRIPs Agreement prescribes the basic rights that must be afforded to each Member's nationals.[22] Article 28 provides that a patent grants an inventor the right to prohibit third parties from making, using, selling, and offering to sell or importing the subject matter of a patent.[23] In addition, the length of time an inventor benefits from patent protection was extended to twenty years.[24]

Numerous enforcement provisions were set forth to help solidify the intent of the Agreement.[25] Article 41 provides that each Member "shall ensure that enforcement

procedures are available under [domestic] law so as to permit effective" and expeditious remedies against any act of patent infringement.[26] Furthermore, many procedural safeguards are built into the Agreement. Under TRIPs, all patent infringement actions must be: (1) decided on the merits; (2) in writing; and (3) reasoned only upon evidence after each party thereto is afforded an opportunity to be heard.[27]

In addition, a party is entitled to judicial review of administrative decisions.[28] In providing remedies for a contesting state, judicial authorities are permitted to award judgment in the form of an injunction, damages, and even an order that the infringing goods be destroyed without compensation.[29]

TRIPs recognizes the need for procedures for multilateral prevention and settlement of disputes.[30] The Agreement provides a suitable binding dispute resolution procedure that previous international intellectual property conventions have lacked.[31] Under Article 64, the dispute settlement procedures set forth in GATT are made applicable to patent dispute resolution and are to be monitored by the Council for TRIPs.[32] Furthermore, all signatories are required to abide by the decisions of the Dispute Settlement Body of the WTO.[33] The Dispute Settlement Body, consisting of a panel of three Members to make initial decisions and another three Member appellate panel, possesses the authority to make findings or recommendations and may authorize a country to take reprisals against an erring WTO Member.[34]

Thus, TRIPs lays the foundation for the international protection of patents.[35] All signatories were required to join the WTO.[36] In addition, in exchange for mutual protection of intellectual property, countries were compelled to make their respective domestic patent laws consistent with TRIPs.[37] Despite its ambitious provisions, TRIPs has had limited success in completely harmonizing world patent law.[38]

One major obstacle in the attempt at harmonization of world patent laws has been the refusal of the United States to shift to a "first to file" system of patentability.[39] While many European nations have implemented this type of system, the United States continues to maintain its system of "first to invent."[40] This difference has resulted in numerous "disputes among native and foreign inventors," involving the question of which party is entitled to a patent for its invention.[41]

TRIPs has attempted to remedy this obstacle by imposing "most favored nation" status requirements, which compel the United States to consider inventive activity abroad.[42] While not perfectly harmonized, these adaptations seek to level the playing field between opposing systems.[43]

One example of the failure of TRIPs to fully realize the International harmonization of patent law is that the Agreement fails to take into account the significance of the *European Patent Convention* **("EPC")**, which created the European Patent Office **("EPO")**, and was signed on October 5, 1973.[44] The EPC sought to unify patent law within the European Community and permitted the EPO to issue a European Patent.[45]

Recent decisions from the EPO indicate that there is a desire to comply with provisions set forth in TRIPs, however, it is still not clear whether TRIPs is binding on the EPC.[46] In *IBM/Computer Programs*, the EPO's Technical Board of Appeals, while accepting TRIPs with reservations, indicated that it was "not convinced that TRIPs may be applied directly to the EPC."[47] Because the EPO is not a Member of the WTO and did not sign the TRIPs Agreement, only Member States and not the EPO itself are legally bound by TRIPs.[48]

Although the EPO gives deference to TRIPs, the failure of TRIPs to reference the EPO represents a lack of insight on achieving the desired intent of movement towards international patent law harmonization.[49] The obvious question that arises is how international patent law could ever be harmonized if the body that issues patents for all of Europe is not bound by the same standards as its Member States and their respective trading partners.[50]

These points only relate to the complex legal harmonization issues that have arisen between developed nations. It is the even more complex application of the TRIPs Agreement to international socio-economic, and scientific issues that this thesis will explore. The two major issues of the thesis are set forth below.

4. Overview of this thesis

(a) Major Issue 1: International Governance through Trade Agreements: Application of the Law to Socio-Economic Issues

One major issue that TRIPs attempts to address is the disparity of legal system maturity between developed and developing nations.

The TRIPs Agreement provides a delayed schedule for its entry into force in developing nations.[51] Pursuant to Article 65, developing Members were entitled to delay implementation of TRIPs for four years.[52] In the case of the least developed Members, application of TRIPs is delayed for ten years.[53] This leniency allows developing nations the opportunity to slowly adapt and further expand their respective economies prior to compliance.[54]

These provisions represent the concessions made by developed nations in order to acquire the consent of the developing Member states.[55] The developing nations rightfully contend that stringent protection of intellectual property would further impede their development. Such nations initially believed that TRIPs would result in a loss of their sovereignty and an increased dependence on more developed signatories.[56] However, many developing nations ultimately assented, believing that the potential gains from free trade were "irresistible."[57] Thus, immediate compliance with TRIPS was not required of all Members.[58]

In the aftermath of the Uruguay Round, TRIPs has been criticized as the direct result of a coercive strategy on behalf of the United States to force developing countries to pass laws which protect U.S. patents.[59] Thus, one must question how developing nations' position at the international negotiating table can be strengthened in such a way that they do not always feel compromised and at the mercy of the more powerful developed nations. Even economically substantial nations such as Canada often fall prey to the desires of its powerhouse neighbor to the South.

The governing body of TRIPs, the WTO has a challenging task at hand. It must continue to secure compliance by member nations with the provisions as well as address emerging issues in international intellectual property law.[60] Some analysts assert that the implementation of TRIPs by developing Member States will have a devastating impact upon them.[61] One feared impact is that TRIPs, in its promotion of patent rights protection, will make pharmaceuticals more expensive in developing nations where the need for such medications is paramount.[62]

Despite these concerns, business interests have refused to compromise, contending that enough additional time has been allocated to non-complying, developing states.[63] In the future, TRIPs will be forced to adapt if it is to endure, and the WTO will need to find a method to arbitrate these competing interests.[64]

(b) Major Issue 2: Patentable Subject Matter under TRIPs: Application of the Law to Scientific Issues

The TRIPs Agreement also sets forth criteria for patentable subject matter.[65] This is another major issue that brings with it substantial debate due to the controversy that has arisen over the past decade or so on the patenting of life products in the area of biotechnology.

Article 27 provides that, "[a patent] shall be available for any invention . . . in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application."[66] Thus, TRIPs requires a patent be made available for any invention, product, or process, regardless of its field of technology.[67] In addition, however, Article 27 sets forth guidelines for subject matter that may not be patentable.[68] These exceptions include inventions necessary to "protect *ordre public* or morality," "diagnostic, therapeutic and surgical methods for the treatment of humans or animals," and naturally existing plants, animals, and "essentially biological processes for the production of plants or animals."[69]

(c) Structure of the thesis

Through a broad application of its terms, nations have used TRIPs to address a wide range of international issues. This is primarily due to the large range of smaller, yet complex issues that the TRIPs Agreement attempts to address and the large number of

issues that various parties have tried to apply TRIPs to. This is achieving very little, and makes the interpretation of the Agreements already vague language even more confusing and laborious.

This thesis demonstrates that it is unrealistic to use an all encompassing umbrella treaty to solve problems ranging from the patent protection of essential medicines in developing nations to the moral issues involved in patenting life. More creative alternative approaches to the current International treaty regime are needed. These approaches may include a more elaborate system of mediation and dispute resolution to be made available to nations - one which is free of the constraints and biases faced by parties under the current regime.

Chapter Two of this thesis consists of a critique of the current regime's ability to accomplish its intended goals. The following two chapters each cover one broad issue that TRIPs attempts to address or that various parties have tried to apply the TRIPs Agreement to. Chapter Three is a discussion of the international social and economic impacts the TRIPs Agreement may have on developing nations and other such surrounding issues. Chapter Four explores how TRIPs attempts to deal with the patenting of emerging life science products, the criteria for patentable subject matter, and other related issues.

The final chapter of this thesis presents six recommendations for change in the international patent law system. The first recommendation is to allow greater freedom

for bilateral negotiations. The second is to pay more attention to global competing interests. The third is to bring greater clarity to the criteria for patentable subject matter debate and how biotechnology can be used to enhance the lives of global citizens. The fourth recommendation is to analyze the economic effects of introducing knowledge-based products into the realm of traditional trade theory. The fifth is to place more emphasis on ensuring that the cultural interests and legal traditions of developing nations are considered under a new international framework. Finally, the sixth recommendation is to more adequately establish the WTO's role in the pursuit of an equitable global patent rights regime.

CHAPTER TWO: FAILURE OF THE INTERNATIONAL PATENT REGIME

In this chapter I conduct a review of literature on TRIPs and examine why the present international patent law regime is ineffective. There are two key questions that must be answered regarding the adequacy of the current international regime. First: Is TRIPs creating an unacceptable inequity between developed and developing nations? Second: Is TRIPs effective in achieving sufficient conformity in international law to adequately govern emerging issues in biotechnology?

This chapter is an introduction to the impact of TRIPs on various international issues: First, the foundation behind why developing nations tend to view TRIPs as primarily serving developed nations is explored. Second is a brief introduction to the inability of the World Trade Organization (WTO) to effectively administer the agreement. This includes an examination of the ability of developed nations, and in particular the United States, to influence this governing body to their benefit and to the detriment of developing nations. Third, a discussion of inhibitors to global protection is undertaken, which primarily focuses on how developing nations lack the resources to create the Intellectual property protection required by current global agreements. Finally, a critique of the current treaty system is undertaken through an introduction to alternative approaches to the International treaty framework. This leads to the conclusion that the current system is not the best method to serve the varying, independent interests of the international community.

All of the above issues are further elaborated upon in the subsequent three chapters, with further analysis on what must be done in order to avoid detrimental pitfalls that may be encountered if a more thorough and elastic international regime is not introduced.

1. Impact of TRIPs on International Conditions

There is no question that treaties offer a basic approach to international technology protection. However, it is unclear whether the resulting international law meets the needs of developing nations.[70] The interests of developing nations have been poorly represented in the language of the TRIPs Agreement, despite the fact that the consumers of such countries comprise a large portion of the global market place for knowledge-based goods.

There are many factors that have lead to this inequity and the task of achieving a more equitable balance at the International bargaining table is more complex than merely increasing developing nations' involvement in drafting Intellectual property treaties. The lack of common social/cultural background and legal traditions between developed and developing nations often prevents cohesive agreement and understanding between parties.[71] Moreover, the varied economic strength and bargaining power of participating nations cause problems when these parties attempt to draft uniform legal instruments. This is especially the case in the area of Intellectual property where emerging

technologies are seen by nations the developed world as essential to the future growth and prosperity of their economies.[72]

There are large gaps between the status of developed and developing nations based on economic and technological progress. The TRIPs Agreement is an inadequate instrument in which to deal with the problems that result from a uniform method of patent protection. Especially when it is primarily based on the interests of developed nations in the global marketplace. This thesis is concerned with TRIPs' lack of flexibility in dealing with the necessary complex socio-economic and scientific issues relating to patents.

If an International treaty such as TRIPs is in fact necessary, the influence of developed nations in drafting and implementation must be limited. The legitimate interests of developing nations must be taken into account so that a fair and flexible regime of global patent protection can emerge.[73]

In addition, developing nations somewhat lack the resources to produce both the legislation and enforcement of patent protection that is called for in TRIPs. Moreover, it is difficult for developing nations to justify the expensive action required to put into place elaborate systems of intellectual property protection in light of the minimal amounts of technology produced by these countries. [74]

These economic factors coupled with the tendency of developing nations to view global treaties as serving only the interests of developed countries makes for difficult sessions at the international negotiating table and for highly critiqued and skeptical results once the treaty has been drafted and ratified by the divergent parties.[75]

(a) Does TRIPs Primarily Serve the Interests of Developed Nations?

The governments of developing nations have taken the standpoint that American and European control of International patent rights are a hindrance to technological development in the developing world.[76] The economic and technological success of developed nations has allowed them to have great influence over the global regulation of patent rights.[77]

Even when they result from fair negotiations, treaties originating in the West can be difficult to sell to a developing country. Such countries have their own distinct cultures, culture where property rights may vest differently than they do in developed nations.[78] Therefore, it is understandable that developing nations begin to assert their own sovereignty as they consider adherence to international law derived mainly from Western principles.[79]

It seems true from an examination of the literature that the present scheme demands that developing nations enforce treaties in whose creation they had little part. Cultural barriers and legal traditions aside, it also seems true that a more balanced negotiation

process would create agreements that developing nations would be more satisfied with and more eager to enforce.

The tension between developed and developing nations is not limited exclusively to intellectual property issues. It can also be seen through the reluctance of developing nations to enforce the laws stemming from developed nations in the context of international environmental disputes.[80] This is known as the "North-South" debate. [81] The basic theory is that the dominance of the "North" or developed nations over the "South" or developing nations results from the adoption of "broad, unenforceable duties or weakened standards in International conventions."[82]

This concept helps explain international intellectual property problems. By looking at the literature that has resulted from this debate, it is clear that the interests of the more powerful developed nations are better represented in global technology protection.[83] Furthermore, even if global treaties could include their interests, developing nations are not financially situated to adopt the treaties. Developing nations also likely become concerned when developed nations assert such strong patent protection is the best method to insure economic development.

The patent issues that divide the interests of developed and developing nations' is further complicated by the delayed schedule provisions of the TRIPs Agreement. Obligatory for those countries wishing to take advantage of the benefits associated with WTO membership, the TRIPs Agreement took effect on January 1, 1995.[84] Developed

nations had one year in which to fully comply. Meanwhile, developing nations had until January 1, 2000 to make the necessary implementation provisions.[85] Least-developed nations have until January 1, 2005 to fully implement the provisions of TRIPs.[86]

A great deal of confusion has been caused by the attempt to classify nations into these broad categories. A clear classification system is essential because, as mentioned above, it is the determining factor in whether a nation had one year or until January 1, 2005 to fully comply with TRIPs. Thus, if a country was prematurely or inaccurately designated as a developing nation instead of a least-developed nation that country might be seriously harmed. The awkwardness of this system is compounded by the fact that the United States and the European Union alone have undertaken the responsibility of defining a 'developing nation.' [87]

Many developing nations, though aware of the economic advantages associated with compliance, find the requirements of TRIPs confusing and even contradictory.[88] The definitions of developing and developed nations are not always clear. Moreover, the issue of which specific provisions are to be applied to which parties seems even less clear, and serious problems arise when these definitions are woven into global treaties. These classifications make many countries feel subservient to the developed nations under the WTO Framework. If developed nations wish to include developing countries in the WTO, these countries must not be made to feel second class.

Recently, in response to the WTO's requirement that India amend its patent laws,[89] India has begun to question the current policy advanced by industrialized nations.[90] India approaches Intellectual property protection seriously, as evidenced by its creation of a specific Indian panel to deal with IP issues.[91] As the January 1, 2005 deadline for least-developed nations to comply with TRIPs looms nearer, many more developing countries may begin to reevaluate the Agreement. Hence, the division of interests between developed and developing nations increases.

Another problem that exists is that the developing nations given grace periods by the WTO have their own cultures. In some instances, these cultures do not embody the same principles common to many WTO procedures. Controversy has arisen over whether Western systems of private ownership is appropriate to protect traditional knowledge. As a result, some countries will be forced to concede many traditions to gain more presence in the global marketplace.[92] For example, countries such as India are rich in technical potential and have a fairly developed legal system. Yet, they are also deeply entrenched in cultures that are drastically different from any known in the West. The cultural perspective found in many developing nations fosters a community rather than individual approach to technological progress.[93] Furthermore, Western style intellectual property systems reward new improvements rather than existing knowledge, which is considered to fall in the public domain. Applying Western style intellectual property theory to non-western legal values undermines traditional cultures and innovations rather than protecting them. Patents are conferred on individuals or legal entities and apply a specific time frame. In contrast, many developing nations

knowledge systems are of a collective nature, depending on a continuous and often informal exchange of knowledge according to traditional beliefs.

It seems apparent that the concessions the WTO has made to developing nations intended as beneficial may only complicate an already unpleasant situation. The significant difficulties developing nations are currently experiencing in adopting and complying with this may be a result of inadequate embodiment of all the interests of the participants. When the divergent interests of the developed and developing nations are addressed by the same laws the laws become over-broad and essentially useless. An appropriate balance must be struck between the desire for a global harmonization of patent laws while at the same time taking into considerations the differing regional interests of the developed and developing nations. This balance is a difficult chord to strike and drafting of quality global treaties is difficult even when all the parties have equal influence.[94]

(b) The WTO: An Ineffective Governing Body?

Nations around the world came together during the Uruguay Round seeking uniform laws and regulations for fair global trade.[95] The WTO sought to address both global Intellectual property questions and traditional trade issues involving the environment and labor.[96] The difficulty with this task is that upon negotiating International treaties under the WTO there is significant room to play one category of issues off another which often results in a less than desirable outcome for some of the parties involved.

In the negotiations to secure strong global Intellectual property protection under TRIPs, the developed nations used labor or environmental incentives as leverage to ensure adherence to intellectual property regulations.[97] Developing nations have often been criticized for inadequately protecting Intellectual property rights. These incentives were attractive to developing nations, as they asserted that developed nations must open textile and agricultural markets.[98]

Developed nations strongly influence the drafting of WTO legislation. This is clear from the language of TRIPs. With minor exceptions, the current framework of TRIPs is dominated by Western legal concepts.[99] The United States in particular uses its industrial market strength to pressure developing nations to adhere to it own high-level of Intellectual property protection.

The U.S. engages in this process through legislative mechanisms such as Special 301, a domestic creation of Congress that addresses global trade issues with developing nations.[100] Under *section 301 of the Trade Act of 1974,* as amended,[101] the U.S. Trade Representative **("the USTR")** must investigate foreign countries' protection of intellectual property rights. Section 301 of the original Trade Act was amended by the *Omnibus Trade and Competitiveness Act of 1988.*[102] This amendment, referred to as Special 301,[103] requires the USTR to annually assess "foreign countries... denying adequate and effective protection for intellectual property rights, or denying fair and

equitable market access to United States [citizens]... relying on intellectual property protection."[104]

In short, Special 301 allows U.S. exporters to file a petition with the USTR if they believe a foreign country is limiting access to one of its commercial markets.[105] If the petition is successful, the President of the U.S. may take action against any "practice of a foreign country that is inconsistent with any U.S. trade agreement or unjustifiably burdens United States commerce."[106]

The USTR responds to opinions or "advice" from a combination of industrial lobby groups, the Patent and Trademark Office **("PTO")** and the Copyright Office.[107] Therefore, any foreign nation not meeting American patent protection standards is subject to textile or agriculture sanctions in American domestic markets.

An elaborate classification and ranking system enforces the USTR's Intellectual property protection mandates. To increase the effectiveness of Special 301, the USTR has divided nations under investigation into two categories.[108] The first classification, called the "watch list," includes countries determined by the USTR "to deny adequate and effective Intellectual property protection or market access."[109]

The second classification of USTR target nations is the "priority watch list."[110] The priority watch list is reserved for those countries that the "USTR considers to have made

less progress in strengthening protection for intellectual property rights than those on the watch list."[111]

In contrast, the watch list includes WTO Member countries whose protection of intellectual property rights is either improving or deteriorating to unacceptable standards.[112] Therefore, the USTR monitors a country whether its protection of Intellectual property is improving or deteriorating.[113]

The provisions of TRIPs are undermined when the U.S. relies on mechanisms such as Special 301. Special 301 allows the U.S. to punish countries that uphold the provisions of TRIPs but have policies that are contrary to U.S. trade interests.[114] Rather than going through the proper WTO channels, the U.S. may place trade sanctions on countries offering inadequate patent protection by U.S. standards.[115] Given such practices,[116] it is understandable that nations might question whether U.S. support for the WTO is indeed genuine.

There is little or no incentive for a developing nation to rush into a global treaty when the U.S. disregards any interests other than its own.[117] Adherence is understandably difficult when nations cannot be certain whether, in a given context, the U.S. will choose to abide by WTO law.

