INTELLECTUAL PROPERTY ARMY: 
FIGHTING WARS AND HEALING THE WORLD

THE COEXISTENCE BETWEEN MEDICAL INNOVATION AND PUBLIC AFFORDABILITY

ABSTRACT

A major phenomenon that has stirred the raging debate over strong intellectual property patent protection for pharmaceuticals is the issue of access to medicines. Such ownership protection has frequently been criticized in both developed and developing countries to be at the expense of public interest. Strong patent protection by pharmaceutical companies on their products inherently leads to a rise in the costs of essential medicines, making them increasingly less accessible to the disease stricken populations.

This paper investigates the possibility of coexistence between patent protection of pharmaceuticals and the effective provision of medicine to the people who gravely need them, with special attention given to the poor in developing countries.

The importance of patents in our society is significantly emphasized in the research-intensive pharmaceutical industry, which is one of the most innovative industries in the world. The evolution and justifications of patents is traced through the conception of intellectual property laws under British influence and theories that have formulated over the years.

Secondly, the role of multinational pharmaceutical companies in fostering global patent protection and its role in improving the world’s health will be explored. Being largely profit-oriented, pharmaceutical companies have often neglected the wider public interests and contribute to the growing gap between patients and their necessary medicines and treatments.

Next, the international legal framework is a central aspect that has vastly influenced the effects of pharmaceutical patents. The consequential impacts of patents on pharmaceuticals are explored through the examination of international responses,
including an in-depth case study of India. India is an example of a developing country that has reaped the benefits of strong patent protection with the appropriate measures, actions and domestic laws its government and other private interest groups have put in place.

Lastly, this paper will assert that the promotion of public health should not be disconnected from the promotion of pharmaceutical inventions. As the presence of incentives is essential in supporting a robust pharmaceutical industry, a multi-layered system comprising of realistic and practical solutions will be advocated as a potential and viable solution to attaining harmonization between medical innovation and public affordability.
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INTRODUCTION
Pharmaceutical Patents in Modern Society

The deliberation over the true meaning of the term ‘intellectual property’ has been ongoing for centuries. From old paradigms of tangible forms to atypical intangible forms, the notion of ‘property’ has evolved dramatically over the years and now includes intellectual work. However, a comprehensive definition still remains elusive due to uncertainty hinging onto whether certain forms of intellectual property are rightly ‘intellectual’ or ‘property’. In essence, a universal understanding of intellectual property may be thought of as a complex mix of different interests that protect an intellectual creation through the grant of an exclusive and proprietary right, while at the same time, guaranteeing an extent of free access to, and use of such works of the mind.

The legal rights conferred upon the creator to protect his invention or creation for a period of time, are known as intellectual property rights which include patents, copyright and registered trademarks. Upon satisfying certain statutory requirements, intellectual works are expressly stated by legislation to be ‘property’ of the creators. At the core of intellectual property rights are the two crucial aspects - property and exclusivity. By oscillating between propriety and the sharing of one’s property, the various domestic and global intellectual property laws are able to accommodate the different and often contradictory interests of intellectual property.

Today, rapid technological advances and powerful waves of new knowledge have amplified the importance of intellectual property laws to promote the changes and contain the excesses. As a reward and incentive mechanism for fostering innovation and creativity, intellectual property plays a vital role in the modern economy by promoting healthy competition and encouraging industrial development. Without IPRs, the wheel of innovation and inventiveness may slow down or even grind to a halt.

This conventional justification of intellectual property receives the greatest empirical

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credibility with the patent regime as patents are notably constructed as engines of public availability and usage. The limited duration of patents reflects this egalitarian characteristic of intellectual property as it allows for the public to enjoy a substantial amount of intellectual creations without the fear of infringement. As such, patent law is seen as an instrument for the empowerment of talented upstarts and the promotion of access through imposing divulgation of the invention as a counterpart to exclusivity.

In our highly globalized and competitive world, patents are an especially powerful form of intellectual property, especially in the highly research-oriented and knowledge-based pharmaceutical industry. While it may seem that the pharmaceutical industry manipulates patents for its own economic ends, a historical approach to the utilization of patents combined with an analysis of current patent issues places this relationship in its proper context. Not only has the pharmaceutical industry continuously adjusted to changes in legislation to ensure an effective system by which to research, invent, regulate and ultimately patent new medicines, it is heavily dependent on the limited monopolies that patents provide in order to recoup investment expenses and to create profits. Regardless of how one views the extensive profits made by innovative drug companies, such profits combined with the hefty number of new products indicate that the pharmaceutical patent system does indeed work and clearly fulfills the goals of intellectual property – To encourage creativity and increase innovation.

However, heated discussions regarding the detriments brought about by the current patent system on pharmaceuticals reveals another side of the coin. There has been skepticism regarding whether the substantial economic profits of pharmaceutical companies are at the expense of larger social implications that arise from the issue of global accessibility to medicine.


The creation of pharmaceutical drugs is undeniably considered the noblest of human productions and yet it is neither freely accessible nor disseminated. For the sake of economic exploitation, pharmaceutical companies overzealously impose patent protection on their medicines and this in turn raises the prices of drugs that are crucial for patients in the less affluent developing nations. This palpable disconnect between the current pharmaceutical Research and Development (“R&D”) agenda and global public health crisis and the apparent flaw in the reward and incentive theory of the patent system makes one question if the possibility for harmonization between medical innovation and public affordability does exist.

This paper argues that a state of co-existence between patent protection of pharmaceuticals and the effective provision of medicine to the disease and illness stricken populations of the world can be achieved. It explores the possibility of balance between these two aspects by investigating the reward and incentive justification of current patent regime on pharmaceuticals. The paper further delves into the misaligned focus of the pharmaceutical industry in relation to the public health crisis, specifically in developing countries, as evidenced by the freezing of access to essential drugs and the industry’s lack of interest in fulfilling its responsibilities towards the disease stricken populations.

Part I of this paper traces the historical origins of intellectual property law that emerged under British influence in the 16th century. It impresses upon the fact that from the beginning, economic justifications were given priority over ideals of free dissemination of knowledge and social welfare, a position that is presently reflected in the profit motivated pharmaceutical industry. Part II then analyzes the motives and duties of multinational pharmaceutical companies. It compares the alleged justifications for higher drug prices against the actual motivations of the pharmaceutical industry. Part III takes a look at the international legal landscape for patent law and the crucial role it plays in influencing the extent of the effects of pharmaceutical patents on developing nations. It also examines the flexibilities present in international agreements that aim to reduce the negative impacts brought about by stricter pharmaceutical patent laws. In Part IV, attention will be given to the responses of the international community and will also accentuate the prospect of

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6 Christopher J. Longo, “Encouraging Pharmaceutical Innovation to Meet the Needs of Both Developed and Developing Countries” (2011) 10 International Journal of Development Issues 92, 96
prosperity of developing countries under the international patent regime. This will be done through a comprehensive review of the steps India has taken to reduce the effects of compliance to international agreements. It will also analyze how India has managed to successfully adapt to stronger patent requirements and to also offer assistance to other developing countries at the same time. Lastly, Part V proposes the development of a multi-layered system that will include stricter patent approval procedures, compulsory licensing, and the establishment of patent pools in order to establish a harmonious environment for medical innovation and public affordability of medicines.

This paper aims to provide potentially practical solutions to tackle the problem of imbalance between pharmaceuticals and public affordability and to motivate pharmaceutical companies to alter their policies or adopt a more accommodating system towards public interests. It seeks to emphasize the possibility of attaining a sustainable profit-making business and the effective provision of medicines in the endeavor to heal the world’s health.