(c) Inhibitors of Global Protection

The key inhibitor to a suitable international regime is a lack of resources in developing nations to create the intellectual property protection regimes required by current global agreements. The complex IP protection systems found in the U.S. resulted from developments taking place over a prolonged and prosperous period of time. Originally, members of the patent bar drafted the *1952 Patent Act* to counteract any possible "Supreme Court anti-patent attitude."[118] In 1982 the U.S. patent system was further strengthened by the creation of the Federal Circuit, whose exclusive appellate jurisdiction for patent cases brings greater uniformity to patent law.[119] The technological dominance that the U.S. experiences today is based on the superiority of its IP protection system. This dominance may have been compromised if other countries had constantly influenced the development of the U.S. domestic patent system through international treaties.[120]

Presently, developing countries lack sufficient resources to provide their citizens with the basic necessities: health care, education, food, and clothing. Intellectual property protection modeled on procedures used in the U.S. would be useless for a country in its early stages of development. The administrative difficulties associated with a patent system alone are too great for a developing nation. Further, even if a developing nation could shoulder the burden of providing a viable patent system, the lack of technological advances in that nation would make the patent system profuse.[121]

Resources are a key factor in determining whether developing nations can fully comply with the conditions set forth in TRIPs.[122] For example, a developing nation that cannot provide for even the most basic health care needs of its citizens is bound to have difficulties complying with many of the complex WTO regulations. Furthermore, when a country such as the U.S. orders a developing country to commit scarce resources to protect intellectual property rights, hostility is bound to result. The small number of citizens actually seeking protection for technological innovations is a further indication that such nations do not need an elaborate system.[123] Despite all the benefits associated with belonging to the WTO, these countries' limited resources are more useful if allocated elsewhere,[124] and it is likely that methods will be sought to do just that without offending the watchful eye of the WTO and incurring sanctions.

Recently, discussion about the limited resources of developing nations and their effect on world intellectual property rights has spurred debate.[125] Proponents of alternative plans to TRIPs argue that governments should be given greater autonomy in making public health decisions and regulating usage of pharmaceuticals. [126] They theorize that meeting the needs of the public, and not the need to protect technology, will result in more useful pharmaceuticals for developing nations.[127] Further, they assert that governments should be able to decide which pharmaceuticals are needed most in their nations and should invest in those particular drugs.

On the other hand, U.S. manufacturers and trade officials argue that the current system, which rewards the labor of pharmaceutical development, distributes the new drugs to developing nations most effectively.[128] Meanwhile, developing nations find it absurd to protect drugs with little benefit to their poverty-stricken citizens[129] and cannot support broad-based funding of all drugs.

Despite having incalculable value in the U.S., an intricate patent system can be costly to a developing nation. Survival is the primary concern of citizens in developing nations. Therefore, providing the most basic and essential necessities must be the primary concern for governments in these nations.[130] This is a complicated task[131] and is complicated by low productivity rates, increasing foreign debt reliance and dramatic population growth.[132]

The importance of adequate intellectual property regimes, however, can not be disregarded entirely by developing nations. The solution too many of the social ills in developing nations are closely interrelated to its economic viability and the technology it may consume or produce. Economic growth has allowed developed countries to make great advances in the eradication of mass poverty and many systemic diseases.[133] Developing countries must satisfy developed nations' interest in patent protection to some extent to ensure that they are provided with much of the technology that will help advance their own economies, be it in the health care or other sectors. That said, the creation of patent systems using solely Western models cannot be justified in light of the minimal amount of technological innovation being produced in developing nations.

Such countries produce a fraction of the new technology that is introduced each year globally.[134]

Industries benefiting most from patent protection in developing nations may assist in solving financial shortcomings that are found in developing nations. By contributing financially to the development of stronger foreign domestic patent protection regimes, pharmaceutical companies, for example, could potentially limit losses resulting from the inability of these countries to implement proper frameworks. This would also bolster the lack of patent protection from an International perspective. Financial support by drug companies to aid in the development of patent protection regimes in developing nations may lead to future revenue gains or at least cut losses for the companies.

It is estimated that India's intellectual property policies cost U.S. drug makers $ 500 million annually.[135] American pharmaceutical companies would likely need to contribute only a fraction of their industry profit to create a viable protective system in developing nations that would substantially offset such losses. Additionally, technology-based companies in the developed world and developing nations could work on more creative solutions together rather than rely on the standardized language of WTO provisions and its effectiveness as an enforcement mechanism.

It is also reasonable to conclude that if developing nations continue to be pressured into providing advanced level patent protection schemes, those benefiting the most should

carry a portion of the financial burden.[136] At present this is obviously American and European industry. This argument is further elaborated upon in Chapter Three.

(d) An Introduction to Alternative Approaches to the International Treaty Framework

Any attempt to propose structural policy changes to the status quo must first grapple with the all-important question: why change? Developed nations have put forth a variety of arguments in support of the current international regime. The primary one is that the current intellectual property regime is necessary to protect corporations from the theft of intellectual property. Developed nations have claimed that they have a right to demand stronger patent protection through TRIPS in order to prevent developing nations from free riding off corporate investment and products.[137] They contend that proposals that force corporations to redistribute wealth to developing nations will serve as barriers to innovation. Appealing to the idealistic vision that technological innovation is the solution to all problems, the developed nations propose that the current international regime will ultimately help the developing nations by producing more socially valuable goods.[138]

Additionally, developed nations propose that developing nations who have not had strict Intellectual property regimes have suffered because these policies have prevented them from attracting foreign capital and from stimulating domestic technological growth. The suggestion has been that governments of the developing nations have pursued strategies

that have inhibited their own growth and that TRIPs is a way to force countries to help themselves.[139]

While these arguments have some credence, collectively they fail to address the concerns raised by the governments of developing nations. These arguments fail to acknowledge the guilt of developed nations in stunting the growth of less developing nations by denying them access to valuable technologies and pharmaceuticals at a price that is appropriate to the purchasing power of their citizens.[140]

At present, both developed and developing nations find themselves in a compromised position. In a modern world where patent infringement and misappropriation have become commonplace, the threat of economic punishment does not deter nations with nothing to lose.[141] Modern intellectual property treaties and U.S. mechanisms such as Special 301 rely heavily on punishment of refractory nations not obeying the rules.[142] As well, the tactics of developed nations involve enforcing broad and confusing treaty provisions created for the overriding benefit of developed nations. The development of many International treaties, including TRIPs, is largely the work of American negotiators[143] working with foreign negotiators in the hopes of drafting treaties which all members can abide by. American legal models likely dominate trade negotiations because the United States has a longer tradition of enforcement of rules. In addition, the force of its economic power as demonstrated by the size of U.S. markets and the volume of foreign investment gives weight to the positions taken by U.S. negotiators. In any

event, developing nations are increasingly coming to the realization that their concerns must be addressed in a more equitable manner.

TRIPs has made outsiders of nations at an economic disadvantage and those who are not at the forefront of technological advancement.[144] Over-broad umbrella treaties may encompass too many objectives to offer true protection. Without constant monitoring and adaptation, socio-economic and scientific advancement factors are basically making TRIPs an inadequate legal framework for dealing with the myriad of patent issues presented.[145] In addition, cultural differences such as the fact that a developing nation's legal system may appear simple may actually be more a function of different legal traditions. And it is important to note that complexity in itself does not guarantee justice. When these factors are coupled with the economic disparity of the nations around the world, TRIPs cannot help but fall short of its goal of harmonization

Various alternative approaches to these problems have been proposed in an attempt to reach a more adequate framework to accomplish the goals mentioned throughout the course of this thesis. One approach is to allow individual countries to reach mutually agreeable solutions outside the confines of global treaties. Representatives of the U.S. biotechnology industry have criticized the current movement of attempting to solve disputes by drafting international treaties rather than by giving nations and corporations autonomy in arriving at a solution.[146] Indeed, giving nations autonomy allows them to work toward resolving a specific dispute rather than trying to get as much as possible

within the confines of a treaty's broad terminology. Nevertheless, power imbalances are likely to arise often in this instance.

Another approach suggested by some commentators is to have global treaties could be replaced by a permanent mediation organization aiding in negotiations between individual countries.[147] In the absence of TRIPs or a similar instrument, disputing countries could be equally represented through an unbiased mediating council. This body would objectively look at the facts of a dispute and facilitate the negotiations with the goal of reaching a mutually satisfactory result. Nations would no longer need to interpret the formalized language[148] of a treaty in light of their particular problems. Instead, the specifics of a dispute might be addressed by guidelines created prior to negotiations by the individual countries involved in the dispute. This would eliminate the confusion developing nations have had with the interpretation of certain provisions of TRIPs.

When nations involved in a dispute come to their own individual solution, rather than a generic, ineffective solution mandated by a treaty,[149] unequal parties can become slightly more equal, thereby allowing international law to work more effectively. The unfair advantage the developed nations have created for themselves in TRIPs should be minimized even though International economics seems to prevent the playing field from ever being completely level.

Another problem that has arisen under the TRIPs framework and has led to the suggestion of alternative approaches to the current International regime is in relation to environmental issues. The leaders of developed nations have repeatedly called on developing nations to enhance their conservation efforts. However, they have simultaneously pushed for legal regimes that deny developing nations compensation when their bio-resources are used commercially by developed nations.[150] The current International regime is ineffective and inefficient when it comes to striking a functional balance between the objectives of innovation and conservation. The difficulty with the majority of approaches is that they fail to acknowledge this tradeoff and attempt to identify one rightful owner. Therefore, the question to be resolved is how can developed nations' patent claims and developing nations' bio-resource claims both recognized as legitimate property rights.[151]

It is important to get a clearer sense of how property rights are distributed in the current international regime. At present, only "raw" biological and genetic resources have been classified as the "common heritage of mankind." This concept serves to prevent the ownership of things of communal interest and to preserve things that are of international interest for future generations.[152] Once corporations develop commercial products from these resources the end products are no longer considered the "common heritage of mankind." The patent system allows such products to become "inventions" and the inventors are rewarded with an individual property right. The current international regime allocates all of the property rights, and therefore, all of the rents derived from the original biological resources, to the corporation that develops the end product. Thus,

it is the developed nations, who have the ability to form these end products, that are awarded the property rights, whereas the developing nations who pay for the conservation of the resources, without which the end products could not be developed, are not conferred any rights.[153]

One scholar has proposed that all biotechnology patents in which the end-product is derived from plant genetic resources should be referred by domestic patent offices to an International Biotechnology Patent Office **(the "IBPO")** that will be created by another international treaty.[154] All signatory nations would agree to refer any biotechnology patent applications for end products derived from plant genetic resources to the IBPO. Some key elements to the basic framework for the IBPO would be that all nations agree to honor and enforce the decisions made by the IBPO in their national courts. The IBPO would take into account the contributions of plant genetic resources in the development of biotechnology products and would determine a royalty to be paid to developing nations based on the contribution made by the resources to the final product. The royalty will be greater if indigenous communities contributed knowledge to the bio-prospectors. The IBPO would also have its own standards that would be established in its charter, and would have an arbitral body to settle disputes. This alternative also provides some insight into different ways that an international regime may exist.[155]

2. Chapter Conclusion

Although the TRIPs Agreement addresses issues in copyright, patent, and trademark law, the patent issues turned out to be the most contentious. The U.S. government took a particularly strong stance, insisting on the inclusion of U.S.-style patent standards. The American pharmaceutical and biotechnology industries were ferocious in their lobbying of these standards, being the entities most in need of strong patent protection. This is because of a combination of the high costs of research and development and the relative ease with which they can be re-manufactured once the technology is understood.

Thus, despite strong opposition, developing nations ultimately had no choice but to sign on to TRIPs. Unfortunately, the regime that has been established by the Agreement seems to be turning out to be more detrimental to their interests than they had originally anticipated. Furthermore, simple non-compliance with TRIPs to ensure their interests are being met is not turning out to be an option. TRIPs is enforced through the World Trade Organization dispute resolution process this means that the threat of sanctions on other areas of trade is proving to be an incredibly strong incentive to comply with the terms of the Agreement.[156] In the next chapter, I will take a more in-depth look at some of the international socio-economic problems that have developed from the outcome of the negotiations that created the TRIPs agreement.

CHAPTER THREE: IMPACT OF TRIPs ON SOCIO-ECONOMIC CONDITIONS

1. Introduction

This chapter is an analysis of the International socio-economic impact of TRIPs. The chapter examines the current conflicts surrounding the implementation of patent protection for pharmaceuticals. This discussion details the debate that is ongoing between developed and developing nations over the affordability of essential medicines and the management of a public health solution.

The point of conflict arises over the preservation of business interests in patent rights and the ability of third world countries to get access to reliable pharmaceuticals at a reasonable cost. Inaccessibly priced medicines are at the core of a dispute that pits the economic interests of developed nations against the social interests of developing nations.

The drafting of TRIPs[157] represented a significant departure from traditional trade negotiations. Traditionally, GATT has operated through a process of negotiating tariff reductions on goods. In the past decade however, this gradual reduction of tariff barriers to the free flow of commodities was supplemented with the establishment of enforceable global standards governing intellectual property.

The inclusion of intellectual property rights as a critical aspect of trade negotiations flowed logically from the explosive growth of value generated by the pharmaceutical and biotechnology industries. Strong Intellectual property protections in an otherwise unregulated market are necessary interventions to encourage innovation by guaranteeing sufficient return on investment in the development of Intellectual property. Rights holders are then able to enjoy monopoly rights on their inventions, a policy which should then be balanced by satisfying opposing social goals of promoting competition and affordability of consumer goods. By establishing positive protection of "rights" for investors in innovation, the global trade regime governs the complex balance of interests between intellectual property owners, producers, distributors, and consumers.[158]

When the product is pharmaceuticals, appropriately managing this balance is a delicate act. Unlike most other consumer goods, access to essential medicines is a basic human need, and an important aspect of many national health policies. According to the World Health Organization **(the "WHO")**, access involves three components: therapeutic access (the discovery and development of appropriate treatments), physical access, and financial access.[159]

The third component, financial access is highly affected by the ability of pharmaceutical companies to exercise monopoly control of pricing through exclusive patent rights. The TRIPs Agreement has become a framework for negotiations over the tradeoff between protection and access. Through active lobbying, international pharmaceutical companies

succeeded in obtaining a high level of pharmaceutical patent protections.[160] Increasingly, poor countries affected by health crises and International health organizations have actively sought to preserve state regulatory powers within the confines of TRIPS.[161] However, these efforts have been met with considerable resistance, particularly from the U.S., which has engaged in aggressive unilateral action to extend patent protection beyond the International agreements.[162]

The specific provisions of TRIPs can be interpreted so as to provide support to either side of the debate. This analysis focuses on how this causal instrument and its subsequent effect of harmonization over global patent regimes is having adverse consequences for both developing nations seeking to devise an essential drugs policy and the pharmaceutical companies that wish maximize their profits. A consideration of the appropriate interpretation of relevant provisions is undertaken. The hope is to satisfy both the goal of supplying reasonably priced medicines to developing nations, while preserving incentives for innovation and retaining profit margins.

Section two is a further look the effect of the harmonization of global patent regimes. Section three examines the delicate balance of health care needs and patent protection. It does this through an analysis of the conditions that are necessary for creating compliance with TRIPs. This section looks at both historical development and more recent disputes. Section four discusses approaches to maintaining international patent rights without making access to medicines for developing nations' consumers unattainable. Section five is on the impact of TRIPs on economic issues. The analysis

in this section includes: general economic issues, incentives for innovation versus access to essential medicines, the role of the WTO, and the potential benefits of differential pricing.

2. The Harmonization of Patent Regimes

The TRIPs Agreement is an exceptional instance of the imposition of minimum standards on domestic legal systems.[163] TRIPs contains fairly detailed requirements for levels of domestic regulation of intellectual property rights. Moreover, parties may provide more extensive coverage to property rights than required by the Agreement.[164]

In addition, the core GATT principles of national treatment and most favored nation status are incorporated into the Agreement. TRIPs provides that each Member requires that nationals of other participating states may not be treated less favorably in domestic protection and enforcement of Intellectual property legislation.[165] Most-favored-nation treatment (included in Article 4 of the TRIPs) mandates that any advantage conferred to one Member country must be extended to all other Member countries.

The provisions most relevant to pharmaceuticals are found in Section 5, which covers patents. TRIPs provides that patent holders are to receive the exclusive rights to prevent third parties from making, using, offering for sale, selling, or importing the product or process without the owner's consent.[166]

Under the agreement, patentable subject matter is broadly applied to "any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application."[167] In legal actions involving infringement of a process patent, the Agreement shifts the burden of proof to the defendant.[168] Discrimination as to place of invention, the field of technology, and whether products are imported or locally produced is proscribed.[169]

In implementing the TRIPS Agreement, the U.S. revised its patent protection period to conform with the single TRIPS standard.[170] The only other change to the U.S. patent scheme required by the Agreement was nondiscrimination on the basis of place of invention. Drugs developed in other countries must now be afforded national treatment with respect to patent approval.[171] On the other hand, some developing nations are being asked to make monumental strides in the development of their Intellectual property law. This includes both drafting legislation and introducing domestic enforcement mechanisms.

This demanding task placed upon many developing nations has been moderated through special provisions for countries that had not provided patent protection prior to the Agreement coming into force. The TRIPs provisions allows countries to ease in patent protection. It requires that a filing procedure, or "mailbox" system, be established so that the subsequent patent grant will be counted from the filing date.[172] This requirement only covers those patents filed from the date of the enforcement of the agreement.[173] A product that is the subject of the patent application must be accorded up to five years of

exclusive marketing rights until the patent application is granted or rejected.[174] Although developing countries are not required to have a fully compliant patent system until 2005,[175] the pipeline requirement for pharmaceuticals expedites the effective recognition of patents, by preserving the place in line for registration and mandating exclusive marketing in the interim.

3. Health Care Needs vs. Patent Protection: A Delicate Balance

Despite the unprecedented level of international obligations to be implemented within domestic legal systems, TRIPs still leaves substantial room for governments to exercise regulatory control over pharmaceutical pricing. In addition to the omission of any express prohibition on the use of parallel imports, there is nothing in the agreements to bar the use of price controls, a common practice in developed countries, with the exception of the U.S.[176] These economic concepts will be elaborated upon in subsequent sections.

Furthermore, TRIPS explicitly acknowledges the necessity of considering public interest, and specifically health policy, in formulating domestic intellectual property regulations. In its General Provisions and Basic Principles, the Agreement allows Members to "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."[177] The Agreement further acknowledges the principle

that Intellectual property rights must be limited so as not to be abused in the restraint of trade or "adversely affect the International transfer of technology."[178]

Members may exclude patents for inventions where the exclusion is needed to protect public order or morality, including to protect human, animal, or plant life or health, or to avoid environmental injury. This statement is predicated, however, on the condition that no commercial use of the invention is permitted in the territory.[179] There is some crossover here with the subject of the next chapter in which an analysis is undertaken of the issues surrounding morality provisions and new technology in the health care arena.

The public order exception, however, seems to lend little support to exempting essential drugs from patent protection requirements under the Agreement. An exemption to patent protection would be put in place so that local industry could produce pharmaceuticals and consumers could obtain medicines at a lower price. This exception, however, is essentially directed to authorize a state to deny patents on harmful substances that are banned for reasons of health, safety, or environmental protection.

Additionally, diagnostic, therapeutic, and surgical methods for the treatment of humans or animals, plants, animals other than micro-organisms, and the biological processes for the production of plants or animals may be excluded. Although this provision also suggests a health exception principle in the Agreement, by its terms, it refers only to patenting "methods" and actual life forms. The U.S. strongly opposed the exclusion of life forms due to its interest in protecting the growing biotechnology industry. The

provision of a five-year review of Article 27 was included in the final draft of the TRIPS Agreement.[180] These issues are further elaborated upon in Chapter Four.

(a) Creating Conditions for Compliance - The Historical Development

At the opening of the Uruguay Round the U.S. first introduced intellectual property into multilateral trade negotiations. Although the Americans were the chief advocates of an international intellectual property regime, they encountered significant resistance at the negotiating table. This resistance was particularly strong on the issue of pharmaceutical patent protection. The entire TRIPs negotiating process spanned a time frame of almost six years and has generated many disputes. The source of many of these disputes has been due to the conflicts that have arisen between developed and developing nations under the gradual system of phase-in of patent protections.

In response to growing insistence by developed countries to include intellectual property within the GATT, a group of developing countries led by Brazil and India offered a draft intellectual property agreement that proposed obligations consistent with the then-current practice in the developing world with respect to patents.[181] However, it was the draft put forth by the United States, the European Economic Community, and Switzerland that largely outlined the terms eventually adopted.[182]

The successful adoption of TRIPs resulted from a number of factors. Passively, it resulted from a trade-off made between the developing and developed nations.

Concessions were made on textiles, clothing, and some agricultural products in exchange for agreeing to higher levels of Intellectual property protection.[183] It is difficult to say who in the long run will benefit most from this trade-off. It is highly probable however that the developed nations will receive the greater benefit as the world continues to move towards a more knowledge-based economy that relies on information intensive products, such as pharmaceuticals and biotechnology. Although trade in the most directly affected products of the Agreement is still a small portion of overall International trade, it is becoming more and more important.[184]

Less and less economic emphasis and value is being placed on basic products such as clothing and textiles, which can be produced at extremely low costs and usually cannot attract a significant profit margin. Therefore, until they are able to build their technology industries up to a point where they are able to compete with those of the developed world, developing nations will likely continue to find themselves in a position of relative disadvantage.

Most importantly, bilateral pressures made acceptance of the developed countries' intellectual property agenda a necessity for some.[185] For example, the U.S. threatened unilateral trade sanctions under section 301 of the U.S. trade law[186] in retaliation against Brazil for its failure to protect pharmaceutical products and processes.[187] Despite U.S. resistance, Brazil sought the establishment of a GATT panel to investigate whether the 100% tariff on a basket of Brazilian exports, including paper products and consumer electronics, was legal within the then-established GATT.[188] Although the Brazilian case

was strongly supported within the GATT membership, it was abandoned in the face of the influence of U.S. market strength. The punitive tariffs were terminated after the Brazilian President announced the introduction of legislation to provide patent protection for pharmaceuticals.[189]

(b) Creating Conditions for Compliance - More Recent Disputes

As mentioned above, many disputes have arisen due to conflicts between developed and developing nations under the gradual system of phase-in of patent protections. For example, the U.S. requested formal consultations with Argentina pursuant to WTO rules in May 1999. The U.S. alleged that Argentina had failed to implement the pipeline and exclusive marketing provisions. [190] Disputes have also arisen between the developed nation Members in GATT, due to differences in their position on where the balance should lie between satisfying social agendas and business interests.

In February 1999, the Dispute Settlement Body of the WTO established a panel to examine Canada's pharmaceutical patent regime at the request of the European Union.[191] Canada's Bill C-91, passed in conjunction with the NAFTA, allows generic producers of patented pharmaceuticals to carry out experiments required for marketing approval, and for the manufacture and stockpiling of patented products six months before the patent expiration without the approval of the patent holder.[192] By encouraging the market availability of generic products as soon as patents expire, the Canadian policy sought to strike a balance between the requirements of patent

protection and the social need of access to pharmaceuticals at an affordable price.[193] The European Union alleged that this provision violated the TRIPs requirements prohibiting unauthorized third parties from making or using the protected good within the 20-year patent period.[194]

The WTO panel decision allowed for the Canadian "regulatory review" exception to patent exclusivity as consistent with the established practice of permitting use of patented substances for experimental purposes. However, the panel found that the stockpiling of patented pharmaceuticals prior to patent expiration did not fall within any of the TRIPs Article 30 "limited exceptions." Even though the Canadian law prohibited introduction into the market until the patent expiration date, manufacture for future commercial sale constituted a competitive commercial activity that substantially curtailed the patent holders' exclusive rights to make and use, and was therefore in violation of Article 28.1 of TRIPs.[195]

Although, these proceedings were between developed nations and WTO decisions do not have precedence over later proceedings, the outcome will likely impact the future policy of developing nations, which have a sophisticated pharmaceutical manufacturing capacity, like South Africa, India, Argentina and Brazil. Individual WTO decisions are still widely viewed, as having persuasive authority and what is past becomes prologue to future.

4. Maintaining International Patent Rights without Hindering Access for Consumers in Developing Nations

The Americans have been the most aggressive in pursuing their intellectual property agenda on an international stage. Although the U.S. successfully negotiated strong rights for the multinational pharmaceutical industry within the TRIPs Agreement, it has continued to push the full agenda not achieved at those negotiations. The U.S. still retains strong domestic law to further support the protection of their intellectual property rights.

For example, under the Special 301 provisions, the USTR is required to prepare a list of "priority" foreign countries that are considered the worst offenders of intellectual property rights. The USTR then enters into negotiations with these countries under the threat of sanctions. Less severe offenders are placed on "priority watch" and "watch" lists to notify them that their levels of intellectual property protections are not satisfactory to the U. S.[196]

Despite the aggressive imposition of primarily American intellectual property values upon other Members of the WTO, there have been some positive aspects for developing countries that came out of TRIPs. These included the exclusion of patents on life forms, the ten-year transition period for developing countries, and the allowance of compulsory licensing, albeit with stringent restrictions. Specifically in regards to compulsory licensing, countries may review particular medicines on a case-by-case basis, and where

there is a determination of emergent need, they may grant a compulsory license after negotiating with the patent-holder.[197]

There have been various initiatives undertaken by parties involved in the debate. Efforts to create viable markets have been undertaken by collaborations among public, nonprofit, and private entities. For example, the WHO together with foundations and nonprofit organizations recently announced an effort to raise at least $500 million to halt the spread of drug-resistant tuberculosis.[198]

Such audacious efforts, however, do not directly address the issue of inaccessible pricing. Public or nonprofit initiatives also must increase funding flows for research in essential areas,[199] and also can consider opportunities to act within the market as Intellectual property rights holders. Rather than conceive of Intellectual property as only a zero sum game between assuring return on investment or facilitating widespread access, creative uses of this valuable asset can be implemented.[200] In any event, there are conscious roles for government and nonprofit, non-governmental organizations. Policy choices and lobbying efforts can be strategically directed such that these parties view themselves as economic actors in the market to obtain social goals.

Governmental organizations are likely more able to promote such ends because they are more flexible and independent. Non-governmental organizations involved in medical research and International health promotion can take a proactive stance within the market and within the policy community based on a strategic assessment of the current

status of the pharmaceutical industry and the public sector's involvement as economic actors. Furthermore, such organizations play an important role in the International social interaction of various parties. Direct political involvement of non-governmental organizations enhances the interaction of different governments so as to promote and facilitate productive global communication channels.

A major problem that lobby groups face when trying to present their platforms is the fact that the pharmaceutical industry is constantly evolving due to the emergence of new technology. This makes it difficult for special interest groups to be certain as to exactly what they should be advocating or who they should be lobbying against. New technology, such as the emergence of biotechnology, is fundamentally changing the nature of pharmaceutical research and development. Nevertheless, the main issues are clear and lobby groups must continue to advocate for their health promotion agendas in order to help maintain a balance of interests.

5. Impact of TRIPs on Economic Issues

(a) General Economic Issues

In this section, the economic impact of the TRIPs Agreement on both developed and developing nations is explored further and the link between patent protection and innovation in essential medicines is analyzed.

As a strategy for promoting investment in the essential drug needs of the developing world, universal Intellectual property protection hardly is optimal. In the first place, diseases suffered by developing populations with no purchasing power are not highly addressed by producers. In fact, treatments for some tropical diseases have begun to disappear from the market due to lack of effective demand, despite significant need.[201] Of the over 1,200 new drugs commercialized between 1975 and 1997, 30% are considered therapeutic innovations, but only 1% are specifically for tropical diseases.[202]

Pharmaceutical companies do not like to undertake the significant cost in terms of time and money required to bring a drug to market unless they are certain that there is a significant consumer base in which to recoup a substantial return on investment. This is not often the case when it comes to developing drugs for the diseases that specifically target the developing world.

Estimates vary on the actual cost of developing a drug from discovery to market.[203] Citing a 1997 study in Pharmacoeconomics, Pecoul et al. state an average of $ 160 million over a period of 8 to 12 years. Industry representatives claim that the amount is closer to $ 500 million in a 12 to 15 year period.[204] Industry observers often point out that most large pharmaceutical research companies spend twice as much on marketing than on research.[205] This disparity can be partly attributed to an accounting problem related to research and development. Money invested in research is a "sunk cost." Much like overhead, the value generated from that investment will not be realized for many years, but the expense must be recorded in the year it is made, rather than capitalized

over time.[206] This, however, is really an accounting discrepancy and it is still clear that a large portion of pharmaceutical companies' expenditure budget is directed towards marketing of existing drugs rather that on research of new ones.

In terms of the TRIPs Agreement as an instrument of the WTO, integrating trade law and intellectual property law is problematic. The economics of products under patent protection, such as pharmaceuticals, can be significantly different from that of the traditional products.

In general economic trade theory, we think of trade as equalizing prices near the lowest available marginal cost, which benefits the world's consumers in the form of lower prices. This is an oversimplification that ignores other economic variables such as the role of currency differences. Nevertheless, it is a reasonable comparison point for the analysis of this paper, which is more qualitative than quantitative.

Trade theory tells us that for "normal" products, the world as well as each nation in it will be better off with free trade. This is because the price of goods will equalize closest to their lowest marginal cost, minimizing consumer cost. When Intellectual property rights are properly enforced, however, there is an increase in sales price away from the lowest marginal cost, creating an economic misallocation.[207] Nevertheless, it is generally believed that Intellectual property rights are necessary to stimulate innovation. However, as will be shown in the next section, there is very little clarity regarding the actual link between patent protection and innovation in essential medicine?

(b) Incentives for Innovation vs. Access to Essential Medicines

When trying to find a balance between maintaining incentives for innovation and reasonable access to existing medicines it must be noted that patent law supports the advancement of technology. The proper enforcement of which has the tendency to raise market prices. Despite this negative factor, a balance must be struck between encouraging future development and making the benefits of past development available for a reasonable price.[208] Thus, in determining the global benefit of patent rights, the question is whether such rights produce a favorable trade-off between the short-term cost to consumers through higher prices and long-term benefit to consumers through increased innovation.[209] In other words, determining whether the enforcement of patent rights' benefits outweigh the costs. The answer depends on social evaluations of which types of knowledge-based products are necessary and at what price. This is the case when analyzing with the issue of essential medicines for developing nations that are in dire need of greater health security programs. Furthermore, obvious differences in perspective exist between developed and developing nations when comparing present costs and future benefits.

The key issue from a global perspective is the allocation of innovation costs. For example, the costs of pharmaceutical research must be reasonably balanced across different economies, which means that the developed-world patient should pay a much larger per-capita share of those costs than does the developing-world patient. It seems

unfair to ask the consumers of developing nations to contribute to investments that are unlikely to benefit them. Moreover, it is quite possible that, the increased profits received on present pharmaceuticals under patent protection in the developing world are often re-directed toward research on medicines for the developed world. This is due to the greater likelihood of developing a financially successful product because the costs of research and development are easier to recover from a first world market base. It is difficult to encourage investment for pharmaceuticals oriented specifically toward developing world needs because the great cost of producing a pharmaceutical is unlikely to be recoverable from developing world markets. This problem may sometimes be resolved through public-sector investment support or product development undertaken with an expectation that costs will be recovered from the developed-world market,[210] while still targeted towards a health issue that is largely a developing world concern such as AIDS.

Furthermore, and seemingly more perverse, is the fact that a large portion of the increased profit generated through patent protection may actually be re-directed towards marketing expenses. As mentioned above, industry observers have claimed that most large pharmaceutical research companies spend twice as much on marketing than on research.[211] There is a definite question regarding the extent to which Intellectual property rents are used for research purposes rather than marketing and whether developing nation consumers should be expected to support such aspects of private industry, when their needs are often pressing, domestic public health epidemics.

Another point that is less persuasive, yet may have some validity, is that it is in smaller research firms, such as university laboratories, that the most innovative and cost efficient research is taking place.[212] The latter often have excellent research capabilities but lack appropriate funding, and increasingly are licensing their technology to large pharmaceutical companies for development. Once the licensing agreement has gone through, the original innovator and patent-holder normally relinquishes their Intellectual property rights to the pharmaceutical company. A question arises as to whether a purchasing company should be able to hold onto patent rights for such a long period when they had basically nothing to do with the original innovative effort. In any event, the legal theoretical link between the need for patent protection rights in order to induce innovation starts to undergo a certain degree of separation and becomes strained.

(c) The Role of the WTO

The practice behind this theoretical debate is being manifested primarily through the WTO. As mentioned above, TRIPs sets significantly higher minimum standards for Intellectual property protection than the various prior multilateral treaties. TRIPs arranges for the enforcement of these standards through the WTO panel process, which can impose trade sanctions against nations that do not comply with panel decisions.[213] WTO panels have thus become the ultimate international authority on intellectual property standards. This may affect the global patent regime significantly.

Take, for example, an American produced pharmaceutical whose European patent was not enforced. If the patent is subsequently enforced in response to a WTO panel decision, the price of the product should go up in Europe and the European consumer should pay more. While this is detrimental to the European consumer, it is a benefit to American industry. The U.S. firm gains additional revenues, and therefore, increased incentive to innovate and invest in research. Thus, we see again that there is a trade-off that results from the enforcement of patent rights. This example may be equally applicable to any case where a developed nation is the patent owner and the developing nation is the consumer.[214]

In this position, the WTO panels are able to make decisions based on specific case situations, which can influence future policy in various directions. This may be considered a powerful role and if used properly could be very instrumental in the enactment of socio-economic change at the International level. However, as has been discussed at various points throughout the thesis the WTO role has often been criticized as constraining, biased, and impotent in the face of pressure from powerhouses such as the United States and in some cases Europe.

The final chapter discusses how the WTO's role will either need to be decreased or significantly increased in order for it to become a more effective governing instrument of global patent protection rights.

(d) The Benefits of Differential Pricing

A final issue of inquiry is the economic implications of differential pricing. TRIPs fails to positively address the problem of parallel imports, or "gray market" goods. It does this by referring to Article 6, which states that "for purposes of dispute settlement under this Agreement ... nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[215]

The exhaustion of rights doctrine holds that once a rights holder introduces protected goods into the stream of commerce, there is no restriction on how the goods may be further distributed. The practice of parallel imports involves the importation of lawfully made products that were not intended for distribution in the country importing the goods.[216] The failure to directly address this issue of exhaustion is especially relevant to the parallel importation of pharmaceuticals, as there are significant price differentials on the same medicines legally produced in, or exported to, different countries.[217]

The result of the Uruguay Round's failure to conclusively address this issue is that importing nations can decide whether they want the exporter's rights exhausted, and can thus decide whether to protect their market from a lower foreign market price. In other words, price discrimination is possible at the option of the higher-priced market. This was precisely one of the disputes between the U.S. and South Africa over the latter's effort to maintain a low price for certain HIV medications.[218]

There are potential economic and social benefits to allowing for price differentials in special markets. From an economic perspective, by practicing market segmentation, pharmaceutical companies may seek to maximize potential marginal returns in countries with low purchasing power, while preserving high prices in stronger markets. Advocates of restricting parallel importation of medicines claim that such a strategy would encourage companies to sell at below world market prices to poorer countries. However, in practice, poor countries are not necessarily the beneficiaries of market segmentation. The ability to shop the world market offers consumers the advantage of price negotiating leverage with companies.[219]

From a social perspective, a developing nation may want to permit parallel imports of pharmaceuticals and not necessarily strictly enforce Intellectual property rights so as to give its consumers a gray market and provide the benefit of lower prices. The issue then comes down to a balance between the global interest in avoiding free riding and the fairness of allocating this share of the cost of innovation to the particular nation.[220] At least for pharmaceuticals, there is a strong argument for promoting an international policy of allowing two or three global prices, specific to developed and developing markets. In such an arrangement, gray markets may still be wide open within each of the tiers, but the price differences between the tiers would be protected.

There seems little question about the desirability of some form of price discrimination for pharmaceuticals. From the perspective of the patent-holder and producer, price discrimination seems to encourage and facilitate the successful development and

marketing of such goods. Moreover, with appropriate market segmentation prices are generally likely to be lower in developing nations and thus can benefit those who are in the greatest need.

6. Chapter Conclusion

Although access to affordable medicines for the developing world is an issue of monumental global importance, technological advancement is a necessary precursor for all the issues that are being discussed throughout this thesis. We must be careful not to stifle such advancement, because it is such advancement that provides us with the medicines that we need whether we are living in the developed or developing world. In addition, new technology is essential to the expansion of the global economy. It is responsible for at least one to two percent per year of the long-term growth in the U.S. economy,[221] and is likely to have a comparable contribution to global growth. Therefore, when striking a balance of the issues discussed throughout this chapter, we need to proceed with caution and insight in order to not place too much value on one prospective benefit, while neglecting others. And it has been shown that it is a delicate balance indeed.

The TRIPs Agreement seems to be only the very beginning to a large amount of work and debate that needs to be undertaken in order to properly address the numerous issues that are involved. What at first glance may seem like a relatively straightforward International treaty to cover the basics of Intellectual property law has in realty become the platform for an increasing array of complex socio-economic issues.

CHAPTER FOUR: PATENTABLE SUBJECT MATTER UNDER TRIPs: THE APPLICATION OF LAW TO SCIENTIFIC ISSUES

1. Introduction

As mentioned in chapter one, the TRIPs Agreement sets forth criteria for patentable subject matter.[222] This has brought with it substantial debate due to the controversy that has arisen over the past decade or so on the patenting of biotechnology products. The key relevant provision is Article 27, which provides that, "[a patent] shall be available for any invention . . . in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application."[223] Thus, TRIPs requires a patent be made available for any invention, product, or process, regardless of its field of technology.[224]

In addition, however, Article 27 sets forth guidelines for subject matter that may not be patentable.[225] These exceptions include inventions necessary to "protect *ordre public* or morality," "diagnostic, therapeutic and surgical methods for the treatment of humans or animals," and naturally existing plants, animals, and "essentially biological processes for the production of plants or animals."[226]

It is the fairly ambiguous wording of this section that has been the cause of great debate over the moral issues that arise when dealing with the patenting of biotechnology products. Moreover, there are copious specific biotechnological inventions that have generated great legal and moral debates over their patent eligibility.[227]

The goal of this chapter is not to advocate a position on the moral quandaries surrounding the patenting of biotechnology products or processes in one direction or the other, but rather to show that the TRIPs agreement is an insufficient framework for dealing with the breadth of the issues. The chapter outlines various national and international legal attempts to deal with some of the complex biotechnology issues that have arisen and how these issues may have differential effects on policy in the developed or developing worlds.

In this chapter, section two discusses patent eligibility of biotechnological innovations in the U.S. and Europe. First, I discuss of the U.S. law as it applies to the patent eligibility of biotechnological inventions. Second, I discuss current European patent laws dealing with the scope of patent eligible biotechnological inventions. The comparative analysis section points out the major differences that exist in the scope of patent eligible subject matter between the two regions and focuses on the U.S. system's absence of a patent statute expressly prohibiting patenting inventions on public policy or morality grounds. The analysis points out some potential benefits and detriments to the lack of such a statutory prohibition.

In Section three, I discuss issues of patent eligibility in the international arena. Part (a) of section three briefly revisits the goals behind recognizing patent rights, with an emphasis on biological innovations. Part (b) focuses on the relevant provisions of the TRIPs Agreement to biotechnology. Part four focuses further on the role of the World Trade Organization in the administration and enforcement of the TRIPs Agreement and is followed by a brief chapter conclusion.