PART I – THE HISTORICAL ORIGINS AND JUSTIFICATIONS OF INTELLECTUAL PROPERTY LAW

1. The History of Intellectual Property Law

With the vast and diverse range of intellectual property rights present today, it would prove a futile effort to try and pinpoint a single, exact source of origination. The roots of IPRs are manifold have developed independently based on different theories, ideologies and geographies.7 Despite the challenging attempts made in tracing the genealogy of IP law, it is accepted that the British model of intellectual property that arose under British guild influence over the Monarchy during the 16th century8 is the most widely recognized instance of origination.


The model dates back to medieval Europe where the English Crown granted patents to raise funds and secure control over industries that were considered to be of political importance. The guilds were given authority by the government to control the regulation and conduct of the various industries, including deciding on which items could be imported, marketed and produced. They also had the power to direct the manner in which new inventions and procedures could be introduced to the sphere of commerce. The development of intellectual property laws by the British guilds at that time was driven by political and religious motivations rather than a genuine interest to promote creation and innovation. In 1556, the Stationers’ Company’s monopoly in England was established with the primary intention of limiting the Protestant Reformation movement's power. By placing the entire printing industry under the control of this company, the government and the church prevented the dissemination of ideas. Instead of encouraging creativity and invention, it seems that the concentration of power by the guilds on the regulation of industries that were not earned by innovation, skill or creativity did more to stifle the intended goals of intellectual property laws.

The industrialization of mechanized commercial printing and manufacturing between the 16th to 18th centuries further strengthened the formulation of intellectual property laws by British guild monopolies. Through the establishment of intellectual property laws, the Monarchy was able to collect hefty revenue taxes and licensing payments. As such, when the risk of disruption by the illegitimate replication of property by the commercial printing press and mechanized manufacturing equipment arose, the Monarchy took legal measures to protect their golden goose by


13 Ibid, 40-42.
ensuring the existence of a monopoly system where the guilds maintained proprietary control and exclusionary rights over their works and products. Although knowledge and creativity was intentionally suppressed and the actions of the government were directed to protecting the national economic interests of England, the extent of success of British model of intellectual property on the nation’s economy was so exceptional that the government could afford to ignore the major issue of stifling the world’s creative and knowledge development.

Eventually, the restrictions of this pervasive system became so intolerably broad and burdensome that they resulted in widespread dissatisfaction and unrest in the population. The guild monopoly system was thoroughly broken in 1623 upon the passing of the English Statue of Monopolies. This law aimed to abolish monopolies so as to protect public welfare. It also relied on the ‘Incentive Theory’, granting time-bound exclusivity to the ‘true and first inventors’ in a bid to balance the distaste for monopolies with the desire to provide incentives for innovation. From that point forward, more specific statutes and British common law continued to develop and intellectual property law began to undergo a process of refinement.

Although patent law is generally known to have originated from the Statute of Monopolies, the trend of granting patents started as early as during 14th century. In its pursuance for technological dominance, England used patent laws to attract artisans and to prohibit the replication of its knowledge and inventions by economically and technologically more powerful countries such as China and India. A supplementary purpose of intellectual property laws was to prevent the

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18 Ibid, 425


sale of illegally replicated products from disrupting the businesses operated by guilds within international markets. By doing so, the British were able to hold trade exclusivity over its commodities and was consequently able to generate the requisite attraction mechanism necessary to draw merchants to its shore.21 With the surge in international trade, technology and communications in the 18th century, the legal tradition sought to promote freedom of trade. Hence, the Statute of Anne was enacted in 1710 under which a further 14-year renewal of patents on top of the initial 14-year protection period was made possible.22

In response to England’s competitiveness, other emerging markets built upon the British model23 and began to enact their own set of intellectual property regimes with the hopes of achieving the same degree of success. Inventors were granted exclusive proprietary ownership over their registered works and products while infringers faced heavy penalties or had to make compensation to the parties they infringed upon.

The success of the British model is reflected in the eminent intellectual property system of the United States of America (“US”). America’s reputation as a technological powerhouse in today’s global innovation market24 is highly attributed to the transfer of knowledge and technology from the British. However, as protecting the interests of inventors and other intellectual workers have not been an important concern of the British, the contemporary Anglo-American IP regime has perpetuated the inherently selfish agendas and shortfalls of its predecessor.25

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22 Ibid, 110.


Additionally, the current patent system embodies the remnants of monopoly privilege under the British model. Rather than spontaneously evolving to meet new needs, as real property rights do, intellectual property rights seem to create a situation of scarcity through heavy-handed state action. This can be observed in the pharmaceutical industry where large multinational pharmaceutical companies control the production of essential drugs in order to maintain a price at which they are able to reap the most profits and ultimately denying the accessibility of the drugs to those who are genuinely in need of them.

2. Justifications for Intellectual Property Law

Although the British model casts a dark shadow on the justifications for intellectual property laws, there are still several cogent arguments supporting its necessary subsistence in our modern world. Many scholars acquiesce the rationalization of IP law to the theory by 17th century Philosopher, John Locke. Derived from Locke’s Second Treatise of Government, the ‘Lockean Theory’ embodies a right-based approach and rests on the concept that a person has the right to the work he produces.

Based on the assumption that an uncultivated ‘common’ exists, this approach submits that when an individual mixes labour and natural resources from the commons, he obtains property rights to his creation and adds value to the public sphere. In this way, exclusive ownership does not deprive the society’s enjoyment of intellectual property as ‘enough and as good’ is left in the commons. Rather, the exclusive rights attached one’s creation encourages individuals to place their property before the public, further engendering new ideas and spurring creativity.


29 Simmons, see Note 27, above, 9
Given the time-limited nature of IPRs, intellectual goods eventually fully return to the public domain.\(^{30}\)

Ayn Rand offers a similar argument to Locke’s theory through a more ethical approach. She justifies IPRs by recognizing that a man’s mind is the most important tool for survival as the exercise of the mind is the means through which one acquires the values to live.\(^{31}\) The respect for a person’s property has also been intimately linked to Wilhem von Humboldt’s theory on self-development.\(^{32}\) As the creator and his creation share an immensely close relationship, the freedom and security afforded by intellectual property rights to the creator’s cultivation of his faculties is a fundamental factor for the development of the human potential.

Another vein of the Lockean Theory is premised around an economic approach. It suggests that property has a vital role in encouraging the expenditure of individual effort since the ability to make use of it can be initiated with the remittance of money.\(^{33}\) The labeling of an intellectual endeavor as property grants the owner the ability to charge a pecuniary premium for the use of his property. This provides an incentive for an inventor to create a commercially viable intellectual product, with the promise of financial reward through royalties paid to him for the use of his property. This financial success not only puts the inventor in a better position to fund further attempts at creation but also provides the assurance that he will be duly recognized for his efforts through the prohibition of illegal replication. The heightened sense of confidence instilled in an inventor to present a protected work to the public also generates social progress and creates a chain reaction whereby others would also be inspired to bring out their inner creative flairs.

Locke’s rights-based approach is also reflected in Article I, Section 8, of the US Constitution which states that the Congress has the power to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the


\(^{31}\) Palmer, see Note 28 above, 842

\(^{32}\) Palmer, see Note 28 above, 845

\(^{33}\) Wertheimer, see Note 21 above, 118
exclusive right to their respective writings and discoveries”. 34 The development of intellectual property rights in the US has largely reflected more pragmatic considerations, particularly the protection of economic investment. By providing economic incentives to authors and inventors, the US hopes to encourage them to make innovations and then reward them for revealing their innovative products to the public.

Another noteworthy justification is founded upon the ‘Law and Economics’ approach that is generally concerned with the role of the law in the efficient allocation of economic resources. There is an underlying assumption that rational individuals will seek to maximize their economic gains and will be disinclined to act if they expect to receive only a marginal economic benefit. However, there is a public goods problem due to the intangible nature of intellectual property, which can be time-consuming to produce and potentially requires a considerable degree of inventiveness or originality. Yet, once this mental investment has been embodied in a material form, it may be relatively cheap and easy to reproduce. Without intellectual property rights, there is nothing to prevent others from free-riding and taking advantage of the intellectual capital without incurring original costs. In this way, commercial bodies would be deterred from making the necessary initial investment to produce intellectual capital and the market would be greatly impoverished. 35

3. The Relationship Between Patents and Pharmaceuticals

“The patent system added the fuel of interest to the fire of genius”. 36 This veracious comment by Abraham Lincoln impresses upon the role of patents in the cultivation of an innovative society.