2. Patent Eligibility of Biotechnological Innovations in the United States and Europe

In order to properly analyze TRIPs as a valuable International instrument it is important to examine the domestic law on this subject that has come out of key jurisdictions. The United States and the European Union will be given as examples because of their predominance on the stage of International scientific issues as well as being at the forefront of drafting and implementing law in this area.

Biotechnology is defined as "any technique that uses living organisms or substances from those organisms to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses."[228] The potential of this technology to improve the quality of life around the world is enormous.[229] While biotechnology is having a great impact on agricultural[230] and environmental issues[231], the technology that will be focused on in this chapter are breakthroughs in human health care science. This is where the most controversial and interesting subject of debate lies. Biotechnology is starting to have a major impact on the development of pharmaceuticals and the methods used to study and treat human disease.[232]

(a) Patent Eligibility in the United States

As mentioned in previous chapters, the U.S. has been the leader in advocating for the inclusion of intellectual property protection in international agreements and in supporting the implementation of uniform patent protection throughout the world.[233] The U.S. biotechnology industry has also led the movement toward the development of International

markets for the products of biotechnology.[234] Global markets reveal the promise of recouping the enormous cost of biotechnology research and development.[235]

At the national level, U.S. law provides the broadest possibility for patent protection in the world and is likely the most highly enforced.[236] Thus, biotechnological innovations born from research in areas ranging from human gene therapy to cloning, as well as processes for their production, are all potentially within the scope of patent eligible subject matter.

The foundational jurisprudence on patent protection of biological organisms is found in the 1980 U.S. Supreme Court landmark decision in *Diamond v. Chakrabarty*.[237] The Court held that an oil-digesting microorganism produced by genetic engineering was not excluded from the patent protection set forth in *35 U.S.C. 101*.[238] According to the Court, the test for patent eligible subject matter in biotechnology is "whether the living matter is the result of human intervention, not whether an invention embraces living matter."[239]

In the U.S., patent eligibility is based on Section 101 of Title 35 of the United States Code,[240] as interpreted by the Federal Courts. Section 101 of Title 35 states in pertinent part that "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."[241] To be patent eligible, a biotechnological invention must fall within one of the four statutory classes of subject matter: process, machine, manufacture, or composition of matter.[242]

There has been a litter of cases argued before the American courts over the past two decades, which has resulted in the evolution of patent law on biotechnological innovations. This case

law has generally led to the broadest patent eligibility possible and the United States Patent and Trademark Office **("USPTO")** and courts have seldom considered public policy and morality when addressing the issue of patent eligibility.

It has been only recently that the courts have had to revisit their stance on the criteria of patentablity. This has been spurred on by how science of biotechnology is now manipulating human biological material. For example, gene therapy uses recombinant DNA technology to introduce functional genes into the chromosomes of patients suffering from genetically based diseases, such as cancer.[243] As a process, gene therapy falls within the scope of patent eligible subject matter under *35 U.S.C. 101*[244] and the USPTO has issued dozens of gene-therapy patents. This type of controversial technology, however, has raised new questions of morality and how public policy should respond.

The American response to such issues is elaborated upon in the comparative analysis section after the discussion on patent eligibility in Europe. European legal institutions have developed a comprehensive regime of law in an attempt to address emerging scientific issues.

(b) Patent Eligibility in Europe

In Europe, existing patent laws expressly prohibit patenting certain biotechnological inventions.[245] In contrast to the U.S. statute, the European Patent Convention **("EPC")** does not expressly state which classes of inventions are patent eligible. The EPC explicitly precludes the patenting of certain biotechnological inventions. It prohibits the patenting of medical treatments such as gene therapy,[246] those inventions "the publication or exploitation

of which would be contrary to *ordre public or morality*,"[247] and "plant or animal varieties or essentially biological processes for the production of plants or animals."[248] The European Union Directive on Biotechnology issued on July 30, 1998 echoes the EPC language. The Directive prohibits the patenting of "plant and animal varieties" and "essentially biological processes for the production of plants or animals,"[249] inventions whose "commercial exploitation would be contrary to ordre public or morality,"[250] and the human body and its gene sequence unless isolated from the human body.[251]

Articles 52 and 53 of the EPC define the type of subject matter that is patent eligible.[252] Article 52(1) provides that "European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step."[253] The broad provision of Article 52(1), however, is narrowed in scope in subsequent provisions of the EPC.

For instance, the EPC expressly prohibits the patenting of gene therapy in the Contracting States under Article 52(4). Under this Article, treatments of the human or animal body by surgery or therapy, and diagnostic methods, are excluded from patentability because they are inventions that are not "susceptible [to] industrial application."[254] The purported reason for excluding gene therapies from patentability is to protect the practice of medicine from disruption by expensive and time-consuming patent litigation that could affect the quality of medical services provided to the public.[255] Unfortunately, restricting the ability to protect research investments decreases research funds, thereby possibly decreasing the quality of medical services provided to the public. Under the European system, compounds and compositions, as well as microbiological products and processes for use in gene therapy are generally patent eligible but are subject to the morality requirement in Article 53(a).[256]

Article 53 further limits the scope of Article 52 by providing exceptions for patent eligibility. In contrast to the U.S. statute on patent eligibility, Article 53(a) of the EPC expressly states that:

"European patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to ordre public or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States."[257]

The concept of *ordre public* could have profound effects upon the development of European patent law regarding animal patents and gene therapy patents.[258] *Ordre public* gives automatic standing to concerned citizens, empowering them to challenge individual patents on the ground that issuance would be morally offensive and allowing the use of the judicial process to shape the law regulating biotechnology patents.[259] In contrast, this type of standing is not available to U.S. citizens following the decision in the case *Animal Legal Defense Fund*.[260] Such changes in the United States must instead come by the legislative process.

Similarly, Article 53(b) expressly states that "European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."[261] The provisions of the EPC, however, do not define the meaning of "varieties" or "essentially biological." The absence of binding definitions creates the potential for differing

applications of these terms and insufficient market valuations for inventions that embody this subject matter.

Although the EPC provides uniform procedures and standards for examining a patent application, the interpretation and enforcement of a patent thus granted are reserved for the laws of the individual Member nations.[262] To pursue a harmonization of patent policy that would give Europe a competitive advantage in biotechnology innovations, the Council of Ministers in 1988 prepared a first draft of a Proposed Directive for the Legal Protection of Biotechnological Inventions.[263] The objective of the Proposed Directive was to outline rules for the patentability of genes, cells, and other biological material derived from humans, animals, and plants, including the patentability of gene therapy.[264]

On July 30, 1998, the European Union issued Directive 98/44/EC to protect inventor's rights in certain biotechnological products.[265] Article 1 of the Directive provided that the Member States must protect such inventions under their national patent laws,[266] and had until July 30, 2000 to reform domestic laws.[267]

As with the EPC, patent protection under the Directive does not reach certain biotechnological inventions. The Directive expressly prohibits the patenting of animal and plant varieties[268] and inventions whose commercial exploitation would be contrary to ordre public or morality.[269] It differs from the EPC by not expressly excluding all treatment methods of the human or animal body by surgery or therapy and diagnostic methods from patent protection. Rather, the Directive specifically prohibits processes for modifying the germ line genetic identity of human beings by proclaiming them contrary to *ordre public or morality.*[270] Additionally, the Directive excludes the human body and its gene sequence from

receiving patent protection, except when the gene sequence is isolated from the human body.[271]

Under Article 4(1), "plant and animal varieties," and "essentially biological processes for the production of plants or animals" are excluded from patent protection.[272] As in Article 53(b) of the EPC, Article 4(3) specifies that the provision of Article 4(1) does not apply to microbiological processes for the production of plants or animals. Additionally, Article 4(2) expressly states that plant and animal inventions are patent eligible if "the technical feasibility of the invention is not confined to a particular plant or animal variety."[273] Unfortunately, the Directive does not provide a clear and workable definition of a "variety."[274]

Under Article 5(1), the human body and its elements, including the sequences of its genes, are also excluded from patent protection.[275] If the elements or sequences are isolated from the human body[276] and their industrial applications are disclosed,[277] however, the elements or sequences can constitute patent eligible inventions.[278]

Article 6 precludes patentability of inventions on the grounds of damage to *ordre public or morality*.[279] This provision is similar to Article 53(a) of the EPC. Unlike the EPC, however, Article 6(2) specifically enumerates types of inventions whose commercial exploitation would be contrary to *ordre public or morality* and therefore not patent eligible.[280] They include:

1) "processes for cloning human beings,"

2) "processes for modifying the germ line genetic identity of human beings,"

3) "uses of human embryos for industrial or commercial purposes," and

4) "processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man and animal, and also animals resulting from such processes."[281]

The differences in the EPC and the EU Directive's provisions may cause some confusion to the interpretation of ordre public or morality in Europe.[282] In particular, it is unclear whether Article 9(2) of the Directive represents an exhaustive list of examples of activities regarded as contrary to public policy or morality.[283]

(c) Comparative Analysis of the U.S. and European Patent Systems

Discrepancies remain in the scope of patent eligible biotechnological inventions between the patent systems of the United States and Europe. As mentioned before, U.S. patent law provides the broadest protection of biotechnological inventions.[284] As long as the subject matter to be patented falls within one of the four statutory classes and involves human intervention, it is patent eligible.[285] While the TRIPS Agreement permits member states to "exclude from patentability" certain inventions, "the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public or morality*," and inventions drawn to "diagnostic, therapeutic and surgical methods for the treatment of human and animals," as well as "plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals,"[286] the U.S. patent system does not recognize such exclusions.

These exclusions were apparently added as a concession by the United States to obtain support of developing countries for the TRIPS Agreement.[287] This is another example of the

U.S. making concessions to developing nations that basically end up being ineffectual due to the relative strength of domestic U.S. patent laws and market strength. De jure, the exceptions are included in the International regime so as to appease the developing nations' position and coerce them into signing the Agreement, but de facto the provisions would be difficult to enforce against U.S. law.

Meanwhile, Europe continues to be more concerned about the issues of morality and how public policy, including intellectual property legislation, should address them. While the European patent laws expressly prohibit the patenting of inventions based on public policy or morality grounds, the U.S. patent system notably lacks any express prohibition on these bases.

The USPTO, however, was coming dangerously close to adopting the perspective of the EPC and the EU Directive on the moral utility requirement in its April 1, 1998 press release regarding the patent application on a human/non-human chimera.[288] Stuart Newman's chimera invention[289] was an attempt to re-ignite a public debate on the patenting of life forms.

In an earlier debate, the USPTO reached a decision not to grant the patent on the claimed human/non-human chimera. The USPTO took the position that "Congress did not intend to allow patents on humans or on creatures that are essentially human when it passed the Patent Act in 1956."[290] The USPTO also argued that granting patents on people would violate the 13th Amendment to the Constitution abolishing slavery, claiming that neither the USPTO nor Congress has ever defined "human."[291] Stuart Newman challenged this argument and subsequently submitted a revised application to the USPTO. The intent was to provoke a

debate about the meaning of "human," and undermine the legal basis for patenting life forms set forth in the *Chakrabarty* decision.[292]

In Europe, Under Article 53(a) of the EPC and Article 6 of the Directive, Newman's chimera might not be patent eligible because its production would contravene *ordre public or morality.*[293] The pursuit of a moral utility argument by the USPTO, however, would be precarious because it will without a doubt open the floodgate for public involvement and scrutiny. This is due to the fact that the case law in the area has traditionally led away from the imposition of asking moral questions on patent eligibility.

While the USPTO appeared to have initially advanced the European morality argument for patent ineligibility of Newman's claimed invention, it ultimately rejected the claimed chimera on a different ground. The rejection was based on the belief that Congress did not intend *35 U.S.C. 101* to include the patenting of human beings or inventions that "embrace human beings."[294]

Both the U.S. Congress and the U.S. courts have indicated that when considering patent eligibility, the appropriate question is not whether living organisms are patent eligible subject matter, but rather, whether the "hand of man" has been involved in a subject invention.[295] *Diamond v. Chakrabarty* paved the way for a variety of U.S. patents involving living materials, including genetically engineered plants and animals and genetic materials. With respect to inventions "embracing human beings," the courts do not provide guidance as to whether a human being is considered patent eligible subject matter. The USPTO, however, has consistently taken the position that a claim directed to, or including within its

scope, a human being is not considered to be patent eligible subject matter under the patent laws.[296]

Newman's attempt to force the USPTO to announce a bright-line rule that will clearly defines what is "human"[297] raises the question whether the patent law itself is an appropriate vehicle to resolve the moral and social issues of technological advance. The generally held view in the U.S. is that the role of defining the limits of patentability should be left to the Congress.[298] Neither the USPTO nor the U.S. courts are equipped to weigh the competing economic, social, ethical, and scientific considerations involved in inventions produced by emerging technologies. Newman asserted that his motivation for filing the patent application was to halt research by others in the area of humanized animal models for medical testing.[299] The denial of patent protection to the chimera invention on purely ethical considerations, however, is not likely to put an end to research in the area.

A bright-line rule on what is "human" could provide the predictability that the biotechnology industry desires,[300] however it will be a daunting challenge to define exactly what is "human." Alternatively, the Congress could enact legislation similar to that currently enforced in Europe, which prohibits the patenting of inventions based on *morality or ordre public* grounds.[301]

This however would give standing to concerned citizens to challenge individual patents.[302] Such discretionary actions by the agency could embroil the USPTO in extensive litigation, but would make it more responsive to societal pressures.[303] Neither of these two legislative options is advisable in this case because each will likely put the USPTO in the position of becoming an advocate in public policy debates on the meanings of "human" and "morality."

At present, as an administrative agency, the USPTO is not equipped to act as an advocate in such public policy debates.

The European patent laws expressly prohibit the patenting of medical treatment methods and inventions that contravene *ordre public or morality*.[304] The EU Directive compromises the EU's aggressive goal for economics reform by including the *ordre public* doctrine, which calls for a case-by-case examination of moral and ethical considerations in each patent application.[305] Under the European system, for an animal invention to be patent eligible, its technical feasibility must not be confined to a particular animal variety.[306] Moreover, benefits to mankind must outweigh the sufferings of the animal and the potential risks to the environment to meet the morality requirement.[307] Problematically, this catchall *ordre public* clause erodes any such bright-line rule and the ability of the biotechnology industry to profit from cutting-edge technology.[308]

Now that a transitory analysis has been undertaken of recent developments in the American and European regimes on dealing with morality issues, we can look at how International law and its governing bodies have influenced regional development and vice versa.

3. Issues of Patent Eligibility in the International Arena

This section outlines the criteria of patent eligibility of biotechnological innovations under the current International regime. The TRIPs Agreement has brought to the forefront the complexities inherent in achieving a harmonization of Intellectual property rights protection.[309] It has been extremely difficult for International parties to reach consensus on

the multitude of divergent interests that surround the field.[310] Such divergent interests are exemplified by the controversy surrounding the patenting of biotechnology products.[311]

The controversy surrounding biotechnology, as with ensuring access to essential medicines, draws into focus many of the challenges of relying on the far-reaching TRIPs Agreement and the unique structure of the WTO to achieve International governance of patent rights through the enforcement of uniform trade standards. Concerns commonly associated with the WTO include: whether it is undemocratic and undermines the sovereignty of governments; whether it values the interests and needs of developed nations to the detriment of developing countries; and whether it is indifferent to advocates for the protection of the environment, health and safety. [312]

(a) International Patent Rights and Biotechnology

Biotechnology issues would at first glance seem to be restricted more to domestic concerns, but actually much of the controversy arises from the cultural and economic differences between developing and developed nations.[313] For example, issues of ownership and access to biological resources have fueled the debate. While innovation and production stems from developed countries, much of the world's biological resources are found in the developing world. [314] It is these resources, which are the source material of biotechnological innovations.

Patent laws create property rights for developers of innovative ideas to compensate them for the labor and resources expended during the creative process.[315] By rewarding research and development, patent systems are intended to foster the creation and dissemination of new

knowledge, thereby benefiting society in general as well as the individual inventors. Most developed nations follow this philosophy and have established extensive systems for the protection of innovative activity. [316]

This dominant philosophy, however, is not globally accepted. Many developing countries regard knowledge as communal rather than private property.[317] These societies value and encourage intergenerational innovation, perceiving inventions not as purely unique personal achievements but as extensions of existing ideas and discoveries.[318] Furthermore, although they are the proprietors of much of the world's biological resources[319] and the caretakers of extensive indigenous knowledge,[320] these nations are less technologically advanced than their industrialized counterparts. As a public policy, countries in this position recognize the value of using imitation strategies as a means of catching up technologically.[321] These cultural and economic forces counsel against strict Intellectual property regimes, and until recently, many developing countries did not adopt or enforce patent rights.[322]

In addition to differing on the general applicability of Intellectual property law, developed and developing nations clash over the appropriateness of creating private property protection in sensitive subject areas such as biotechnology.[323]

Despite widespread medical, agricultural, and environmental applications, there is substantial International variation in the protection afforded biotechnological innovations.[324] These may be due to differences in perception as to whether such innovations should be classified as scientific discovery or invention.[325] The line is often blurry in the case of biotechnology because of the complexity of process frequently required to discover potentially valuable biological components. The industrial applicability of such discoveries

is also often unclear at the time of detection, but may become apparent shortly after. Commentators have also debated whether biotechnological innovations meet the standard patentability requirements of novelty[326] and non-obviousness.[327] Thus, differences between nations on biotechnology patent issues encompass many cultural and administrative concerns not easily harmonized through one International agreement.[328]

Traditionally, the substantive aspects of patent laws have been determined nationally rather than Internationally, and thus have reflected each country's unique stand on the relevant philosophical and policy issues.[329] Fundamental differences between nations in the substantive and procedural protections of Intellectual property systems have been an accepted part of International Intellectual property agreements.[330] Prior to the adoption of the TRIPs Agreement, the multinational agreements most relevant to the controversy surrounding the protection of biotechnological inventions were the Paris Convention for the Protection of Industrial Property, the International Union for the Protection of New Varieties of Plants, and the Convention on Biological Diversity.[331]

It was the TRIPs Agreement, however, that resulted specifically to address the increasing emphasis on expanding International Intellectual property rights and has led the movement towards the harmonization of global patent rights.

(b) Provisions of TRIPs Relevant to Biotechnology

(i) General Provisions of the TRIPs Agreement

The objective of the TRIPs Agreement is that:

"the protection 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 technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[332]

This objective reflects the harmonizing of interests between developed and developing nations, and specific provisions in the Agreement further reflect this balancing act.[333] The TRIPs Agreement adopts the substantive provisions of the existing Intellectual property conventions, including most of the Paris Convention.[334] The principle of national treatment is also expressly incorporated into the TRIPs Agreement.[335] The benefits of being a TRIPs Member are guaranteed through the incorporation of most-favored-nation treatment.[336] Most-favored-nation treatment requires signatories to afford to all other Members any privileges their national Intellectual property rights system gives to foreigners.[337] Most-favored-nation treatment is a common feature of GATT agreements, but a new development for International Intellectual property regimes.[338] The TRIPs Agreement also establishes enhanced substantive and procedural enforcement mechanisms designed to give it more strength than previous treaties.[339]

As mentioned in previous chapters, the TRIPs Agreement also establishes minimum national standards for patent protection. It does so, however, with an exception that permits members to "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."[340] This public policy exception allows Member nations to retain a considerable degree of legislative flexibility, subject to the caveat that "such measures are consistent with the provisions of this Agreement."[341] It is likely that this provision will allow nations to take steps that conflict with individual TRIPs provisions, so long as they are consistent with the Agreement as a whole.[342]

(ii) Specific Provisions of The TRIPs Agreement Relating to Biotechnology

The specific provisions of TRIPs set broad boundaries for the protection of biotechnological inventions, with much ambiguity remaining because of the liberal public interest exception, as well as the incorporation of intentionally vague terms.[343]

As mentioned above, the key relevant provision relating to Biotechnology issues is Article 27. This Article addresses protection through patents.[344] It states that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[345] Member states must offer this protection on a non-discriminatory basis, regardless of the location of invention, the field of technology, or whether a product is imported or locally produced.[346] In addition to this general requirement, Article 70.8 outlines the application of this protection to pharmaceutical and agricultural chemical products.[347] This Article requires that intermediate steps be taken to ensure protection of these

products.[348] Protection is granted even during the transitional period incorporated into the TRIPs Agreement that allows less developed nations time to acquire appropriate infrastructure to support compliant Intellectual property regimes.[349] This specialized treatment is a reflection of the social and economic significance of pharmaceutical and agricultural chemical products. It is noteworthy that this treatment is limited to the final product being marketed and does not encompass the creative processes or component parts of these products.[350] Rather than mandating protection, the TRIPs Agreement specifically exempts these more controversial innovations from its general patent requirements.[351]

Article 27.2 is the specific provision that is the source of controversy in terms of the moral debates that have arisen from certain innovations. This Article allows members to exclude from patentability inventions whose commercial use would jeopardize the "ordre public or morality" of their state.[352] This broad provision explicitly authorizes the exclusion of certain inventions from patentability in order to "protect human, animal or plant life or health or to avoid serious prejudice to the environment."[353] The only limitation to this broad exception is that simply having a domestic law prohibiting the exploitation of an invention will not by itself sufficiently implicate the ordre public to qualify under these terms.[354] In addition to the potentially far-reaching *ordre public* exception created by Article 27.2, Article 27.3(a) specifically allows Members to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals."[355] This exception reflects the acknowledged public interest in stimulating widespread dispersion of therapeutic innovations.[356]

Article 27.3(b) is the most direct language used by the Agreement in terms of application to biological entities.[357] This Article expands the types of subject matter that may be excluded

from patentability to include "plants and animals other than microorganisms."[358] This wholesale language creates an exception to patentability broader in scope than that adopted by European nations and other legislative bodies adopting a European stance.[359] Under Article 27.3(b), Members may also exclude from patentability "essentially biological processes for the production of plants or animals."[360] This exception, derived from European law, is generally thought to turn on the degree of technical intervention involved in creating the process.[361] The greater the need for intervention, the less likely the process is to be classified as "essentially biological" and the more likely it is to be patentable.[362] In contrast non-biological and microbiological processes related to the production of plants or animals are patentable under the text of Article 27.3(b).[363] A non-biological process refers primarily to a therapeutic treatment of plants that is generally recognized as patentable in Europe.[364] Microbiological processes are harder to define; generally, they are thought to involve the use of microorganisms such as "viruses, algae, bacteria and even cells or cell lines," although the definition of a microorganism may vary by country.[365] Additionally, it is not clear how processes involving only "microbiological" steps are to be treated.[366] These terms and others used in Article 27.3(b) are not defined in the TRIPs Agreement; they are thus subject to national interpretation.[367]

The language of Article 27.3(b) is both sweeping and vague due to the real complexities involved in classifying biotechnological innovations.[368] It allows for a temporary compromise among the many competing interests in the protection of biotechnology. The provisional nature of this compromise is evidenced by the inclusion of an early revision date for these provisions. The provisions of this subparagraph are to be reviewed four years after the date of entry into force of the WTO Agreement.[369] The first review was scheduled for January 1999.

This Article is the "only provision in the TRIPs Agreement subject to an early revision, special treatment that again indicates the controversial nature of these issues.[370] The drafters of this Article anticipated a negotiated revision of the terms of Article 27.3(b) as the primary way of resolving this controversy and being able to adapt to issues.[371] In addition to lobbying for new agreements favorable to their interests, countries may also seek modification and clarification of these nebulous terms through the use of the World Trade Organization's administrative committees and dispute settlement procedures.[372]

A brief overview of the role and function of the WTO follows in order to understand its administrative capacity over the TRIPs Agreement. A specific focus on the required review of Article 27.3(b) is used as an example to show some of the difficulties the current regime is having with dealing with the controversial and mutable issues of biotechnology.

(c) The Role of the WTO

The WTO is a rules-based organization whose primary objective is "to help trade flow smoothly, freely, fairly, and predictably."[373] Its main functions are administration of trade agreements,[374] establishment of a forum for trade negotiations, resolution of trade disputes, review of national trade policies, cooperation with other international organizations,[375] and provision of support for developing countries in trade policy issues.[376] The Ministerial Conference is the top-level decision-making body within the WTO.[377] It is composed of all WTO members,[378] meets at least once every two years,[379] and acts by consensus to affect matters under any of the multilateral trade agreements.[380]

Between Ministerial Conference meetings, the General Council supervises the WTO's day-to-day work, which is carried out by committees focused on specific tasks or areas of trade.[381] Among these specialized committees, the Council for Trade-Related Aspects of Intellectual Property **("TRIPs Council")** monitors the operation and implementation of the TRIPs Agreement.[382] The transparency commitments of the TRIPs Agreement facilitate this monitoring process by requiring members to disclose relevant laws, regulations, final judicial decisions, and administrative rulings.[383] Whereas Part III of the TRIPs Agreement provides limited instruction as to requisite domestic enforcement measures,[384] the TRIPs Council is more a facilitator of the agreement than an enforcer of its terms.[385] The TRIPs Council may recommend changes to or interpretations of the TRIPs Agreement, but only the Ministerial Conference, and at times the General Council, may actually adopt such alterations.[386]

This administrative framework means that any modifications to Article 27.3(b) of the TRIPs Agreement as a result of the early review procedure must be adopted through consensus of the entire WTO membership.[387] Additionally, disputes between members are intended to be resolved not by the TRIPs Council, but through the structures created by GATT Article XXIII and the process defined by the Understanding on Rules and Procedures Governing the Settlement of Disputes.[388] This incorporation of a system for multilateral resolution of intellectual property disputes is one of the most significant features of the TRIPs Agreement.[389]

4. Chapter Conclusion

As mentioned above, the TRIPs Agreement mandated review of Article 27.3(b) beginning in January 1999, but it did not define the procedure or scope for that review.[390] Because of the extended timeframe for transitional arrangements for developing countries,[391] this review was slated to begin before most members will even have attempted to implement the current TRIPs provisions.[392] Moreover, the lack of information regarding the effects of the first phase of provisions increases the difficulty of redefining the Agreement's understanding on issues related to patenting biological entities.[393]

Some WTO Members argued that the review should be an examination of the extent to which the current provisions have been implemented.[394]Developed nations seem to have the viewpoint that the vague terms of Article 27.3(b) should be defined or deleted. They worry, however, that any attempt to change the terms will lead to a weakening of protection. Other Members favored a more substantive process that might encompass changing the text of the article.[395]This tends to be the view of the developing nations.

Other commentators simply proposed a summary execution of the review, postponing any significant substantive or procedural changes until more information is available.[396] Such preservation of the status quo would maintain the tentative compromise reached on issues of patent rights in relation to biotechnology and life forms.[397] Opponents of this suggestion maintained that Members might attempt to bypass WTO amendment procedures and define the vague terms of Article 27.3(b) through other means.[398]

For example, some commentators have suggested that the TRIPs Council may have the power to modify the Agreement without requiring the approval of the Ministerial Conference.[399] This procedural loophole turns on interpretation of the language of Article 71.1 of the agreement, which empowers the TRIPs Council to "undertake reviews in the light of any relevant new developments, which might warrant modification or amendment of this Agreement."[400] Some commentators argue that this broad language gives the TRIPs Council the authority to issue statements of interpretation that the Ministerial Conference is not able to review so long as they only modify existing TRIPs terms.[401] Whether the TRIPs Council has this power under Article 71 is debatable,[402] as is whether the Council would exercise that power if it were available. It should be noted, however, that the potential bypass of the consensus-based decision making of the Ministerial Conference was suggested specifically in relation to revision of Article 27.3(b).[403]

Another possible means of bypassing the Ministerial Conference is through the WTO's Dispute Settlement Body, whose panels issue decisions that become binding on the parties involved and set precedents for other members in future disputes.[404] These panels could be used to define indistinct terms and effectively limit the ability of member countries to determine the precise rights of patent holders under domestic laws.[405] The central concern with clarifying terms through case-by-case decision making is that it will produce shortsighted decisions with unfortunate local and international effects.[406]

To date, no complaints have been filed concerning the terms of Article 27.3(b),[407] therefore no attempts have been made to abuse the dispute settlement process by circumventing the negotiating bodies of the WTO. Despite the lack of direct legal action, the threat of such action may still affect domestic policy decisions regarding interpretation of the terms of the

Article.[408] This potential effect in addition to general dissatisfaction with the Article's current terms make it likely that alterations to the specific provisions of Article 27.3(b) will be required.[409] Both procedural and substantive revisions of Article 27.3(b) will likely continue to pose many challenges due to the different courses of action that might be taken under WTO structure.

In any event, the only thing clear is that the ambiguity and uncertainty of the intentionally vague and sweeping language used in the Article 27 provisions that relate to biotechnology has not satisfied many commentators on how to appropriately deal with this subject area.

CHAPTER FIVE - RECOMMENDATIONS FOR CHANGE IN THE CURRENT INTERNATIONAL PATENT SYSTEM

1. Introduction

Despite the criticisms presented throughout the course of this thesis, TRIPs remains an effective compromise that, while imperfect, has definitely taken unprecedented steps towards the harmonization of international patent law. While, this is the general direction that we want to head, much more work must be done to deal with the intricate issues that the Agreement attempts to address and the issues that have arisen under its framework.

One must remember in analyzing TRIPs that the Agreement represents a compromise. As with any compromise, it attempts to balance the needs and desires of all Members in order to fulfill a common goal. The Agreement has sought to treat all Member States equally by implementing the most-favored nation status, while at the same time making concessions to those states in need of additional compliance time due to their socio-economic positions. This has led to the construction of a regime that has at certain times worked effectively and at other times has left various parties confused and has lead to disputes.

This thesis has not advocated a complete dismantling of the current global treaty system protecting patent rights. Rather, the methods used to construct these treaties should be re-evaluated. Developed nations' dominance in the drafting and implementation of global treaties needs to be re-directed towards a system that will ensure that the interests of all parties are met on a more equitable basis.

The recommendations I propose here are by no means complete, yet I believe all of them would be a further step in the right direction. Many of the unanswered questions will have to be worked out by the governments of both developed and developing nations through negotiation and compromise. These recommendations, however, may guide them in the furtherance of their goals towards greater co-operation, clarity, and a more equitable balance of interests.

Recommendation One: Allow Greater Freedom for Bilateral Negotiations

The only truly effective method to ensure proper patent protection is to foster good relationships among all nations. Such relationships are almost impossible under the vague classification system set out in TRIPs. Classifying nations as developed, developing or least developed makes the provisions difficult to apply and unclear as to the extent of their enforcement. Furthermore, to place all of the parties involved under an umbrella framework makes for difficult sessions at the negotiating table where more problems are often created rather than solved.

A more effective way to ensure patent rights are met while considering a balance of competing interests in nations with varying social, economic, and political systems may be through individual, bilateral negotiations. These rights would be better addressed on a case-by-case basis when disputes arise and allow nations to negotiate free of the relatively strict, yet unclear provisions that the TRIPs Agreement has set forth. Nations will be more likely to uphold terms in which they have a vested national interest, rather than paternalistically mandated terms that likely have not taken into consideration the complexities of the individual situation.

Recommendation Two: Pay More Attention to Global Competing Interests

In order to balance the competing interests involved in patent protection, more value will must be placed on socio-economic issues in the international forum and not only on Western business interests and the legal theory behind what is required to stimulate and reward innovation.

Pharmaceutical companies seem to be fragmenting into separate research & development and marketing functions. This situation may provide increased insight as to which consumers should be responsible for what portion of a profit margin artificially increased by patent rights. The citizens of developing nations, with their relatively low purchasing power, cannot be reasonably expected to pay prices on par with the citizens of developed nations. Presently, there is general lack of transparency regarding which dollars are allocated directly back into investment in research and which end up strictly being used for other business functions. On the International plane, the TRIPs Agreement has served to muddle the problem by channeling resolution of conflict through a regime of elaborately articulated property "rights."

Resolutions to the affordability problem are only part of a larger public health challenge to the infectious disease crisis in the developing world. The mechanisms for patent protection established through the TRIPs Agreement and the current administrative effectiveness of the WTO are not suited to overcome this dilemma. Not only do they operate in an inconsistent

manner, but they also are not entirely reflective of the actual nature of the competing and intertwined developing world interests.

If the developed world does not start taking a more global perspective towards the health crises issues of the developing world, the future costs will likely begin to outweigh the present benefits created by a regime that is directed toward the maximum protection of Intellectual property rights. It is also a regime that currently serves more to the benefit of the developed world than their weaker counter-parts. In a world where viruses such as the recent outbreak of SARS travel borders like citizens without passports the developed nations will eventually feel the brunt of a disease that may have been avoided had more importance been placed on recognizing and resolving some of the health care problems that the developing world is currently facing. While the rights of patent holders are canonized at the International level, the balancing of public health and consumer needs remains a residual category relegated to the domestic sphere. From the perspective of trying to build a more co-operative global community, this is socially irresponsible.

Recommendation Three: Bring Greater Clarity to the Criteria for Patentable Subject Matter Debate and how Biotechnology can be used to enhance the Lives of Global Citizens

The demand for increased patent protection for biotechnology has also generated significant International debate. From an socio-economic standpoint, some of these International issues were introduced in Chapter Three in the form of a debate over what type of balance must be achieved when it comes to the protection of patent rights versus access to essential medicines. This debate also applies generally to the area of biotechnology, which was the

topic of Chapter Four, since research in this area has the potential to revolutionize pharmaceutical industries and health care systems worldwide in the form of new therapies.

Achievements in the biotechnology arena are essential to improving health care needs in developing countries, however as we has seen patent protection generally increases the immediate cost of utilizing such innovations, and many developing nations are concerned about imposing this added cost on their impoverished citizens.[410]

There are many areas of controversy that fall under the realm of International biotechnology issues and patent rights. For example, patent protection, lauded as a means to foster research and development, tends to focus on what will ultimately be commercially marketable.[411] These market-based priorities may not coincide with the innovations most needed by patients and other participants in less developed economies.[412] Concerns have also been raised over the safety and moral issues of the many new biotechnology products reaching consumers.[413]

The increased profitability and commercialization of biotechnology has also led to heightened awareness concerning issues of biopiracy and biotechnology's potential ramifications on resource drain and disruption of the environment.[414] Biopiracy is the use of traditional knowledge without authorization from native communal caretakers. For example, in the early 1990s, pharmaceutical company Eli Lilly discovered the cancer-fighting properties of the Rosy Periwinkle plant, based on the knowledge of traditional healers in Madagascar. The company reaped substantial financial benefits while the people of Madagascar received no compensation whatsoever.[415] Mechanisms to prevent this type of exploitation need to be further implemented in the international regime. Although curbed by

the emergence of prospecting agreements between the governments of biologically rich countries and private corporations seeking use of those resources,[416] these concerns still exist.[417] The demand for enhanced patent protections for the robust yet controversial biotechnology industry was a significant factor in the overall development of the 1994 TRIPs Agreement, and directly influenced specific provisions of that Agreement.[418]

Patents help attract the investments needed to continue research and facilitate the relationship between government, academia and the private sector. The patent system stimulates disclosure of research results that others can build on. Disclosure occurs not only via the publication of the patent document, but also by facilitating more open communication between scientists.[419] Without patent protection, many research scientists would be less willing to publicize their work and collaborative efforts and progressive developments would be diminished.[420]

In the U.S. the patent system is vital to the growth of the biotechnology industry, particularly because small biotechnology companies invest enormous sums of money in research and development. Often Intellectual property is the only product that a young company can show its potential investors; and patents are ideally suited to protect technology-based Intellectual property.[421]

The patent laws of developing nations, on the other hand, are noted for desiring greater limitations upon patent eligibility.[422] Countries that invest little in research and development may obtain a temporary advantage by limiting patent protection and free riding on the research investments of the more developed countries. The scope of patent eligible subject

matter typically expands as a nation realizes increasing economic growth and industrialization.[423]

This happens to a certain extent in competition between developed nations as well. The U.S. has capitalized on its strong biotechnology research base and broad concepts of patent-eligible subject matter to lead the world in biotechnological research and development.[424] Europe to a certain extent is in the position of playing catch-up. Just as developing countries can gain a temporary free-rider advantage by providing minimal patent protection, Europe has limited their patent protection in those biotechnological areas that trail the U.S. While such limited patent protection provides short-term benefits, it also runs the risk of locking Europe into long-term positions of technological inferiority by failing to adequately protect research and development investments in biotechnology.[425]

In addition, Europe's express prohibition of patenting inventions that contravene *ordre public or morality* tends to encourage private citizens' involvement in the patent granting process.[426] Whether public policy will strongly affect the position of patent policy in the U. S. remains to be seen and it will be interesting to see how this area develops, as innovative products become more and more controversial.

Recommendation Four: Further Analyze the Effects of Introducing Knowledge-Based Products into the Realm of Traditional Trade Theory

Trade in knowledge-based products is different from trade in "normal" products. It benefits consumers in both exporting and importing nations; but prices are often artificially high

based on quasi-monopoly pricing. Thus, the application of a well-designed patent protection system in every nation is a clear benefit, but individual nations may not necessarily benefit immediately. Therefore, the role of the global system is one of preventing free riding, while at the same time inducing a fair allocation of the costs of creating the Intellectual property rights.

In traditional trade, the WTO process is assisting nations in parallel moves towards a mutually beneficial goal of removing trade barriers. In Intellectual property, it is supervising a system, which can provide global benefits if the patent protection system is of the right strength. More Intellectual property protection is not necessarily better.[427] Moreover, the role of the WTO in knowledge-based trade should be directed more towards allocating the costs of creating Intellectual property and avoiding free-riders, which is very different from ensuring that trade barriers are removed.

Intellectual property is important to the future of the world and its encouragement necessarily involves trade: Thus, WTO involvement in TRIPs and other mechanisms created to better govern International patent issues should be continued. Nevertheless, its role must be fairly seriously refined. This implicates many legal and procedural adaptations to the deficiencies that the WTO has faced in the past with regards to being a truly effective global governing body, even in the face of American or European pressure. Many of these issues were laid out in the previous chapters and they will need to be addressed further.

The collection of statistics on intellectual property outcomes would be a new WTO activity that might better equip the administrators of TRIPs or other mechanisms to resolve some of the myriad of issues that have been laid out through the course of this thesis. One example

of this would be the collection of statistics to estimate whether the cost of patent protection is being reasonably allocated among nations of differing economic status. This would enable policy-makers to implement strategies that equitably burden consumers with different relative purchasing power.

Also more empirical information is needed to estimate the effectiveness of the current international regime to actually promote innovation, with an comparative analysis of the profits derived from the use of patent law in different nations. This type of analysis could lead to a better extrapolation of how advanced a developing nations' patent regime should really be and possibly allow them to better allocate their limited resources elsewhere. Patent regimes in developing countries do not necessarily have to be exactly harmonized with developed nation standards. When countries are still developing they often have more pressing immediate needs, such as advancing their health care and education programs, before they can be entirely concerned with the enforcement of Intellectual property rights to promote innovation. Thus, a reasonable analysis of what each country is able to implement and enforce must be taken into consideration when attempting to harmonize global patent law.

These are difficult tasks and may be possible only on a very approximate basis.[428] Yet, the WTO is already an important compiler and distributor of trade statistics and trade now includes Intellectual property. The types of studies mentioned will help determine if the integration of TRIPs into the WTO was beneficial and will help the various parties involved to make any necessary modifications.[429] If they do show that the TRIPs system is beneficial to global interests, they will contribute to the legitimacy of TRIPs in the global community. If they show otherwise, however, more focus must be continued to be placed on the various

recommendations presented in this chapter in order to more fully develop the International regime for the benefit of all parties involved.

The next two recommendations assess the implications of possible developments in the field of International patent law and the future of the WTO. These issues are discussed both in a general sense and in the specific sense of biotechnology issues under Article 27 of TRIPS.