There is no end to the diseases that afflict humanity as new diseases are continually


being discovered while known diseases mutate. Even when cures are found, the imperative for a more economic approach to disease control as well as for the mitigation or elimination of the side effects of existing drugs compel a continuing quest for pharmaceutical innovation.

The pharmaceutical industry is the engine of health services delivery and general health promotion in both developed and developing countries. It is a highly research driven and intensive industry that thoroughly asserts the essential role of R&D in pharmaceutical innovation. The process of innovation in the pharmaceutical sector is both lengthy and expensive as it transverses upstream activities like platform research to downstream activities like clinical trials, regulatory approvals, drug manufacturing and other capital-intensive promotional activities.\(^{37}\) It is estimated that the cost of bringing a new drug into the market is close to US$800 million while the elongated time frame is said to be between a 10 to 15 years\(^{38}\). Over the years, there has been a rapid increase in the spending for pharmaceuticals from approximately US$28 in 1980 to US$870 in 2007.\(^{39}\)

Despite the capital-intensive and complex landscape for pharmaceutical innovation or R&D, large multinational pharmaceutical companies and their stakeholders argue that there is not much guarantee for profitability of investment in breakthrough drugs.

Much of the industry’s growth is driven by the rapid rate of innovation, which is fueled by the financial rewards afforded to the pharmaceutical industry through intellectual property protection. The ability of firms to appropriate at least some of the value created by their innovations is essential if there is to be incentive to innovate.\(^{40}\) Furthermore, the justifications for intellectual property protection suggest

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\(^{38}\) Ibid, 557.

\(^{39}\) Longo, Christopher J., “Encouraging Pharmaceutical Innovation to Meet the Needs of Both Developed and Developing Countries” (2011) 10 *International Journal of Development Issues* 92, 97

that the presence of incentives is directly proportional to the effect of stimulus. This justifies the overpricing of pharmaceuticals on the basis that pecuniary reward is a necessary mechanism that provides creators with an incentive to continually create or innovate.

Given its unique nature, it is often argued that without a strong patent protection, innovation in the pharmaceutical sector would be difficult to sustain as pharmaceutical development loses its profitability and ultimately its momentum. Hence, patents provide pharmaceutical companies with the needed assurance that they will reap the profits of their hard labour in the creation of new medicines.

Being a critical component in the intensely competitive pharmaceutical environment coupled with the growing need for the effective distribution of medicines at the local and personal level, patents are increasingly regarded as essential tools for insuring that future strides are made to ensure new life-saving drugs are created. The historical justifications for intellectual property rights are shown to be most fitting in the context of the pharmaceutical industry. Hence, there is a vital need for a stronger and more exclusive protective regime in the industry for greater developments in pharmaceutical innovation.41

4. The Current Conflict: Criticisms of Patents in the Pharmaceutical Industry

It is commonly held that patents are a crucial factor in spurring development of new medicines, and must be protected even if doing so prevents access by those who need them the most. Yet the preference for protection over access is not universal, particularly when the product at issue relates to human health. Many scholars believe that intellectual property protection should not be a barrier to distribution of pharmaceuticals in areas facing a human health crisis.

Nevertheless, the rapid rate of pharmaceutical innovation comes at a price. Although many pharmaceutical innovations offer much promise at improving the health of global populations, their high costs often result in equity of access issues. This negatively affects the poor in both developed and especially developing countries, as

41 Oguamanam, see Note 37 above, 567
they are unable to afford the expensive new medicines. In fact, the expansion of TRIPS that extended compulsory patent rights on pharmaceuticals to developing countries further aggravated the accessibility issue. Additionally, the desire for profits and the lack of financial incentives have induced the pharmaceutical industry’s failure to direct a sufficient amount of attention towards solving the distressing health issues present in developing countries.

In particular, the magnitude of the AIDS crisis has drawn attention to the alarming fact that millions of people in the developing world lack access to medicines that are needed to treat disease and alleviate suffering. With close to 8000 people dying of AIDS in the developing world each day, the demand for life-saving medication is growing expeditiously. Yet patent-holding pharmaceutical companies have carelessly neglected the interests of the suffering population.

Presently, many new medicines that are vital for the survival of millions are too costly for the vast majority of people in poor countries. In addition, investment in R&D towards the health needs of people in developing countries has almost come to a standstill. Three-quarters of the world population live in developing nations yet these countries account for less than 10% of the global pharmaceutical market. It is unlikely that TRIPS will encourage adequate R&D in developing countries for diseases as poor countries do not provide sufficient profit potential to motivate R&D investment by the pharmaceutical industry. Developing countries have constantly come under pressure from industrialized countries and the pharmaceutical industry to implement patent legislation that goes beyond the obligations of TRIPS.

Our world is currently in a transitory period where the global governance regime for intellectual property rights has been established but the political community on which the justification of intellectual property itself depends on is far from globalized. While mechanisms exist at the national level to ameliorate problems that the balance of private rewards and public benefits might produce, few mechanisms

42 Christopher J. Longo, “Encouraging Pharmaceutical Innovation to Meet the Needs of Both Developed and Developing Countries” (2011) 10 International Journal of Development Issues 92, 97

exist at the global level.\textsuperscript{44} It seems that the private rights of patent holders in the pharmaceutical industry are being purchased at too great a social cost in the developing world.

On the other hand, pharmaceutical companies have argued that the health pandemic in developing countries will not be halted merely by the abrogation of drug patents as such social issues inherently involve the presence of an effective government and appropriate policies that are able to alleviate poverty in the country. In addition, multinational enterprises claim that extending strong intellectual property rights to the developing countries would bring them greater inflow of Foreign Direct Investment (“FDI”) in production and transfer of technology, all of which help raise the living standards in these countries.\textsuperscript{45} Regardless, this phenomenon raises an important and problematic aspect of the globalized regime for intellectual property rights.\textsuperscript{46}

It is truly a feat to achieve the optimal level of pharmaceutical patent protection for a given economy but it is also impossible. This is where the level in which the contribution of incentives of the patent system to the pharmaceutical innovation and the contribution of access to medicines to the health level is maximized.\textsuperscript{47} In attaining this proper balance between innovation incentives and access to medicines, both developed and developing countries will be in a better position to achieve its economic growth potential than those with unbalanced systems.

\textsuperscript{44} Tvedt, Morten Walloe, “One Worldwide Patent System: What’s in it for Developing Countries?” (2010) 31 Third World Quarterly 277, 281


\textsuperscript{46} Christopher May, “Why IPRs are a Global Political Issue” (2013) 25 European Intellectual Property Review 1, 2

\textsuperscript{47} Cardenas T., Jose Luis, “Toward a more Balanced Pharmaceutical Patent System for Developing Countries: Some Preliminary Thoughts” 8 Journal of Generic Medicines 104, 107
PART II – THE PURSUIT OF PROFITS: ROLES AND MOTIVATIONS OF THE PHARMACEUTICAL INDUSTRY

This research-based pharmaceutical industry is one of the most innovative sectors in the world. Over the past century, it has played a unique role in developing new and improved medicines and vaccines to prevent and treat diseases and conditions. However, the trade-off between promoting competition and protecting intellectual property has also emerged as a principal issue in international policy.

The major complaint concerning current international patent law is the imbalance between rights of the pharmaceutical companies and the lack of obligation to provide access to essential medicines. Despite the assurance from the developed countries that the global patent system is a stimulant for pharmaceutical innovation, research, and development, these processes are in reality, almost exclusively confined to the private sector and areas of profitable return.