Recommendation Five: When Adjusting the International Regime more Emphasis should be placed on ensuring that the cultural interests and legal traditions of Developing Nations are being considered under the Framework

Global harmonization of substantive patent laws arguably offers significant benefit to the global economy as well as to specific nations.[430] Harmonization should encourage research in beneficial areas and stimulate the distribution of the products of scientific development. International agreements on patent rights have slowly moved in the direction of establishing global minimum protective standards.[431] These standards have tended to emerge from the existing laws and philosophies of developed nations with little accommodation for the divergent cultural interests and legal traditions of less developed countries.[432] The argument being that developing countries will nevertheless receive benefits from an attendant increase in the transfer of technology. The TRIPs, however, Agreement has generally turned out to be a prime example of developed countries asserting their influence over developing nations. The TRIPs Agreement combines basic guidelines for patent protection with significant enforcement mechanisms, effectively revolutionizing International Intellectual property law,[433] in a direction that satisfies developed nations desires' and legal tradition.

Although the TRIPs Agreement signifies a giant step towards the harmonization of global patent rights, this movement has just begun and the debate between developed and developing nation interests is still underway. One major point of contention is finding common ground between the many divergent interests affected by patent standards. These differences are particularly notable in the area of protection of biotechnology innovations. The concept of patenting life forms has moral, social, economic, cultural, and religious implications, making mutual agreement on issues difficult to achieve.[434] For example, a narrow compromise on these issues was reached with the creation of *Article 27.3(b)* of the TRIPs Agreement.[435] Future review of the terms of this compromise is likely to produce many conflicts over the language of the provisions.

Although officially a representative body of global interests, the WTO is constantly criticized for having limited accountability and not giving equal weight to the interests of all its Members.[436] In order to produce lasting achievements in establishing substantive patent policies, the WTO must first ensure that its actions are perceived as legitimate by Member States of developed and developing nations. Thus, for example, the process of revising the terms of *Article 27.3(b)* will prove just as important as the outcome since many different cultural interests and legal traditions will have to be taken into consideration as there will be many diverging parties at the negotiating table.

Recommendation Six: Re-establishing the Role of the WTO in the Pursuit of a Global Patent Rights Regime

The WTO faces many barriers to achieving its desired goal of being a truly representative global body and is having a difficult time administering the TRIPS Agreement. The WTO faces difficulty of action issues. According to the WTO Agreement[437] unanimous action by either the Ministerial Conference or the General Council is required to amend the TRIPS Agreement.[438] This requirement of consensus is likely to hinder attempts to significantly revise the terms of *Article 27.3(b)* during the review processes. The divisive differences among WTO Member States concerning patent protection of biological entities is extremely noticeable between developing and developed nations.[439]

Member States quarrel over whether to encourage the cheapest and most extensive use of technology or to prevent misappropriation of innovations.[440] Developing countries are concerned about the privatization of knowledge and the increased cost of acquiring knowledge-based products[441] however developed nations' economies are becoming increasingly dependent on knowledge-based products.[442] Such dependency makes developed nations watchful of impotent patent regimes that allow for the misappropriation of technology products. This is especially the case when it comes to biotechnology and thus, the divergent economic interests between developed and developing nations will make it difficult to reach consensus on issues such as how the terms of *Article 27.3(b)* should be revised.[443]

As mentioned previously, cultural differences between WTO member nations also pose challenges to achieving consensus on these issues.[444] The frameworks for patent regimes in

most developed nations recognize the rights of the inventor to the knowledge he or she has created.[445] Developing nations and in particular indigenous cultures, on the other hand, would like to broaden the definition of who can be a holder of a patent right[446] towards a recognition of communal rights in intellectual property.[447]

This is a particularly contentious area for the divergence of views on biotechnology and is likely to become more prominent as each side attempts to alter or do away with the parts of *Article 27.3(b)* most in conflict with their norms and priorities.[448] The antagonistic debates that are likely to arise will make achieving new consensus on these issues difficult. Thus, the consensus requirement imposed by the WTO's structure will likely make significant developments in this and other areas difficult. [449]

Legitimacy of action by the WTO has also come into question and will need to be re-established if the WTO is to succeed as a governing body. Despite the requirement of consensus, developing countries distrust the WTO and the TRIPs Agreement because they perceive them as a means for developed nations to assert power over them.[450] In the case of decisions concerning patent protection for biological entities, there are economic, religious, health, and cultural identity implications.[451]

The harmonization of patent law may also have implications for the concept of national sovereignty.[452] Although the TRIPs Agreement does not dictate the manner in which its provisions are incorporated into members' domestic policies,[453] the scope and nature of the rights it establishes represent a significant augmentation of International influence over domestic policy making.[454] The can be seen in an analysis of the review of *Article 27.3(b)*.

The current text of *Article 27.3(b)* represents a compromise among the different policy interests of WTO Member States. It provides greater protection than the developing nations would have liked and less than most developed nations would like.[455] Minimum standards have been established, although nations are allowed to provide greater protection than mandated by the TRIPs Agreement.[456] Any advocated changes would likely lead to less flexibility and greater substantive harmonization of domestic patent laws.[457]

The trend in harmonization of patent laws is to move toward the standards established by developed countries.[458] With respect to *Article 27.3(b),* this would mean deleting the patentability exceptions of *Article 27.3(b).*[459] Deleting these exceptions would bring the terms of the TRIPs Agreement into line with U.S. patent laws. This change is generally supported by the biotechnology and pharmaceutical industries as well.[460]

This change would alter the patent regimes' level available in most developing nations by a substantial amount. Such a change would not only entail a shift in policy but would also require a significant adjustment to enforcement mechanisms to ensure such rights.[461] Requiring a developing country to use its limited resources to enforce primarily developed nations' property rights presents a significant impediment to asking these nations to establish more expansive patent rights.[462] Another issue is the significance of relinquishing such important decisions to an International body with questionable equity among Member States.[463]

Concerns about loss of individual national identity and sovereign control abound from developing nations.[464] In the past, international law focused on duties and obligations owed between sovereign states and affected citizens only through the intermediary of their

sovereign.[465] This area of law focused on issues over which conflicts between nations were likely to arise and domestic policies and interests were typically weak.[466] In this context, conflicts between International law and domestic law were minimal.[467]

New International laws that have emerged from evolving globalization are different from their predecessors.[468] The new laws operate through International bodies that promulgate rules constraining individuals fairly directly, and these bodies have a much more formal institutional structure than did their predecessors.[469] Functionally, many of the recent laws promulgated by these international bodies effectively supplant domestic regulations.[470] These changes have led to concerns over the waning importance of the nation state and the increasing influence of global corporations and other non-governmental actors.[471] Notwithstanding the significance of these developments, the weightiest criticism of this new-world order is that it brings with it a striking deficit of accountability.[472]

The legitimacy of domestic government is typically gauged by the ability of its citizens to hold lawmakers accountable for their actions.[473] In the planning stages, accountability can be achieved through the peoples' influence over the content of the decisions made.[474] As International organizations begin behaving in ways similar to national governments, questions of the legitimacy of such conduct and the demand for accountability become relevant as well.[475]

One of the most frequently cited concerns about the WTO is that it displaces national policymakers and operates through an unrepresentative decision-making process.[476] In response to this, supporters of the WTO model emphasize its voluntary membership and operation by consensus.[477] Nevertheless, this does not address the issue of lack of public

influence over an increasingly powerful standard-setting body.[478] As the members of the WTO attempt to deal with highly controversial issues such as those implicated by *Article 27.3(b)*, questions surrounding the legitimacy of such decisions are likely to become more pronounced.[479] Who is involved in making these decisions and whether and how their voices are heard and valued will affect the outcome of the review process.[480]

2. Thesis Conclusion

The recommendations presented should help guide future policy makers in developing a more comprehensive and equitable International regime of patent protection rights.

The patent issues turned out to be the most contentious of the TRIPs Agreement. The U.S. government was insistent in its lobbying for high standards, and despite opposition eventually developing nations signed the Agreement. Thus, the regime is constantly struggling to find a balance between the many competing interests involved. Access to affordable medicines in the developing world is an issue of monumental importance, but so are legal rights that may be put into place in order to promote scientific innovation.

In addition, points of contention will continue to arise over how to address the many conundrums that arise on issues of biotechnology. The difficulty of defining the Agreement's understanding on issues related to patenting biological entities is becoming seemingly impossible as an ever-increasing and dazzling array of innovations are becoming the subject of patent applications. Procedural and substantive revisions to any of the articles that relate to biotechnology matters will likely continue to pose many challenges due to the

different directions that might be taken when WTO policy makers are subjected to pressure from a vast range of interested parties.

Therefore, when finding the right balance on the issues discussed throughout this thesis, all parties involved will need to proceed gradually and judiciously in order determine what course of action can maximize benefits for developed and developing nations. Again, the TRIPs Agreement seems to be only the very beginning to a large amount of work and debate that needs to be undertaken in order to properly address the numerous issues involved. What at first glance may seem like a relatively straightforward International treaty to cover the basics of Intellectual property law has become the framework for many socio-economic and scientific issues of monumental future importance.

ENDNOTES

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[1]See generally, John E. Guist, *Noncompliance with TRIPs by Developed and Developing Countries: Is TRIPs Working?*, 8 Ind. Int'l & Comp. L. Rev. 69, 69 (1997).

[2]See generally, Marshall J. Welch, *International Protection of Intellectual Property,* 1 Tex. Intell. Prop. L.J. 41, 41 (1992).

[3]See generally, Owen Lippert, *One Trip to the Dentist is Enough: Reasons to Strengthen Intellectual Property Rights Through the Free Trade Area of the Americas,* 9 Fordam Intellectual. Property. Media & Entertainment. Law. Journal. 241, 243 (1998).

[4] International Treaties on Intellectual Property 1 (Marshall A. Leaffer ed., 2d ed. 1997) at 587.

[5] *Ibid.* at 585.

[6] Guist, *supra* note 1, at 70.

[7] See International Treaties on Intellectual Property, *supra* note 4, at 1. The Paris Convention and the Berne Convention are the major intellectual property conventions that preceded TRIPs.

[8] Lippert, *supra* note 3, at 273.

[9] See generally, Marshall J. Welch, *International Protection of Intellectual Property,* 1 Tex. Intell. Prop. L.J. 41, 41 (1992).

[10] See generally, Melvin Simensky et al., Intellectual Property in the Global Marketplace O.6 (1999).

[11] *Ibid.*

[12] *Ibid.* (an invention fails to meet the non-obviousness criterion if the differences between the invention and the prior art would be obvious to a hypothetical person skilled in the field to which the invention pertains).

[13] *Ibid.*

[14] *See* Welch, *supra* note 9, at 42.

[15] John G. Byrne, *Changes on the Frontier of Intellectual Property Law: An Overview of the Changes Required by GATT,* 34 DUQ. L. REV. 121, 125 (1995) at 126-127.

[16] *Ibid. at 126.*

[17] See generally, G. Bruce Doern, Global Change and Intellectual Property Agencies 93 (1999).

[18] Agreement on Trade Related Aspects of International Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, preamble, Legal Instruments--Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994), [hereinafter TRIPs Agreement].

[19] See TRIPs Agreement, *Ibid*, art. 1(1).

[20] Lippert, *supra* note 3, at 253.

[21] Michael O'Sullivan, *International Copyright: Protection for Copyright Holders in the Internet Age*, 13 N.Y. Int'l l. Rev. 1, 12 (2000) at 13.

[22] TRIPs Agreement, *supra* note 18, art. 28.

[23] *Ibid.* art. 28(1).

[24] TRIPs Agreement, *supra* note 18, art. 33.

[25] TRIPs Agreement, *supra* note 18, art. 41(1).

[26] *Ibid.*

[27] *Ibid.*

[28] TRIPs Agreement, *supra* note 18, art. 41(4).

[29] *Ibid.* arts. 44(1), 45(1), 46.

[30] See generally *ibid.*

[31] *See* O'Sullivan, *supra* note 21, at 15.

[32] TRIPs Agreement, *supra* note 18, art. 64(1),(3).

[33] O'Sullivan, *supra* note 21, at 15.

[34] *Intellectual Property Provisions of GATT, at* http://www.ladas.com/gatt.html.

[35] *See generally* TRIPs Agreement, *supra* note 26.

[36] Byrne, *supra* note 15, at 129.

[37] See generally *ibid.*

[38] *See* Byrne, *supra* note 15, at 135.

[39] *Ibid.*

[40] See, e.g., International Protection of Intellectual Property, at Fra 11, Bel. 9 (Dennis Campbell ed., 1995) at Fra. 6-10.

[41] Byrne, *supra* note 15, at 135.

[42] *See* TRIPs Agreement, *supra* note 18, art. 3(1).

[43] Byrne, *supra* note 15, at 135.

[44] International Treaties on Intellectual Property, *supra* note 4, at 673. The following states are party to the European Patent Convention: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland, and United Kingdom.

[45] European Patent Convention, Oct. 5, 1973, art. 2(1), *13 I.L.M. 268 (1974).*

[46] IBM/Computer Programs, [1999] E.P.O.R. at VII, 2.3.

[47] *Ibid.* at VII, 2.1.

[48] *Ibid*

[49] See ibid. at VII, 2.3.

[50] *See generally* IBM/Computer Programs, [1999] E.P.O.R. at VII, 2.3.

[51] TRIPs Agreement, *supra* note 18, art. 65(2).

[52] *Ibid.* Developed countries were required to comply with TRIPs' provisions by 1996, with developing nations' compliance delayed until January 1, 2000.

[53] TRIPs Agreement, *supra* note 18, art. 66(1).

[54] See Guist, *supra* note 1, at 79.

[55] See Lippert, *supra* note 3, at 273.

[56] See *Ibid.*

[57] *Ibid.* at 273. Increases in trade actually may be the result of avoidance of the U.S.' "Super 301" processes, a process where the U.S. Trade Representative can withhold intellectual property trade benefits if countries present an unfair burden to American trade.

[58] See Guist, *supra* note 1, at 79.

[59] See generally, Adam Isaac Hassonn, *Domestic Implementation of International Obligations: The Quest for World Patent Law Harmonization*, 25 B.C. Int'l & Comp. L. Rev. 373 (2002).

[60] *Intellectual Property Rights, supra* note 52.

[61] *Ibid.*

[62] *Ibid.*

[63] *Ibid.*

[64] *Ibid.*

[65] TRIPs Agreement, *supra* note 18, art. 27.

[66] *Ibid.* art. 27(1).

[67] *Ibid.*; See also Guist, *supra* note 1, at 72.

[68] TRIPs Agreement, *supra* note 18, art. 27(2), (3).

[69] *Ibid.* art. 27 (2), (3)(a), (b).

[70] See generally, No-Hyoung Park, *The Third World as an International Legal System*, 7 B.C. Third World L.J. 37, 43 (1987).

[71] Maura Mullen de Bolivar, *A Comparison of Protecting the Environmental Interests of Latin-American Indigenous Communities from Transnational Corporations Under International Human Rights and Environmental Law*, 8 J. Transnat'l L. & Pol'y 105, 125 & n.138 (1998).

[72] See Carlos J. Moorhead, *Improving Our Patent System for a Stronger America*, 11 St. John's J. Legal Comment. 465 (1996).

[73] See Joakim E. Parker, *Cultural Autonomy: A Prime Directive for the Blue Helmets,* 55 U. Pitt. L. Rev. 207, 237 (1993).

[74] See Todd M. Rowe, *Global Technology Protection: Moving Past the Treaty*, 4 Marq. Intell. Prop. L. Rev. 107 (2000).

[75] See generally, *Ibid.*

[76] Enforcement of Intellectual Property Rights May Hinder Growth in 3rd World, Says Lahore Chamber Chief, Bus. Recorder, Dec. 3, 1998, available in *1998 WL 23892063.* A politician in Pakistan expressed his apprehension that current intellectual property legislation and enforcement of the legislation are "likely to hinder the development in the third world.

[77] *Ibid* at 411. Developed nations signify the greatest concentration of wealth, and therefore "dominate the international economic system.

[78] Myung Hoon Choo, Comment, *An Institutionalist Perspective on Resolving Trade-Environment Conflicts*, 12 J. Envtl. L. & Litig. 433, 433 (1997). This new international trade regime incorporates new subject matters, including trade in services and intellectual property. Developing countries have resisted the introduction of new issues, such as environment, labor, and intellectual property, into the international trade system.

[79] *Ibid.* at 433-34. India's representative to the WTO ministerial conference... asserted that "any attempt by the WTO to overstep the legitimate boundaries of trade... is bound to create serious problems and raise basic questions about WTO's competence and credibility."

[80] See Patents Act Amendment - A Faustian Alternative, Bus. Line (Hindu), Dec. 19, 1998, available in *1998 WL 20734242.*

[81] C. Russell H. Shearer, *International Environmental Law and Development in Developing Nations: Agenda Setting, Articulation, and Institutional Participation,* 7 Tul. Envtl. L.J. 391, 412 n.127 (1994) at 393. Originally applied in environmental law, this term distinguishes the "interests of the developed nations against those of the developing nations."

[82] See Ibid. Two other concepts contrived for the "North-South" debate include the inhibition of full international consideration of "certain global... issues" and lack of unanimous decision making among participating countries.

[83] See Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights,* 28 Wake Forest L. Rev. 89, 121 (1993). Developing countries become skeptical when developed countries assert that strong IP protection is the proper means to insure economic development.

[84] See Recent Development, *E.U. and U.S. Emphasize Need for WTO Members to Adhere to TRIPS*, 9 J. Proprietary Rts. 26, 26 (1997).

[85] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 1197 art. 65.

[86] See TRIPs, *ibid*, art. 66; Fact and Fiction on EMRs, Hindu, Dec. 31, 1998, available in *1998 WL 22058503;*

[87] See Recent Development, *Bulgaria Faces Two Actions*, 9 J. Proprietary Rts. 27, 27 (1997).

[88] See generally, *Fact and Fiction on EMRs, Hindu,* Dec. 31, 1998, available in *1998 WL 22058503.*

[89] See Recent Development, *WTO Requests Amendment to India Patent Laws*, 10 J. Proprietary Rts. 23 (1998).

[90] See Special Correspondent, People's Panel to Look into IPR Issues, Hindu, Oct. 25, 1998, at 10, available in *1998 WL 15916440.*

[91] *Ibid.*

[92] Indigenous Knowledge at Risk, Afr. News Serv., Dec. 18, 1998, available in *1998 WL 21358015.* A major controversy has developed about whether this Western system of private ownership and monopolistic control is appropriate to protect traditional knowledge. Existing intellectual property systems reward new improvements rather than existing knowledge, which is considered to fall in the public domain.

[93] See *ibid*:

Mechanisms such as patents and copyrights are conferred on individuals or legal entities, and generally on a temporal basis. In contrast, many local knowledge systems are of a collective nature, depending on a continuous and often informal exchange of knowledge and resources according to traditional beliefs and practices.

[94] Charles O. Roehrdanz, *Reducing the U.S.-Japan Trade Deficit by Eliminating Japanese Barriers to Foreign Direct Investment,* 4 Minn. J. Global Trade 305, 325 (1995). Often, two arguably equal bargaining parties even have trouble coming to an agreement. Industrialized nations fail to see eye-to-eye on some issues of international intellectual property protection.

[95] See Judith Hippler Bello & Alan F. Holmer, *The GATT Uruguay Round: Its Significance for U.S. Bilateral Trade with Korea and Taiwan,* 11 Mich. J. Int'l L. 307, 310 (1990). A primary aim of United States efforts in the Uruguay Round is to expand the GATT to include several new areas of growing importance to world trade: trade-related investment, services, and intellectual property.

[96] See generally *Ibid.*

[97] See Jeffrey L. Dunoff, *Rethinking International Trade*, 19 U. Pa. J. Int'l Econ. L. 347, 347 (1998):

In recent years, "linkage" issues - such as "trade and environment," "trade and labor," and "trade and intellectual property" - have moved from the periphery to the center of the trade agenda. Despite the investment of substantial diplomatic capital, meaningful multilateral agreements in many of these areas have been elusive. This Symposium offers an ideal opportunity to explore why these issues have come to the fore now, and why they appear to be so intractable. My focus is on a related question: Can the trade regime accommodate these new issues - or do they call into question fundamental premises of the trade regime?

[98] See generally, Frank Emmert, *Intellectual Property in the Uruguay Round - Negotiating Strategies of the Western Industrialized Countries*, 11 Mich. J. Int'l L. 1317, 1325 (1990)

[99] See generally, C. Russell H. Shearer, International Environmental Law and Development in Developing Nations: Agenda Setting, Articulation, and Institutional Participation, 7 Tul. Envtl. L.J. 391, 412 n.127 (1994).

[100] See generally, Nicole Telecki, *The Role of Special 301 in the Development of International Protection of Intellectual Property Rights After the Uruguay Round,* 14 B.U. Int'l L.J. 187 (1996).

[101] *19 U.S.C. 2411* (1994 & Supp. IV 1998).

[102] Pub. L. No. 100-418, 102 Stat. 1107 (amending *Trade Act of 1974*).

[103] See Robert J. Pechman, *Seeking Multilateral Protection for Intellectual Property: The United States "TRIPS" over Special 301,* 7 Minn. J. Global Trade 179, 179 (1998). Congress amended the Trade Act of 1974 to provide protection for intellectual property rights. Before the amendment in 1984, section 301 addressed trade barriers imposed by foreign nations, but intellectual property rights were not expressly mentioned.

[104] U.S. General Accounting Office, Fact Sheet, Intellectual Property Rights - U.S. Trade Representative Investigations of Foreign Country Practices, GAO/GGD 94-168FS (July 1994), available in *1994 WL 838098* [hereinafter GAO Fact Sheet].

[105] For a more detailed description of the procedures of Special 301, see Bello & Holmer, *supra* note 95.

[106] *Ibid.*

[107] GAO Fact Sheet, *supra* note 104, at 3.

[108] *Ibid.*

[109] *Ibid.*

[110] *Ibid.*

[111] *Ibid.*

[112] See GAO Fact Sheet, *supra* note 104, at 3.

[113] *Ibid.*

[114] See Anju Ghangurde, Learn to Patent Products the US Way, Fin. Express, Mar. 23, 1998, available in *1998 WL 8708545.*

[115] See generally *Ibid.*

[116] *Steele v. Bulova Watch Co., 344 U.S. 280, 281, 95 U.S.P.Q. (BNA) 391, 392 (1952).* The United States has always been apprehensive about surrendering its sovereignty to international law.

[117] See Intellectual Property and International Issues: Hearings Before the Subcomm. on Intellectual Property and Judicial Administration of the House Comm. on the Judiciary, 102d Cong. 7 (1991) at 190.

[118] Donald S. Chisum et al., *Principles of Patent Law* 16 (1998) at 23.

[119] *Ibid.*

[120] See generally Rowe, *supra* note 74.

[121] See Gutterman, *supra* note 83, at 122. Although certain developing countries have nurtured their own domestic industries, most fail to recognize any potential advantages flowing from granting greater IP protection. Less prosperous countries lack the resources necessary for domestic research and development, and research findings indicate that, historically, the implementation of a new patent regime within a developing country has led to few inventions and fewer relative benefits.

[122] Shearer, *supra* note 31, at 411-12, Distribution of resources operates to the detriment of developing nations: While the developed nations, including Eastern Europe, have only a quarter of the world's population, they control four-fifths of the world's income. The developing nations, including China, control one-fifth of the world's income, but have three billion people, three-fourths of the world's population.

These figures point out that the developed nations occupy a special position because of their disproportionate power. Developed nations can effectively direct the course of international law.... International decision making ought to be in a global context, and not based simply on the drive for purely national benefit and advantage.

[123] See Gale Research, Inc., *Statistical Abstract of the World 418* (Marlita A. Reddy ed., 1994).

[124] Nicky Jatana, Casenote, *Did Whirlpool Make Its Mark in India?: N.R. Dongre v. Whirlpool Corp.*, 10 Transnat'l Law. 331, 332 n.2 (1997). Emerging consumer markets may expand India's resources.

[125] See Samuel Goldreich, *U.S. Drug Makers Fear Loss of Patent Protection*, Wash. Times, Apr. 30, 1998, at B8.

[126] *Ibid*, Proponents like the World Health Organization (WHO) urge reevaluation of current patent trade agreements to "ensure that public health rather than commercial interests have primacy in pharmaceutical and health policies."

[127] *Ibid.*

[128] See generally Intellectual Property Rights: Hearings Before the Subcomm. on International Economic Policy and Trade of the House Comm. on International Relations, 106th Cong. (1999) (testimony of Charles M. Caruso, Esq., International Patent Counsel, Merck & Co., Inc.), available in *1999 WL 27595603.*

[129] See generally Gutterman, *supra* note 83.

[130] See Shearer, *supra* note 31, at 397.

[131] *Ibid.* at 408.

[132] *Ibid.* at 411.

[133] John Ntambirweki, *The Developing Countries in the Evolution of an International Environmental Law*, 14 Hastings Int'l & Comp. L. Rev. 905, 906 (1991).

[134] See Rowe, *supra* note 74, at 133.

[135] See Goldreich, *supra* note 125.

[136] Gutterman, *supra* note 83, at 138; "Developed countries should consider providing funds to developing countries for research activities on products that have commercial potential in the domestic market in which the research is being conducted. Developing countries have little stake in a global technological community that fails to address their unique needs."

[137] Chetan Gulati, *The "Tragedy of the Commons" in Plant Genetic Resources: The Need for a New International Regime Centered Around an International Biotechnology Patent Office,* 4 Yale H.R. & Dev. L.J. 63 (2001).

[138] See generally *Ibid.*

[139] *Ibid.*

[140] *Ibid.*

[141] See Stephan Zamora, NAFTA and the Harmonization of Domestic Legal Systems: The Side Effects of Free Trade, 12 Ariz. J. Int'l & Comp. L. 401, 416 (1995).

[142] Marshall J. Welch, *International Protection of Intellectual Property*, 1 Tex. Intell. Prop. L.J. 41, 50 (1992).

[143] See *Public Citizen v. Office of United States Trade Rep.*, 804 F. Supp. 385, 388 (D.D.C. 1992). American courts tend to place less importance on international law than do international treaty negotiators.

[144] *Ibid.*

[145] See generally, Kenneth L. Port, *Trademark Harmonization: Norms, Names & Nonsense,* 2 Marq. Intell. Prop. L. Rev. 33, 45 (1998).

[147] See Shearer, *supra* note 31, at 427.

[148] See Port, *supra* note 143, at 41. Because each country has its own unique legal culture, it is rather optimistic to presume that the exact language of any treaty will be interpreted and applied the same in all countries.

[149] See Bethany Lukitsch Hicks, *Comment, Treaty Congestion in International Law: The Need for International Coordination, 32 U. Rich. L. Rev. 1643 (1999)* at 1646-47.

[150] See Gulati, *supra* note 137, at 72.

[151] *Ibid.*

[152] B.M Knoppers, Human Dignity and Genetic Heritage (Ottawa: Law Reform Commission of Canada, 1991).

[153] *Ibid* at 87.

[154] See generally, Gulati, *supra* note 137.

[155] See generally, Gulati, *supra* note 137.

[156] *Ibid* at 86.

[157] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments - Results of the Uruguay Round Vol. 31, 33 I.L.M. 81 (1994).

[158] See generally, Judy Rein, *International Governance Through Trade Agreements: Patent Protection for Essential Medicines* 21 J. INTL. L. BUS. 379 (2001).

[159] See generally, World Health Organization, at http//:www.who.int.

[160] See Robert Weissman, *Long Strange Trips: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries,* 17 U. Penn. J. Int'l Law 1069 (1996).

[161] See Revised Drug Strategy, Res. WHA 52.19, Fifty-Second World Health Assembly, May 24, 1999.

Recognizing that the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) provides scope for the protection of public health;

Taking note of concerns of many Member States about the impact of relevant international agreements, including trade agreements, on local manufacturing capacity and on access to and prices of pharmaceuticals in developing and least developed countries;

1. URGES Member States: ...

(3) to explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs.

[162] See Office of the United States Trade Representative, USTR Announces Results of Special 301 Annual Review (Apr. 30, 1999), at http://www.ustr.gov/releases/1999/04/99-41.html [hereinafter Special 301 Annual Review].

[163] The Agreement on Trade-Related Investment Measures ("TRIMS"), part of the Marrakesh Agreement, also establishes positive requirements, but it does not entail the same quantity of elaboration with respect to highly specific harmonizing rules.

[164] See TRIPS, *supra* note 1, art. 1 (1).

[165] See TRIPS, *supra* note 1, art. 3.

[166] See TRIPS, *supra* note 1, art. 28.

[167] See TRIPS, *supra* note 1, art. 27 (1).

[168] See TRIPS, *supra* note 1, art. 34.

[169] See TRIPS, *supra* note 1, art. 27 (1).

[170] See Uruguay Round Agreements Act, Pub. L. No. 103-465, 532(a)(1), 108 Stat. 4809, 4984 (1994) (amending *35 U.S.C. 154* (1988)).

[171] See European Commission, 1999 Report on United States Barriers to Trade and Investment 25 (Aug. 1999), at http://europa.eu.int/comm/external<uscore>relations/us/trade<uscore>barriers <uscore>report<uscore>99/usr bt 99.pdf.

[172] TRIPS, *supra* note 1, art. 70 (8).

[173] *Ibid.*

[174] *Ibid.* art. 70 (9).

[175] *Ibid.* art. 65 (4), which provides a 10 year transition period for developing countries which previously did not protect pharmaceuticals to implement a product patent system.

[176] Jeff Gerth and Sheryl Gay Stolberg, *Drug Makers Reap Profits On Tax-Backed Research,* N.Y. Times, Apr. 23, 2000, at A1. Offering the example of a six-week supply of a glaucoma drug that costs a French patient $ 18.78, U.S. federal agencies $ 25.37, and a U.S. patient purchasing in a drugstore $ 49.69.

[177] TRIPS, *supra* note 1, art. 8 (1).

[178] *Ibid* art.8 (2).

[179] See *Ibid.* art. 27 (2).

[180] See Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. Intell. Prop. L. 41, 45 (1998).

[181] General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194, Art. XXIV [hereinafter GATT].

[182] See Roy Maclaren, *The Geo-Political Changes During the 1980s and Their Influence on the GATT, in The Uruguay Round and Beyond*, (Jagdish Bhagwati & Mathias Hirsch eds., 1998) at 44.

[183] See generally, *Multilateralism and Regionalism After the Uruguay Round* (Riccardo Faini & Enzo Grilli eds., 1997).

[184] PhaRMA Annual Survey, Table 12, at http://www.phrma.org/publications/industry/profile00/phrma Tables.pdf.

[185] See *supra* note 35 at 45.

[186] See Trade Act of 1974 301, *19 U.S.C.A. 2411* (West. Supp. 2000). Section 301 authorizes the U.S. Administration to take action against any foreign country practices it determines to be discriminatory or restrictive of U.S. commerce.

[187] See Reagan, *Charging Patent Piracy, Imposes Sanctions on $ 39 Million of Brazilian Goods*, 5 Int'l Trade Rep. (BNA) 1415 (Oct. 26, 1988).

[188] GATT art. XXIII. GATT panels were the precursor to the current and more binding WTO dispute settlement body. Because panels could be blocked and consensus was required for the adoption of decisions, countries enjoyed essential veto power over the establishment of panels and adoption of results.

[189] See *Determination to Terminate Increased Duties on Certain Articles From Brazil*, 55 Fed. Reg. 27,324 (Jul. 2, 1990).

[190] See *U.S. Requests Consultations at WTO on Argentine, Canadian Patent Protection,* 16 Int'l Trade Rep. (BNA) 820 (Dec. 5, 1999).

[191] See WTO, Request for the Establishment of a Panel by the European Communities, WT/DS114/5 (Nov. 12, 1998) [hereinafter Request for the Establishment of a Panel].

[192] See Drug Price Competition and Patent Term Restoration Act of 1984, *35 U.S.C.A. 156* (West 2000).

[193] See WTO, Report of the Appellate Body: WTO Dispute Panel Report on Canada, WT/DS114/R (Mar. 17, 2000), available at http://www.wto.org/English/tratop<uscore>e/dispu<uscore>e/74 28d.doc [hereinafter WTO Dispute Panel Report].

[194] See TRIPS, *supra* note 1, arts. 28-1(a) and 33.

[195] See WTO Dispute Panel Report, *supra* note 40.

[196] See, *USTR Initiates WTO Consultations on IPR with Argentina, Canada, EU,* 16 Int'l Trade Rep. (BNA) 763 (May 5, 1999).

[197] See TRIPS, *supra* note 1, arts. 27-3(b), 65-4, and 31.

[198] See Judith Miller, *In Fight Against Tuberculosis, Experts Look for Private Help,* N.Y. Times, Nov. 2, 1999, at A8.

[199] See Elizabeth Olson, Drug Groups and U.N. Offices Join to Develop Malaria Cures, N.Y. Times, Nov. 18, 1999, at A5. The recently launched "Medicines for Malaria Venture" involves a partnership among international pharmaceutical companies, WHO, the World Bank, government agencies, and the Rockefeller Foundation to engage in drug discovery and development for malaria.

[200] See J.H. Reichman and David Lange, Bargaining Around the TRIPs Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions, *9 Duke J. Comp. & Int'l L. 11 (1998).*

[201] See Bernard Pecoul et al., Access to Essential Drugs in Poor Countries, A Lost Battle?, *281 J.A.M.A. 361, 364 (1999).*

[202] See *Ibid.*

[203] See Danzon, *supra* note 25, at 5. Danzon estimated that average after-tax cost of drug development in the United States in 1993 was $ 194 million, based on data from the Office of Technology Assessment ("OTA").

[204] See PhRMA Policy Papers: Strong Patent Protection is Essential (Sept. 26, 1999), at http://www.phrma.org/issues/protect.html.

[205] See Addicted to Mergers?, supra note 64, at 88, showing expenditures in research and development as 13% and marketing and sales as 29% of sales revenues.

[206] Thus, given the time value of money, the actual expense/risk to the industry is higher than income statements reflect. See Danzon, *supra* note 23, at 5-8.

[207] John H. Barton, "Global Trade Issues in the New Millennium: The Economics of TRIPS: International Trade in Information-Intensive Products" (2001) *33 Geo. Wash. Int'l L. Rev. 473.*

[208] See generally, *Ibid.*

[209] See *The Patents Act*, 1970, No. 39 (1970) (India). Note that different nations may have genuine reasons for different balances among these short and long-term factors. It may not have been unreasonable for India to decide, in 1970, that a low consumer cost for pharmaceuticals was more important than incentives to develop new pharmaceuticals.

[210] See generally *supra* at 60.

[211] See Addicted to Mergers?, Bus. Week, Dec. 6, 1999, at 8., showing expenditures in research and development as 13% and marketing and sales as 29% of sales revenues.

[212] See Addicted to Mergers?, *supra* note 64, at 88.

[213] See Carlos M. Correa & Abdulqawi A. Yusuf, *Intellectual Property and International Trade: The TRIPs Agreement 88* (1998).

[214] See generally, Rein, *supra* note 157.

[215] TRIPS, *supra* note 1, art. 28 (1)(a)(n. 6).

[216] See Laurinda L. Hicks and James R. Holbein, *Convergence of National Intellectual Property Norms in International Trading Agreements,* 12 Am. U. J. Int'l L. & Policy 769, 810-11 (1997).

[217] See Patricia M. Danzon, Pharmaceutical Price Regulation 84-88 (1997) (arguing that savings from parallel importation usually accrue to intermediaries rather than to consumers). Price differentials are usually the result of varied approaches to price regulation in different countries. Parallel importing of pharmaceuticals is widely practiced within the European Union.

[218] Emily Miao, *TRIPs Agreement Impacts Pharmaceutical Sector,* Nat'l L.J., at C11, July 24, 2000.

[219] See Mohamed Lahouel and Keith Maskus, *Competition Policy and Intellectual Property Rights in Developing Countries: Interests in Unilateral Initiatives and a WTO Agreement, World Bank Global Conference on Developing Countries and the Millennium Round* (Sep. 20-21, 1999), at http://redem.buap.mx/rm19.htm.

[220] See generally, *supra* note 60.

[221] See generally, *supra* note 71.

[222] General Agreement on Tariffs and Trade-Multilateral Trade Negotiations (The Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, art. 2.1, *33 I.L.M. 81 (1994),* art. 27. [hereinafter TRIPs Agreement].

[223] *Ibid.* art. 27(1).

[224] *Ibid*; However, the TRIPs Agreement fails to define "invention." Although patents traditionally are available for useful inventions, advances in biotechnology are blurring this line.

[225] TRIPs Agreement, *supra* note 1, art. 27(2), (3).

[226] *Ibid.* art. 27 (2), (3)(a), (b).

[227] Martin J. Adelman et al., *Patent Law* 83 (1998). "Patent eligibility" is used to describe the subject matter open to patenting, as opposed to the word "patentability." "The latter term implies not just that the subject matter is appropriate under the patent statute, but that the invention has been approved following an individual determination of novelty, nonobviousness and the other requisites."

[228] Office of Technology Assessment, U.S. Congress, Biotechnology in a Global Economy, app. f, at 268 (1991).

[229] Former President Clinton proclaimed January 2000 "National Biotechnology Month." See Proclamation No. 7269, 3 C.F.R. 19 (2001) [hereinafter Proclamation].

[230] See Melinda Kimble, et al., Press Briefing of the U.S. Delegation to the Sixth Meeting of the Working Group on Biosafety Convention on Biological Diversity (Feb. 18, 1999), available at http://www.usinfo.state.gov.

[231] See Stephan A. Duzan, *The 1992 Biotechnology Agenda: A Message for Candidates Bush and Clinton,* 9 Healthspan, Sept. 1992, at 12.

[232] See generally, *Frontiers in Biotechnology: Biotech Gets a Grip on Cell Adhesion*, 260 Science 906 (May 14, 1993).

[233] See Duzan, *supra* note 230, at 13.

[234] See Duzan, *supra* note 230, at 14-15.

[235] Angela Sanchez, *Environment: Debate Over Transgenics Heats Up, Inter Press Serv.*, Feb. 23, 1999, LEXIS, Nexis Library, News File.

[236] See *Diamond v. Chakrabarty, 447 U.S. at 309.*

[237] *Ibid.*

[238] *Ibid at 310.*

[239] *Ibid. at 309-10.*

[240] *35 U.S.C. 101* (1984).

[241] *Ibid.*

[242] *Ibid.*

[243] W. French Anderson, *Human Gene Therapy*, 256 Science (1992) at 811-13. Explaining that the concerns of safety, ethics, and social implications of human gene therapy.

[244] *35 U.S.C. 101* (1984).

[245] See Convention on the Grant of European Patents, Jan. 11, 1978, arts. 52, 53, at 271-72, [hereinafter European Patent Convention].

[246] *Ibid.* art. 52(4), at 270-71.

[247] *Ibid.* art. 53(a), at 272.

[248] *Ibid.* art. 53(b), at 272.

[249] See Council Directive 98/44 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13, 18 [hereinafter Council Directive].

[250] *Ibid.*

[251] *Ibid.*

[252] European Patent Convention, *supra* note 244, arts. 52, 53, at 271-72.

[253] *Ibid.* art. 52(1), at 371.

[254] *Ibid.* art. 52(4), at 271.

[255] BRUKER/Non-invasive measurements T 385/8, 6 Eur. Pat. Off. Rep. 357, 359 (1988).

[256] European Patent Convention, *supra* note 244, art. 53(a), at 272.

[257] *Ibid.* art. 53(a), at 272.

[258] David G. Scalise & Daniel Nugent, *Patenting Living Matter in the European Community,* 16 Fordham Int'l L.J. 990, 1014 (1993).