1. Responsibilities of the Pharmaceutical Industry

Pharmaceutical R&D has dramatically improved the lives of patients. Medical discoveries have increased the life expectancy and resulted in a better quality of life for many. The industry has also developed more than 20 antiretroviral treatments for HIV/AIDS, essential in control of the epidemic. The number of AIDS related deaths worldwide peaked at 2.1 million in 2004 and has since fallen to an estimated 1.8 million deaths in 2009.48

The industry’s success rests on continuous innovation. Despite challenging business conditions, the industry undertakes investments that are considerably more risky than those in other high-technology sectors. By investing billions of dollars and long hours in R&D, it pushes the limits of science, improves global health and contributes to the prosperity of society. Accordingly, the research-based pharmaceutical industry globally spent over USD$120 billion on pharmaceutical R&D in 2008. Today, the

cost of developing a single medicine can go above a billion dollars.\textsuperscript{49} Rising R&D costs and more stringent testing requirements have been accompanied by a decline in new medicine approvals. Without patents, it is estimated R&D outlays would be reduced by 64%, jeopardizing the well being of future patients and the innovation process itself.\textsuperscript{50}

Beyond innovation, companies hold a wider responsibility to ‘do no harm,’ by acting with integrity, complying with national laws, respecting human rights, applying fair labour norms, protecting the environment, and working against corruption to prevent harm to people, communities and future generations.

At present, Novartis and the Novartis Foundation for Sustainable Development (NFSD) are involved in a wide range of measures to improve patient access to medicines and health services, including for the poorest in developing countries. In 2011, an estimated 1.1 billion people were protected and treated with Novartis products and 89 million of these disadvantaged people benefited from Novartis access-to-medicine programmes valued at US$1.7 billion.

2. Motivations of the Development of Medicines

Generally, there are several reasons that multinational pharmaceutical companies give in support of patents on pharmaceuticals. In relation to alternative schemes to encourage innovation, the patent system has endured as a resilient mechanism. For many pharmaceutical industry advocates, the patent regime is not entirely satisfactory as a guarantor of risk capital for pharmaceutical innovation.\textsuperscript{51} Pharmaceutical companies are unrelenting in their campaign for proprietary protection of ancillary information and regulatory data generated from downstream protocol for the approval of new drugs. They have continued to push for longer patent terms to leverage market competition in the industry and to delay the entrance


\textsuperscript{50} Mark T. Hoekenga “The Role of Pharmaceuticals in the Total Health Care of Developing Countries” (1983) 32 American Journal of Tropical Medicine and Hygiene 437, 442

\textsuperscript{51} Mainak Mazumdar, Performance of Pharmaceutical Companies in India (Physica-Verlag HD, 2013), 5-8
of generic drug makers to the market and have been immensely successful in those endeavors. Indeed, the only significant reward and incentive mechanism in pharmaceutical innovation is patent-based pharmaceutical R&D.

Firstly, without tight control or legal assurance regarding the exclusivity of the manufacturing process and the resulting product, it is quite easy for others to replicate the breakthrough drugs and produce generic versions. With the right information, a free-rider can put such replicates into the market within a period short of about 6 months when it took 10 years of pharmaceutical R&D to produce the original product. The pharmaceutical industry is one of three technology-based industries in which the patent virtually equals the product. Unlike industries that produce products requiring expensive and complex manufacturing infrastructures, the patented products of pharmaceutical companies can be easily and cheaply replicated by copiers with little capital investment. Since capital investment in the pharmaceutical industry disproportionately is directed to laboratory research and clinical trials rather than the manufacture of the final product, patent exclusivity is the only effective way to protect and receive a return on that investment.

Second, even with legal assurance of exclusivity for the manufacturer of a breakthrough drug, market exclusivity is not necessarily guaranteed. It does not foreclose the entrance of follow-on drugs, which are new drug entrants to a therapeutic class that has already been defined by a separate drug entity that has obtained a regulatory approval for marketing. However, these drugs bring additional values worthy of patent protection as they may involve a simplified and cost-effective delivery or dosage regimen or may target a specific population group that is vulnerable to extreme side effects of a breakthrough drug. Overall, they assist in making drug prices competitive, suggesting that even with patent protection, drugs can still be made affordable to the public.


54 Kumariah Balasubramaniam, “Pharmaceutical Patents in Developing Countries: Policy Options” (1987) 22 Economic and Political Weekly AN-103, AN-113
Thirdly, in addition to its expensive nature and elongated duration, pharmaceutical R&D is a particularly risky venture from both an investment and a health perspective. The apprehension about drug failure is a constant cause for worry. A combination of scientific and economic reasons, not to mention safety considerations, accounts for high failure rates for new drugs. In any event, when drug failure happens or when drug development research is terminated prematurely, this underscores the risky and expensive nature of the economics of pharmaceutical R&D.

The culture of medical research emphasizes very early disclosure of inventions, usually long before a resulting product can be placed on the market. This is because scientists working in the field of human pathology have an obligation to share their findings as soon as possible with their peers so that those peers will be able to benefit from the new knowledge in their own research. The pharmaceutical industry is also heavily regulated by government agencies to assure the safety and efficacy of products that will be sold to consumers. As such, the lengthy time period between patent filing and placing a product on the market means that pharmaceutical manufacturers receive far shorter periods of patent exclusivity than is the case for other patent dependent industries.

Nowhere has the patent incentive been more successful in attracting investment in technology that in the commercial pharmaceutical industry. In the US, a combination of a strong patent system and a market without price controls led to a massive flow of investment into the American industry. Expenditures on research increased from $1.7 billion in 1977 to $26.4 billion in 2002. The result for the US economy is that since 1990, the patent-driven pharmaceutical industry grew twice as fast as the economy at large.

55 ‘t Hoen, see Note above 43, 39
56 Ruth Gana, “Prospects for Developing Countries Under the TRIPS Agreement” (1996) 29 Vanderbilt Journal of Transnational Law 735, 751
3. Fulfilling its Role: Analysis of the Pharmaceutical Industry’s Justifications for Patent Protection

Although pharmaceutical companies often claim they need intellectual property enforcement to help recoup their investments but a close look reveals that a substantial part of R&D is paid for by the public. Jamie Love argues that the pharmaceutical companies do not even own the rights to the drugs in the first place as many of the anti-retroviral drugs used to treat HIV/AIDS today stem from the government-funded cancer drug research of the 1980s. The rights to government-created innovations were sold to pharmaceutical companies at low prices. Given the public investment on drugs, drug companies do not possess the moral authority to determine who can or can’t access them.

While pharmaceutical companies have no doubt created life-saving drugs that have saved millions of lives, they have also participated in controversial practices around the world that are seen to conflict with their duties to society and have come under a growing amount of criticism.

**Dumping onto Poor Countries and the Testing of Drugs**

There have been instances where pharmaceutical companies appear to show their humanitarian side and purport to want to improve the access to medicines in developing countries. US-based drug company, Eli Lilly, made the largest pharmaceutical donation to provide an antibiotic to 1.3 million people in Rwanda during their refugee crisis in 1994. However, the drug was not listed under the World Health Organization’s ("WHO") list of essential drugs for treating refugees. Furthermore, many of the pills were past their expiration date. Instead of alleviating the situation in the country, Eli Lilly further aggravated the suffering from the aftermath of a civil conflict.

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In an effort to reduce production costs, pharmaceutical companies have carried out human trials on people in the developing world, without their permission. Upon news of a northern Nigerian town of Kano being severely affected by meningitis, the world’s biggest and richest drug company, Pfizer, moved quickly into Nigeria with a new drug, Trovan and claimed that it was a “potential life-saver and a potential billion dollar money spinner”, despite the fact that the drug had not undergone any formal trials beforehand.