[259] *Ibid.*

[260] See generally, *Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 924 (Fed. Cir. 1991).*

[261] European Patent Convention, *supra* note 244, art. 53(b), at 272.

[262] Robin Beck Skarstad, *The European Union's Self-Defeating Policy: Patent Harmonization and the Ban on Human Cloning*, 20 U. Pa. J. Int'l Econ. L. 353, 363 (1999).

[263] Commission Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, 1989 O.J (C10) 3,3.

[264] See generally, Claire O'Brien, *European Parliament Axes Patent Policy*, 267 Science 1417, 1417 (1995).

[265] Council Directive, *supra* note 248, at 13.

[266] *Ibid.* at 18.

[267] *Ibid.* at 20.

[268] *Ibid.* at 18.

[269] *Ibid.*

[270] See *Ibid.* A "germ line" is the sequence of cells in the line of direct descent from zygote to gamete (egg or sperm), as opposed to somatic cells (all other cells in the body)).

[271] Council Directive, *supra* note 248, at 18.

[272] *Ibid.*

[273] *Ibid.*

[274] *Ibid.* at 15.

[275] *Ibid.* at 18.

[276] *Ibid.*

[277] Council Directive, *supra* note 248, at 18.

[278] *Ibid.*

[279] *Ibid.*

[280] *Ibid.*

[281] *Ibid.*

[282] Richard Ford, *The Morality of Biotech Patents: Differing Legal Obligations in Europe*, 6 Eur. Intell. Prop. Rev. 315, 315 (1997).

[283] *Ibid.* at 316.

[284] See, e.g., *Diamond v. Chakrabarty, 447 U.S. at 308-18.* Discussing congressional intent to have broad umbrella of protection for Intellectual property.

[285] *Diamond v. Chakrabarty, 447 U.S. at 308-09.*

[286] See TRIPS Agreement, supra note 1, art. 27(2), (3), at 1207.

[287] See generally, David G. Scalise & Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture,* 27 Case W. Res. J. Int'l L. 83, 115 (1995).

[288] John Travis, *Biology: Patently Unpatentable*, 156 Science News 127, 127 (1999).

[289] Thomas A. Magnani, *The Patentability of Human-Animal Chimeras,* 14 Berkeley Tech. L.J. 443, 452 (1999).

[290] See Rick Weiss, *U.S. Ruling Aids Opponent of Patents for Life Forms*, Wash. Post, June 17, 1999, at A2.

[291] *Ibid.*

[292] See Jenna Greene, He's Not Just Monkeying Around, Legal Times, Aug. 16, 1999 at 17.
[293] *Ibid.*

[294] *Ibid.* at 18.

[295] *Diamond v. Chakrabarty, 447 U.S. at 309.*

[296] Animal - Patentability, 1077 Official Gazette of U.S. Pat. and Trademark Off. 24 (1987) at 24.

[297] Greene, *supra* note 69, at 17, 20 (stating that Newman and Rifkin re-submitted the application to the PTO, with the intent of provoking a debate about what it means to be "human.").

[298] *Diamond v. Chakrabarty, 447 U.S. 315.*

[299] Greene, *supra* note 291, at 17-18.

[300] *Ibid.* at 25.

[301] European Patent Convention, *supra* note 244, art. 53, at 272; Council Directive, supra note 248, at 18.

[302] *Animal Legal Defense Fund v. Quigg, 932 F.2d at 925.* Dismissing the case due to appellant's lacking of standing to sue to challenge a biotechnology patent grant.

[303] See *35 U.S.C. 287*(c) (Supp.1999).

[304] European Patent Convention, *supra* note 24, art. 53(a), at 272.

[305] Robin Beck Skarstad, *The European Union's Self-Defeating Policy: Patent Harmonization and the Ban on Human Cloning*, 20 U. Pa. J. Int'l Econ. L. 353, 363 (1999) at 378.

[306] Decision T 19/90-3.3.2, 1990 O.J. Eur. Pat. Off. at 487.

[307] *Ibid.* at 490.

[308] *Ibid.* at 377-78.

[309] General Agreement on Tariffs and Trade-Multilateral Trade Negotiations (The Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, art. 2.1, *33 I.L.M. 81 (1994)* at 13-15.

[310] See *Ibid.* at 15.

[327] *Ibid. at 466-67.* The non-obvious, or inventive step, requirement demands that the invention not be evident to a person of ordinary skill in the relevant technical field.

[328] Doris Estelle Long, Underlying Theories: *Harmonization, in International Intellectual Prop. Law 82, 82-83* (Anthony D'Amato & Doris Estelle Long eds., 1997).

[329] *Ibid.*

[330] Frederick M. Abbott, Introduction: *The Current System for the International Protection of Intellectual Property: Treaty Regimes, in International Intellectual Prop. Law, Ibid*, at 13-14.

[331] Boulware et al., *supra* note 325, at 17-18.

[332] TRIPs Agreement, *supra* note 308, art. 7.

[333] See generally, Carrie P. Smith, *Patenting Life: The Potential and the Pitfalls of Using the WTO to Globalize Intellectual Property Rights,* 26 N.C.J. Int'l L. & Com. Reg. 143 (2000).

[334] See TRIPs Agreement, *supra* note 308, art. 2.1. The TRIPs Agreement is intended to coexist with prior conventions without derogating any of the obligations of those agreements. Ibid. art. 2.2.

[335] *Ibid.* art. 3.

[336] *Ibid.* art. 4.

[337] *Ibid.*

[338] Yusuf, *supra* note 320, at 16.

[339] German Cavelier, Enforcement of Intellectual Property Rights, in Intellectual Prop. & International Trade: A Guide to the Uruguay Round TRIPs Agreement, (Tania Saulnier et al. eds., 1996), *supra* note 3, at 65. The TRIPs Agreement's enforcement mechanisms are discussed in depth in Part IV.

[340] TRIPs Agreement, *supra* note 1, art. 8.1.

[341] *Ibid.* See also Yusuf, *supra* note 320, at 13. The only restriction imposed upon legislation on IPRs by member states to the TRIPS Agreement is that such legislation is consistent with the Agreement's provisions. This seemingly broad principle is a reflection of the Agreement's objective of balancing the diverse needs of member countries.

[342] Yusuf, *supra* note 102, at 13.

[343] See generally Tansey, *supra* note 322. The TRIPs Agreement was born from intense debate and a compromise between various national interests. Article 27.3 (b) of the TRIPs Agreement most directly relates to the patenting of biotechnological innovations. It includes nine words that are subject to interpretation.

[344] See generally TRIPs Agreement, *supra* note 308 (defining patentable subject matter).

[345] Lakshmi Sarma, *Biopiracy: Twentieth Century Imperialism in the Form of International Agreements*, 13 Temp. Int'l & Comp. L J. 107, 107 (1999).

[346] See *Ibid.* art. 27.1. This provision reiterates the generally accepted principle of national treatment.

[347] Ibid. art. 70.8.

[348] *Ibid.* art. 70.8. Intermediate protection is obtained by allowing exclusive marketing rights for a product to be granted to the applicant while a patent is pending. *Ibid.* art. 70.9. Exclusive marketing rights extend five years or until the patent is granted or rejected, whichever period is shorter.

[349] *Ibid.* arts. 65.1-65.3, 66.1. Article 65 sets forth the timeline according to which the original parties to the TRIPs Agreement must comply with its minimum standards. Developed countries had to implement the Agreement within one year of its entry into force; developing countries had an extra four years (until January 2000). Economies in transition from centrally planned to market-based economies also had until January 2000 to comply. The least developed countries have at least a ten-year transition period (until January 2006), with the option to apply for additional extensions.

[350] See Carlos M. Correa, *Patent Rights, in Intellectual Prop. and International Trade: The TRIPs Agreement*, *supra* note 212, at 220-21.

[351] TRIPs Agreement, supra note 308, arts. 27.2-27.3.

[352] Tansey, *supra* note 322, at 6. "Ordre public" is a nebulous term that refers to the fundamentals of a society that cannot be derogated from without endangering the society's basic institutions.

[353] TRIPs Agreement, *supra* note 1, art. 27.2.

[354] *Ibid.*

[355] *Ibid.* art. 27.3(a).

[356] See Group of Negotiations on Goods (GATT) Negotiating Group on Trade-Related Aspects of Intellectual Property Rights Including Trade in Counterfeit Goods, Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, Uruguay & Pakistan, ch. 2, arts. 4(1)-4(2) (1990).

[357] Tansey, *supra* note 322, at 6-7.

[358] TRIPs Agreement, *supra* note 308, art. 27.3(b).

[359] Correa, *supra* note 212, at 194. The United States does not exclude from patentability any form of subject matter that meets the statutory definition of being a "new and useful process, article of manufacture, machine or composition of matter." *35 U.S.C. 101* (1994);

[360] TRIPs Agreement, supra note 308, art. 27.3(b).

[361] Correa, supra note 212, at 195.

[362] *Ibid.*

[363] TRIPs Agreement, supra note 308, art. 27.3(b).

[364] Correa, supra note 212, at 196.

[365] *Ibid.*

[366] See *Ibid.* European law generally considers such limited incorporation of a microbiological step sufficient to deem the process patentable; other countries may take a more restrictive view.

[367] Tansey, *supra* note 322, at 7.

[368] See Tansey, *supra* note 322, at 7.

[369] TRIPs Agreement, *supra* note 1, art. 27.3(b). The WTO Agreement entered into force on January 1, 1995.

[370] Correa, *supra* note 212, at 198.

[371] See Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPs Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. Intell. Prop. L. 41, 43-45 (1998) at 45.

[372] See *Ibid.* at 63.

[373] World Trade Organization, The WTO in Brief: Part 2 The Organization, at http://www.wto.org/wto/english/thewto<uscore>e/whatis<uscore>e/inbrief&u score;e/inbr02<uscore>e.htm.

[374] In addition to the TRIPs Agreement, the WTO also administers the Agreement on Trade in Goods and the Agreement on Trade in Services (GATS). World Trade Organization, The Agreements, Overview: A Navigational Guide, at http://www.wto.org/ english/thewto<uscore>e/whatis<uscore>e/tif<uscore>e/agrm1<uscore>e.htm.

[375] For example, one of the provisions of the TRIPs Agreement involves cooperation with the World Intellectual Property Organization, which administers the Paris Convention and other significant treaties. TRIPs Agreement, *supra* note 1, art. 68.

[376] See generally McCabe on World Trade Organization, *supra* note 370.

[377] *Ibid.*

[378] *Ibid* at 1. There are 135 member governments in the WTO.

[379] *Ibid.*

[380] World Trade Organization, About the WTO: Whose WTO is it anyway?, In addition to administering the TRIPs Agreement, the WTO monitors the implementation of the General Agreement on Tariffs and Trade - Multilateral Trade Negotiations: Agreements on Trade in Goods, *33 I.L.M. 28 (1994)* and the General Agreement on Tariffs and Trade - Multilateral Trade Negotiations: General Agreement on Trade in Services, *33 I.L.M. 44 (1994).*

[381] *Ibid.* These focused work groups are also made up of all members of the WTO.

[382] Daphne Yong-d'Herve, *Implementation and Administration of TRIPs and Dispute Settlement, in Intellectual Prop. & International Trade: A Guide to the Uruguay Round TRIPs Agreement,* (Tania Saulnier et al. eds., 1996) at 74.

[383] TRIPs Agreement, supra note 308, arts. 63.1-63.2.

[384]See TRIPs Agreement, *supra* note 308, arts. 42-49. Member states are required to establish fair and equitable civil and administrative procedures and remedies to enforce IPRs.

[385] Yong-d'Herve, *supra* note 381, at 72.

[386] *Ibid* at 74.

[387] Tansey, *supra* note 322 at 13.

[388] Robert J. Gutowski, The Marriage of Intellectual Property and International Trade in the TRIPs Agreement: Strange Bedfellows or a Match Made in Heaven?, *47 Buff. L. Rev. 713, 717-18 (1999)* at 734-35.

[389] Yong-d'Herve, supra note 381, at 75.

[390] TRIPs Agreement, supra note 308, art. 27.3(b).

[391] *Ibid.* arts. 65.2-65.4.

[392] Tansey, supra note 322, at 13.

[393] *Ibid.*

[394] See *ibid.* at 13-14.

[395] See *Ibid.* at 13-15.

[396] Michael L. Doane, The Uruguay Round Negotiations, in International Intellectual Prop. Law, (Anthony D'Amato & Doris Estelle Long eds., 1997), at 274-75.

[397] See *Ibid.*

[398] J.H. Reichman, Universal Minimum Standards of Intellectual Property Protection under the TRIPs Component of the WTO Agreement, in Intellectual Prop. and International Trade: The TRIPs Agreement, at 78, 91. See also Article 67 of the TRIPs Agreement.

[399] McCabe, *supra* note 370, at 63-64.

[400] TRIPs Agreement, *supra* note 308, art. 71.1.

[401] See *Ibid.*

[402] Article 71.2 of the TRIPs Agreement outlines the limited situation in which modification actions may be taken by force of recommendation from the TRIPs Council.

[403] McCabe, *supra* note 370, at 63-64. McCabe suggests that the United States, with the help of Japan and the European Union, could lobby the TRIPs Council to issue a statement of interpretation ruling that Article 27.3(b) requires the extension of patent protection to plants or animals made by non-biological and microbiological processes.

[404] Reichman, supra note 397, at 78, 91.

[405] See Moncayo von Hase, Andres Moncayo von Hase, *The Application and Interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights, in Intellectual Prop. and International Trade* (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998), at 141.

[406] See Reichman, supra note 397, at 91.

[407] Tansey, *supra* note 322, at 17.

[408] *Ibid.*

[409] See *ibid.* at 14-15. In September 1999, Kenya, on behalf of many African countries, tabled a proposal to institute a moratorium on implementing Article 27.3(b) of the TRIPs Agreement. Non-governmental organizations also supported this proposal.

[410] See Geoff Tansey, Trade, Intellectual Prop., Food and Biodiversity: Key issues and options for the 1999 review of Article 27.3(b) of the TRIPS Agreement at 3 http://www.zen.co.uk/home/pge/g.tansey/trips-bw.pdf (Feb. 1999) at 19-20.

[411] See Tansey, *supra* note 409, at 20.

[412] See generally Tansey, *supra* note 409.

[413] See Terence P. Stewart & David S. Johnson, *Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade,* 4 Drake J. Agric. L. 243, 246 (1999).

[414] Tansey, *supra* note 409, at 19-21.

[415] Valentina Tejera, *Tripping Over Property Rights: Is It Possible to Reconcile the Convention on Biological Diversity with Article 27 of the TRIPs Agreement?*, 33 New Eng. L. Rev. 967, 971 (1999).

[416] Lakshmi Sarma, Biopiracy: *Twentieth Century Imperialism in the Form of International Agreements,* 13 Temp. Int'l & Comp. L J. 107, 107 (1999) at 122. For example, the U.S. pharmaceutical firm Merck has arranged to compensate Costa Rica in exchange for the right to systematically explore its native plant species.

[417] *Ibid* at 122-123.

[418] Tejera, *supra* note 414, at 976-77.

[419] *Ibid.*

[420] See *35 U.S.C. 102*(a)-(b) (1984). Public disclosure in the U.S. or a foreign country by the applicant or others can bar patentability.

[421] See generally, Jasemine Chambers, *Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How much Patent Policy is Public Policy?* (2002) 34 Geo. Wash. Int'l L. Rev. 223.

[422] See Adelman et al., *supra* note 226, at 85.

[423] *Ibid.*

[424] See Chambers *supra* note 420, at 246.

[425] *Ibid.*

[426] See Patent Leaders Endorse Efforts to Harmonize Protection Systems No.7, 13 World Intell. Prop. Rep. (BNA) (1999) at 245.

[427] See generally Warwick A. Rothnie, *Parallel Imports* (1993). Discussing the difficulties in collecting data and producing studies that measure the effectiveness of international intellectual property regimes.

[428] *Ibid.*

[429] John H. Barton, *Global Trade Issues in the New Millennium: The Economics of TRIPS: International Trade in Information-Intensive Products* (2001) 33 Geo. Wash. Int'l L. Rev. 473 at 500.

[430] See Kate H. Murashige, *Harmonization of Patent Laws* (1994) 16 Hous. J. Int'l L., at 592-95.

[431] See Monroe et al., *International Overview of Trademarks and Copyrights, in International Intellectual Property Law: New Developments 5* (Dennis Campbell & Susan Cotter eds., 1995) at 6-19.

[432] Long & D'Amato, Underlying Theories: Harmonization, in International Intellectual Prop. Law, (Anthony D'Amato & Doris Estelle Long eds., 1997) at 9.

[433] See Lynne Saylor & John Beton, *Why the TRIPS Agreement?, in Intellectual Prop. & International Trade: A guide to the Uruguay Round TRIPS Agreement 15* (Tania Saulnier et al. Eds., 1996) at 13-15.

[434] Tansey, supra note 409, at 18-22.

[435] Michael L. Doane, The Uruguay Round Negotiations, in International Intellectual Prop. Law 274, at 275.

[436] Sara Dillon, *Fuji-Kodak, the WTO, and the Death of Domestic Political Constituencies*, 8 Minn. J. Global Trade 197, (1999) at 204-06.

[437] Abdulqawi A. Yusuf, *TRIPs: Background, Principles and General Provisions, in Intellectual Prop. and International Trade: The TRIPs Agreement 3, 4-5* (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998).

[438] See Daphne Yong-d'Herve, *Implementation and Administration of TRIPs and Dispute Settlement, in Intellectual Prop. & International Trade: A Guide to the Uruguay Round TRIPs Agreement,* (Tania Saulnier et al. eds., 1996) at 74.

[439] Tansey, supra note 409. The marked contrast between the interests of developed and developing countries overshadows the divergence of interests between nations within each of these groupings.

[440] Carlos Alberto Primo Braga, *Conflicting Theories of Economic Value, in International Intellectual Prop. Law,* (Anthony D'Amato & Doris Estelle Long eds., 1997) at 50-51.

[441] Tara Kalagher Giunta & Lily H. Shang, *Intellectual Property Protection in Developing Countries, in International Intellectual Prop. Law*, (Anthony D'Amato & Doris Estelle Long eds., 1997) at 445-46.

[442] *Ibid.* at 446.

[461] See Reichman, *supra* note 436, at 87.

[462] Gutowski, *supra* note 387, at 749.

[463] See Tansey, supra note 409, at 18-19.

[464] See generally, *Lynton K. Caldwell, Is World Law an Emerging Reality? Environmental Law in a Transnational World,* 10 Colo. J. Int'l Envtl. L. & Pol'y 227, 227-29 (1999).

[465] See generally, *Paul B. Stephan, The New International Law-Legitimacy, Accountability, Authority and Freedom in the New Global Order,* 70 U. Colo. L. Rev. 1555, 1563 (1999).

[466] *Ibid. at 1561.*

[467] *Ibid.*

[468] See Stephan, *supra* note 464, at 1563.

[469] *Ibid.* Examples of these bodies include the WTO, the European Court of Justice, and the International Monetary Fund.

[470] *Ibid.* at 1561.

[471] *Ibid.* at 1562.

[472] Stephan, supra note 464, at 1562.

[473] *Ibid.*
[474] *Ibid.*

[475] *Ibid.*

[476] See World Trade Organization, Seattle: What's At Stake? A Resource Booklet for the Seattle Ministerial Meeting,http://www.wto.org/english/thewto<uscore>e/minist<uscore>e/min99<uscore>e/english/book<uscore>e/stake.pdf (Nov. 1999).

[477] Sara Dillon, *Fuji-Kodak, the WTO, and the Death of Domestic Political Constituencies*, 8 Minn. J. Global Trade 197, 204-06 (1999).

[478] *Ibid.* at 205.

[479] *Ibid.* Article 27.3(b) addresses the level of IPR protection and thus the potential cost of biotechnology products essential to the life and health of the world's citizens.

[480] Tansey, *supra* note 409, at 14. In addition to member states, non-governmental organizations are likely to have a significant influence on the outcome of the review process, at least indirectly.

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