**Reluctant Attitudes**

Despite the serious state of the world’s health due to the lack of access to medicines, the pharmaceutical industry does not seem bothered and have been reluctant to change their business strategies to cater more to the public. Representatives of pharmaceutical companies like Bernard Lemoine, the director-general of the National Pharmaceutical Industry Association displayed his annoyance at the campaign being waged on this issue and stressed that positive action such as temporary price reductions and monetary grants to foundations, have been made by the laboratories. Yet the present situation sees pharmaceutical companies setting their own prices, selecting the markets that will push their share prices up and opposing every outside initiative.62

Before 1998, Thailand’s only drug, Triflucan that could treat a fatal disease associated with AIDS was manufactured locally by American laboratory, Pfizer. It was effective but extremely expensive at US$330 for a pack of 50 tablets, an amount that equated to one and a half times an executive’s salary in that country.63 Subsequently, two Thai companies managed sell an equivalent product at a price that was much more affordable than Triflucan. However, Pfizer alerted the US


government and banned the sales of the drugs under the Thai companies and even threatened the Thai authorities that it would impose a duty on their main exports if they did not stop producing the drug.

**Lack of Emphasis on Tropical Diseases**

There more emphasis is placed on profitable research and cures for problems such as impotence and ‘diseases of affluence and longevity’, while many tropical diseases are given far less attention. Tropical diseases are almost entirely confined to the developing world and do not represent a profitable market for the pharmaceutical industry. In recent years, thousands of new compounds have been created but only 1% of the 1,400 new medicines created in the last 25 years were developed for the treatment of tropical diseases. Multinational pharmaceutical companies neglect the diseases of the tropics, not because the science is impossible but because there is essentially, in the terms of the harsh economics of the drugs companies, no market.

In developing countries with relatively small commercial markets and low levels of disposable income, there is very little incentive for pharmaceutical companies to conduct extensive research and development in creating drugs for life-threatening diseases limited mostly to the developing world. Pharmaceutical companies often tout their strengths of having vast capital resources to do research, bringing benefits to humanity the world over. Unfortunately though, the quest for more profits is a hindering factor to what they will research. Tropical disease cures are not profitable for them because most people with such diseases are too poor to afford cures. Pharmaceutical companies judge that they would not get sufficient return on research investment and both with creating drugs for diseases that plague the poor. Instead, they argue that their obligation is to their shareholders, who demand that they put the effort into trying to find cures for the diseases of affluence and longevity such as

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64 Mark T. Hoekenga “The Role of Pharmaceuticals in the Total Health Care of Developing Countries” (1983) 32 American Journal of Tropical Medicine and Hygiene 437, 444


66 Bhaven N. Sampat, “Academic Patents and Access to medicines in Developing Countries” (2009) 99 Health Policy and Ethics 9, 13

heart disease, cancer and Alzheimer’s.⁶⁸

Although several posters of major drug companies present the image of a caring company that brings benefit to humanity and relieves the suffering of the sick, the truth is that their humanity has not extended beyond the limits of the pockets of the sick.⁶⁹

The industry makes a major contribution to the prosperity of the world economy. It is a robust sector that has been one of the pillars of industrialized economies and is increasingly proving to be an important sector in the developing world as well. It contributes to employment, trade, expenditure on R&D and technological capacity building. It is also a necessary foundation for the existence of the generic industry.

In actuality, it is not that patent legislation is bad but simply that pharmaceutical companies have manipulated its loopholes to secure high profits. Patents are shown to have important and pervasive effects on information diffusion and R&D spillovers, and perhaps, in turn, on the efficiency of innovative effort. This information diffusion effect of patents deserves at least some recognition in the development of essential medicines. Ultimately, pharmaceutical companies should look towards changing priorities as they have at present, failed to thoroughly fulfill their responsibilities to the society.

PART III: THE INTERNATIONAL LANDSCAPE

1. Dissecting the TRIPS Agreement

The present international standard of patent protection in the pharmaceutical industry is governed primarily by the TRIPS agreement that was adopted by the World Trade Organization (WTO) at the end of the Uruguay Round in 1994. Prior to the creation of the WTO, national intellectual property laws were largely unregulated within the system under the General Agreement on Tariffs and Trade (“GATT”). Although the details of patent protection remained largely left to national discretion after the

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⁶⁸ May 2001 the Guardian newspaper
formation of the WTO, it is observed that TRIPS substantially utilized the limits of intellectual property rights and generated clear gains for the pharmaceutical industry and the developed world.\textsuperscript{70}

As the result of powerful members of the international community coming together to create a uniform set of international intellectual property rules, TRIPS establishes the minimum level of patent protection that all countries within the WTO are subjected to apart from other broad provisions in the GATT treaty.\textsuperscript{71} The agreement stipulates a minimum of 20 years patent protection on pharmaceuticals, prohibiting potential competitors from producing and marketing cheap generics of pharmaceutical products during this period. This gives the pharmaceutical patent holder a monopoly based on the exclusive marketing rights on its patented product for at least 20 years.

Up until the entry into force of TRIPS in 1995, developing countries could and did disallow patent protection for pharmaceutical products in their national patent laws. TRIPS gave developing countries a transition period of 10 years from 1995 before they were required to enact a bill incorporating product patent protection while least developed countries have until 2016 to comply with its provisions.\textsuperscript{72} In addition, all member countries are required to take steps to provide for the receipt of product patent applications in all areas of technology and on the basis of such applications, they should grant exclusive marketing rights for 5 years or until the patent is granted, whichever is earlier.\textsuperscript{73} The WTO’s Dispute Settlement Board ensures member country compliance and stipulates that the governments of member countries have to introducing the stringent patent laws provided in TRIPS in their domestic laws. In the event of the failure to meet such obligations, countries face severe penalties from the WTO or trade sanctions from prosecuting countries.


\textsuperscript{72} Ping Xiong, “Pharmaceutical Patents in the TRIPS Agreement and the Right to Health – Can These Rights Be Reconciled?” (2012) 36 University of Western Australia Law Review 115, 129.

In 2003, the WTO adopted a decision to amend TRIPS in order to enhance access to essential medicines in developing countries. In working towards a mutually supportive relationship, the World Intellectual Property Organization ("WIPO") also adopted an agenda to further the development of countries by considering different intellectual property regimes appropriate to the circumstances of a particular country or region. The amendment provided that all Members of the WTO have to make available, with limited exceptions, both product and process patents in every sector, including pharmaceuticals. Professor A. Samuel Oddi opines that the driving force behind the amendments in TRIPS was motivated by the endeavor to protect the rights of inventors, active lobbying by multinational pharmaceutical firms and strong pressure received from the US and other developed countries.\(^\text{74}\)

TRIPS was theoretically designed as a social policy tool to encourage innovation by establishing minimum standards for the protection of intellectual property and to ensure that the measures and procedures to enforce intellectual property rights should not hinder legitimate trade. The major justification for the issuance of patents is seen to be in line with historical theories with Article 7 of TRIPS providing that exclusivity given by intellectual property rights will promote both technological innovation and the transfer and dissemination of new products in an advantageous manner that is ‘conducive to social and economic welfare’.\(^\text{75}\)

The standards developed under TRIPS are based on the Western European and North American property law in wealthy developed countries with little regard for the needs of developing countries.\(^\text{76}\) On the surface, the WTO seems to administer the current international trade rules when its actions are actually dictated by the governments of developed countries and powerful pharmaceutical companies. Although TRIPS has further increased pharmaceutical trade in developed countries, it has failed to generate substantial gains for developing countries. The unequal trade between developed and developing countries raises the worrying issue of access to medicines.


\(^\text{75}\) Ping, see note 72 above, 131.

\(^\text{76}\) Smith, see note 70, 686.
The application of TRIPS in developing countries has become increasingly important with the full entry into force of the patent obligations in 2005. The global patent protection system has created an extremely profitable and powerful group of multinational pharmaceutical companies that are, by law, allowed to deny access to life-saving medicines. By restricting the right of governments to allow the production, marketing, and import of low-cost copies of patented medicines, known as generic drugs, the WTO’s rules restrict competition, increase prices, and further reduce the already limited access of poor people to vital medicines. Without reform, the access of poor people in developing countries to medicines will continue to be severely diminished.

It is important to note that even under the TRIPS regime, patents are to be granted only on applications received from 1995 onwards for new, patentable pharmaceutical inventions. Thus, the prices of existing pharmaceuticals already on the market, or even those covered by patent applications prior to 1994 anywhere in the world, should not be affected as these markets could continue to be as contestable as before.

In an attempt to tackle inequality in access issue, the concept of situational flexibility has been considered. This willingness to take individual circumstances into account is a significant development for developing countries as the approach is distinctly relevant to the issue of extending transition periods and striking the appropriate balance between the rights of producers and users of intellectual property. In particular, the least developed countries want to strengthen such special and differential treatment measures in TRIPS. Additionally, Paragraph 44 of the Doha Ministerial Declaration reaffirms the mandate that "provisions for special and

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80 Condon, see note above 77, 23
differential treatment are an integral part of the WTO Agreements” 81. However, while there is recognition of the need to adopt special and differential treatment to the individual circumstances of WTO members, the negotiating progress regarding the appropriate criteria to be applied has been rather stagnant.

In its current form, TRIPS has been criticized to be a ‘vehicle for Western imperialism’ over developing countries as it has resulted in the forcing open of markets to several United States pharmaceutical corporations regardless of the social costs and detriments to human health. It is strongly argued that the strong patent protection in TRIPS was enacted to benefit private industry at the expense of poorer nations, rather than to promote innovation and benefit society as a whole.

Matthew Kramer, describes the adoption of TRIPS as one aspect of the gradual move towards economic globalization and a step in a multinational effort spanning half a century. This modern theory focuses on the idea that the strong patent protection is essential to a stable international economy not solely because it promotes innovation but rather, its role as a major component for maintaining and strengthening the multilateral trading system. 82

2. The Doha “Solution”

The implications for public health of the TRIPS agreement led developing countries to propose, and obtain adoption in 2001, of the WTO ministerial Declaration on the TRIPS agreement and public health (“the Declaration”). This declaration affirmed WTO members’ rights under Art.8 to the sovereign right to take measures to protect public health through certain flexibilities in the TRIPS agreement designed for that purpose. These include identification of patentability standards that might exclude the patenting of trivial developments, grants for compulsory licenses to allow third parties to produce or sell a drug, against payment of a royalty to the patent owner when drugs are not sufficiently supplied or are not affordable and admittance of parallel imports that allow access to patented drugs legitimately sold in a foreign country at reduced prices without the consent of the patent holder. 83 Many public

81 Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (14 November 2001) <http://www.wto.org/english/tratop_e/minist_e/min01_e/mindecl_trips_e.htm> at 3 October 2013

82 Barnes, see note above 931

health advocates welcomed Doha as an important achievement because it gave primacy to public health over private intellectual property, and clarified WTO Members’ rights to use TRIPS safeguards.

The Declaration was initiated by a statement from the African community to the TRIPS Council highlighting the grave nature of the matter on the access to medicines with reference to the devastating AIDS crisis in Africa. The TRIPS Council then held a discussion regarding intellectual property issues in the context of public health for the first time and the African Group proposed issuing separate declarations on access to medicines. The text for the Declaration drafted by the chair of the WTO General Council, Mr. Stuart Harbinson, that was the basis for the negotiations in Doha as it was one which recognized that measures can be taken or health in general and not just instances of health crisis.

After 3 days of negotiation, the participating embers reached a compromise that was built mainly upon negotiations between Brazil and US. The text acknowledged the unmitigated right of countries to take measures to protect public health and may override intellectual property rules if they act as barriers to that cause.

Paragraph 5 of the Declaration set out the safeguards in TRIPS that can be used to overcome obstacles by intellectual property and it was also made clear that the use of compulsory licenses is not restricted to cases of national emergencies only. Although several members of developed nations proposed for the language of the agreement to limit measures like compulsory licensing to emergency situations like pandemics or specified diseases like HIV/AIDS, they were unsuccessful. The Declaration expanded the scope of interpretation of what constitutes a national emergency and made the process issuing of compulsory licenses much faster and easier.

Although the Doha Declaration broke new ground in guaranteeing Members’ access to medical products, it did not solve all of the problems associated with intellectual property protection and public health. Many developed countries did not keep to the promises made in the Declaration and there was also the failure to reach an agreement to allow the production and export of generic medicines in the face of current health needs in developing countries. Hence, there is indication that the

optimism felt at Doha was premature considering the severity of the lack of access issue that presently plagues the poor in both developed and developing countries.\textsuperscript{84} In relation to the flexibilities in the TRIPS Agreement, Alan O’ Sykes takes the same view as Ellen ‘t Hoen in recognizing the inadequacy of the Doha declaration.\textsuperscript{85} He stands in favour of the TRIPS Agreement in solving issue on the lack of access to medicines in developing countries, a clear humanitarian issue that must be approached with both a soft heart and a hard head.\textsuperscript{86} He is of the view that in holding out the prospect of compulsory licensing and parallel importation policies, the Doha Declaration cast doubt on the future credibility of patent rights for pharmaceuticals in the developing nations. The stationary nature of research into tropical diseases prevalent in developing countries is due to the lack of patent protection.\textsuperscript{87} It is argued that drugs that treat serious and widespread conditions are most valuable to society and upon which R&D has the greatest potential payoff. However, in adhering to the Doha Declaration, the requirement of developers of such drugs to sacrifice their intellectual property rents when countries declare a ‘national emergency’ in order to take advantage of compulsory licensing, discourages research in the areas where it has the most potential to yield high returns.\textsuperscript{88}


The greatest conflict between intellectual property protection and human health occurs when a nation faces a severe health emergency but the average person cannot afford access to essential medicines. In order for equal access to life-saving medicines, there needs to be equal access to legal rights that affect that access. There are implicit and explicit exceptions contained within TRIPS through which member states can utilize to meet national needs with respect to public health.\textsuperscript{89} These

\textsuperscript{84} Erik Alsegard, “Global Pharmaceutical Patents after the Doha Declaration – What Lies in the Future” (2004) 1 SCRIPT-ed 12, 41-44

\textsuperscript{85} Sykes, O., Alan, ‘TRIPS, Pharmaceuticals, Developing Countries and the Doha “Solution”’ (2002) 3(1) Chicago Journal of International Law 51, 63

\textsuperscript{86} Ibid, 63.


flexibilities, if used effectively, could mitigate the present tension in TRIPS and provide developing countries with ammunition to combat some of their lack of access problems.

It should be noted that any Articles (“Art.”) referred to in this section are those found under the TRIPS.

**Art. 8**

Art.8 is an implicit exception, which mandates that in creating domestic laws, member countries may adopt measures necessary to protect public health and to promote the public interest in sectors of vital importance to their socio-economic and technological development. Hence, it provides possible grounds that developing country governments could use to combat tropical diseases such as HIV/AIDS. Although, the word ‘necessary’ used in the article indicates that the government does not have complete discretion to use these measures and that its use is subject to review by the WTO, the WTO could use this discretion to help developing country governments combat life-threatening diseases. For instance, it could grant a developing country government ‘substantial latitude’ if the country is facing a health crisis as pursuant to the clarification of TRIPS in the Doha Declaration.  

Additionally, since Art.8 was intended to be a guiding principle, developing country governments can take public health and development measures reflected in the flexibilities contained in Art.30 and 31 while still being consistent with TRIPS.

**Art.30**

Under TRIPS, patent owners are given the exclusive right to prevent third parties from making, using, selling or importing a patented product without their consent. Art.30 and 31 play a key role in balancing the rights of patent owners against the needs of consumers of patented products or pharmaceuticals as they authorize exceptions to the rules. These explicit exceptions to the exclusive rights conferred by TRIPS equip developing country governments with significant tools to improve access to essential medicines and to successfully cater to the public interest of their citizens aside from the proprietary claims of patent holders.

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Art.30 permits ‘limited exceptions’ to patent rights, which are satisfied by the presence of three criteria, namely that the exception must be limited, must not unreasonably conflict with the normal exploitation of the patent and must not unreasonably prejudice the legitimate interests of the patent owner. There has been a divergence of several academic opinions regarding the interpretation of Art.30 in the authorization of generic exports.

In Canada-Patent Protection of Pharmaceutical Product, it was argued that any exception that entirely removes the right to exclude making and using the patented product is not considered a ‘limited exception’. Yet another interpretation minimally reduces the legal rights of the patentee and allows for a generic manufacturer to produce a limited quantity of patented drugs to submit to a national regulatory review process. As it could take generic producers several years to develop the generic product and to obtain regulatory approval, permitting these activities during the course of the patent could significantly reduce the length of time that the patent owner would enjoy a monopoly in the market and thereby reduce their profits. In particular, pharmaceuticals are subject to rigorous government scrutiny due to their potential to cause serious harm to human health through unintended side effects. Patent owners cannot claim a ‘legitimate interest’ in the economic benefits caused by the length of time required to get regulatory approval for generic drugs. In this way, Art.30 seems to open an avenue to reduce protection for pharmaceuticals as it states that limited exceptions apply if they do not conflict with the normal use of the patent or are prejudicial against the legitimate interests of the patent owner.

This exception has been given limited scope in WTO disputes and it is doubtful that a refusal to patent a particular drug or to enforce exclusive rights to sell during the mandatory period of the patent could be viewed as a ‘limited exception’. At present, few developing nations relied on Art.30 but have instead turned to compulsory licensing in Art.31 to deal with the lack of access issue.

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93 Nicol, see note 91 above, 537
Art.31 - Compulsory Licensing

A compulsory license is a license granted to a third party, without the consent of the patent holder, to make, use or sell the patented product.\(^{94}\) WTO member countries are able to override a patent by authorizing a compulsory license for production of a drug on public health grounds to authorize production of patented drugs, subject to adequate compensation to the patent holders. Although the grounds upon which compulsory licenses can be granted are not limited by TRIPS, is not explicitly addressed by TRIPS although it does mention national emergencies, other circumstances of extreme urgency, and anti-competitive practices as possible grounds for compulsory licensing.\(^{95}\) Overall, it appears that countries seeking to use compulsory licensing have a fair bit of discretion at their disposal, something that has been a source of major concern for pharmaceutical companies and other supporters of strong intellectual property rights.

Governments can also use compulsory licenses to curtail excessive prices and to increase domestic production or importation of pharmaceuticals, which is highly relevant in the context of lack of access to medicines. However, there are significant obstacles for developing countries in being able to grant compulsory licenses either for domestic production or for parallel importation. To make effective use of a compulsory license for domestic production, a country must possess both a reasonably sophisticated pharmaceutical industry to produce medicine and a sufficient manufacturing capacity to create economies of scale to keep the costs down and the price of the medicine affordable.\(^{96}\) With regards to a compulsory license for importation, the country must be able to import the pharmaceuticals at an affordable price in the quantity and quality required. Many developing countries are unable to fully utilize compulsory licenses either because they do not have sufficient manufacturing capacity or because a potential importer is prohibited from


manufacturing and exporting the drug from a member country with sufficient manufacturing capacity. Art.5 of Doha confirms that WTO Member States have the freedom to determine the grounds for compulsory licensing and that public health crises, including HIV and other diseases, can represent a national emergency or other circumstance of extreme urgency.97 After Doha, several compulsory licenses were issued for generic manufacture of patented pharmaceuticals. Countries like Thailand, developed an express strategy of using compulsory licensing to reduce health-care costs.

Art.31(f) has constrained countries that do have manufacturing capacity in their ability to provide assistance because it requires that manufacture under compulsory licensing be predominantly for supply of the domestic market, even when the licence is issued for a national emergency or other circumstance of extreme urgency or for public, non-commercial use.

This restriction on the use of compulsory licenses for importation is even more significant as many developing member countries like India. Until 2005, India was able to export huge quantities of generic drugs because its domestic patent laws were not TRIPS compliant. Although it has the sufficient manufacturing capacity, it is now more limited in its ability to export medicines to other developing and LDCs, which do not have sufficient manufacturing capacity to produce life-saving medicines. Yet the smart moves made by India has enabled it to rise amongst the other developing countries and to reap the benefits of TRIPS.

This problem was recognized in Doha negotiations and resulted in the adoption of the Paragraph 6 Implementation Decision (“the Implementation Decision”), an agreement to waive reliance on Art.31(f) was adopted along with the Protocol Amending the TRIPS Agreement (“the Protocol”).98 In essence, the Implementation Decision and the Protocol allowed countries with manufacturing capacity to adopt legislation that permit the granting of compulsory licenses for the production of pharmaceuticals for export, and countries that lack manufacturing capacity to introduce equivalent legislation to facilitate import. However, both instruments impose stringent conditions on the terms of the implementing legislation and to date,


98 Ibid, 133-134
there is little to suggest that they contribute to reversing the failure of the industrialized world to supply essential medicines to the countries that need them the most.\textsuperscript{99} There does not appear to be widespread enthusiasm for using Implementation Decision and Protocol mechanisms to facilitate the provision of low-cost or no-cost pharmaceuticals to those most in need. Few countries have implemented the Protocol and only Rwanda has used the system to import antiretrovirals (ARVs) from Canada. It seems that the Implementation Decision was never intended to deliver medicines at affordable prices, but rather, to ensure that countries lacking manufacturing capacity in the pharmaceutical sector could benefit from the TRIPS compulsory licensing regime.

\textit{Article 27}

Another provision that may afford developing nations an opportunity to lower pharmaceutical prices relates to an important qualification on the exclusive right to import under Art.27 with reference to Art.6. Art.6 is an obscurely worded provision that questions whether a patent holder retains his rights over the resale of a product once it has been introduced into the stream of commerce or if he has exhausted it after the initial sale.\textsuperscript{100} If his rights are exhausted, a patent holder loses his ability to price discriminate across markets and there may be undercutting of the desired price of his product in a particular market. However, developing countries that face relatively high prices for a particular drug when it is sold directly into its market by a patent holder may be able to ameliorate the problem by importing the drug from another country where a lower price is charged.

4. Effects of Other International Agreements: TRIPS-Plus

There should also be attention brought to the issue of TRIPS-plus and how this form of increased protection is not justified in developing countries where there are weak scientific and technological infrastructures and where a majority of the population is poor.\textsuperscript{101} However, the rising occurrence of bilateral agreements that focused on the


\textsuperscript{100} Ruth Gana, “Prospects for Developing Countries Under the TRIPS Agreement” (1996) 29 Vanderbilt Journal of Transnational Law 735, 749.

adoption of high protection of intellectual-property rights entered into by developing countries in order to create a favorable climate for foreign direct investment. The impetus behind changes in intellectual property rights is observed to be the need to pay for trade concessions 102 and this has led to the immediate effect of preventing access to medicines. This suggests that the problem of access is not solely due to strong patent protection but as a result of developing countries’ own actions in a bid to attain significant economic growth.

Currently, developing countries are not making full use of flexibilities built in to TRIPS Agreement to overcome patent barriers, such as compulsory licenses and parallel imports as advocated by the Doha. 103 The main reason is possibly due to the absence of domestic resources and capacity, resulting in dependency on donor financing and in turn constraining the ability to exploit international trade provisions. Similarly, inequalities in power and influence between countries leave many vulnerable to pressure to protect broad trade and economic interests. In addition, widespread misunderstandings also exist, such as the misconception that countries have to declare a national emergency before invoking a compulsory license. 104

PART IV – THE EFFECTS AND RESPONSES OF THE INTERNATIONAL COMMUNITY: CASE STUDY OF INDIA

India is an example of a less developed country that has embraced the international landscape relating to pharmaceutical patents. It is relatively better off than other less developed countries due to the effective steps adopted by the government in setting up a reasonably well-developed pharmaceutical sector. Previously, the lack of patent protection in India made it unprofitable to develop better cures for diseases as any invention was readily copied and the original inventor was unable to recover research costs. India’s patent laws had to undergo major changes to comply with product patent requirements on pharmaceuticals in TRIPS but the heightened patent protection is observed to drive Indian firms to undertake research in finding cures for


104 Ibid, 76
diseases common in the society. Although there has been controversial debate regarding the effects of TRIPS on less developed countries, India displays the possibility that such nations can benefit from the international agreement if the right policies and laws are implemented.

(a) History of the Patent System in India

Protectionism has shaped the patent legislation in India. Before gaining independence in 1947, India was an English Colony that held patent laws based upon those of England. The first act relating to patent rights passed in 1856 was replaced by the Indian Patents and Design Act of 1911 when the newly independent nation sought to revamp the inherited British system to bring it into alignment with its rapidly transforming and dynamic industrial economy. During that time, the system was being exploited by foreigners to achieve monopolistic control over the market in vital industries like pharmaceuticals. Indian drug prices were among the highest in the world and arguably unaffordable to the general populace. In a bid to reduce foreign control and to protect national interests, the Patents Act of 1970 (“the Act”) was passed by the Indian parliament. Ironically, it is essentially "a copy of the English Patent Act of 1949" with much less patent protection.

The objectives of the Act were to spur the development of a strong domestic pharmaceutical industry and to ensure the provision of affordable medicine for Indian consumers. Under the Act, India only recognized process patents over a 7-year period and deliberately disallowed product patents to prevent monopoly control of items like medicine. India found that the share of multinational pharmaceutical firms gradually declined to about 40% in 1999 and Indian companies eventually gained 85% percent of the bulk drugs market. In addition, policies consistent with

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106 Ibid,508


108 Pradeep Agrawal and P. Saibaba, “TRIPS and India’s Pharmaceutical Industry” 36 Economic and Political Weekly 3787, 3787

109 Drug resistance, patent resistance: Indian pharmaceuticals and the impact of a new patent regime, M. Halliburton a
the Act’s objectives were introduced, including drug price controls, restrictions on capacity expansion and limits on multinational equity shares that have both kept pharmaceutical prices low and encouraged the development of the Indian pharmaceutical industry.

While pharmaceuticals themselves could not be patented, the process patents covering methods of their manufacture allowed for ‘reverse engineering’ by Indian companies where they could reproduce and market newly invented drugs in the Indian market through different production processes at only a small fraction of cost of patented drugs in developed countries. Since then, many Indian drug companies have emerged as leaders in the pharmaceutical industry because of their low costs. The price controls imposed by the government and stiff competition between Indian pharmaceutical firms offered medicine at low prices, benefiting the locals, especially the poorer sections of the society.

However, the liberalization era in 1991 affected the Indian pharmaceutical industry and led to the introduction of the ‘New Drug Policy’ that progressively reduced drugs under price control in 1994. Around the same time, India also signed TRIPs and was subjected to the minimum standards regarding patents for pharmaceuticals. India introduced the Patents (Amendment) Act 1999, which paved the way for stronger patent rights in the country. Under TRIPS, the patent term increased to 20 years and patent owners are granted the exclusive right to prevent others from making, using, selling or importing the invented product or process in India.

In keeping with its commitments under TRIPs, a new set of provisions have been added to permit pre-market testing of generics during the patent term to enable them to be marketed immediately upon expiration of the patent. This pro-patent shift culminated in India's accession to the Paris Convention and its subsidiary, the Patent Cooperation Treaty in December 1998. Finally, product patents were introduced for pharmaceuticals under the enactment of the Patents (Third Amendment) Act, 2005. The amendments included a statement omitting the use of ‘reverse engineering’ and

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110 Agrawal, see note 108 above, 3787-3788
112 Sudip Chaudhuri, “TRIPS Agreement and Amendment of Patents Act in India” (2002) 37 Economic and Political Weekly 3354, 3357
Indian firms could no longer survive on that basis and the pharmaceutical industry once again began to face competition from multinational corporations.\(^{113}\)

To restrict the number and type of pharmaceutical patents, India introduced Section 3(d), which prohibits patents on variants of existing compounds that do not show enhanced efficacy. Despite being extremely contentious as the transnational pharmaceutical industry and the US-India Business Council regard it as establishing an unacceptably high barrier to patenting, this section is defended by many observers, including the United Nations Programme on HIV/AIDS on the grounds that it displays India as a model for developing countries attempting to use TRIPS flexibilities to promote public health.\(^{114}\)

(b) Fighting Patent Wars: The Success Story India’s Pharmaceutical Industry

Over the years, the Indian pharmaceutical sector has witnessed rapid growth and transformation to a point where it is now the world’s largest producer of formulations in terms of volume and one of the world’s largest producers of bulk drugs. Its commendable 17% annual growth rate\(^{115}\) can be attributed to the flexible provisions of the 2005 Patent Act and other supportive policies of the government that have played an instrumental role in the development of the industry.

Up until the 1970s, India’s pharmaceuticals were mainly supplied by large international corporations. However, the sector’s growth was built upon the production of cheap bulk drugs by the state-owned companies under the assistance of the WHO. The decline of state-run companies began in the 1980s because of increasing central government bureaucracy and insufficient corporate governance. Today, no entirely state-owned pharmaceutical companies exist. By contrast, the weakening of the patent system and numerous protectionist measures sped up the development of a major national pharmaceutical industry on a private sector basis,

\(^{113}\) William O. Duperon, “Global Competition Versus Regional Interests: FDI and Pharmaceuticals in India” (2010) 5 Journal of International Commercial Law and Technology 181 - 200


making it possible to provide the population with a large number of drugs.

Previously dominated by multinational subsidiaries, Indian-owned firms become leading players and major exporters by 2001, gaining international recognition as a manufacturer of pharmaceuticals. 116 Between 1996 and 2006, nominal sales of pharmaceuticals were up 9% per annum and expanded much faster than the global pharmaceutical market as a whole.117 Since the end of the 1980s, India has been exporting more pharmaceuticals than it imports. Over the last 10 years, the export surplus widened to EUR 2 billion and will likely continue to rise further in the coming years.118 As production location, the country is benefiting from its wage cost advantages over western competitors when it comes to producing medicines.

The wave of globalization and the liberalization policy of the government have opened up new opportunities for the industry and large numbers of firms are also competing at the global level. Pharmaceutical exports are destined for around 175 countries, which include the lower regulated markets of Sri Lanka and African countries.119 However, the bulk of India’s export of pharmaceutical products are however, destined toward the US and other European nations. This shows the relative strength of Indian pharmaceutical firms in producing high quality generic products.

Legal changes in India made it considerably more difficult to produce generic versions of drugs. Indian companies can no longer simply copy medicines with foreign patents by using alternative manufacturing processes and offer them on the domestic market. A reorientation in India’s pharmaceutical industry has seen a shift towards a focus on drugs developed in-house and contract research or production for western drug makers. India took advantage of the compulsory licensing flexibility in TRIPS to ameliorate potentially negative effects that pharmaceutical patents might

117 Ibid, 287
have on the supply of medicines. Domestic companies began producing imitations of patented products and could eventually formulate better processes for the same product. However, compulsory licensing potentially discourages commercial R&D necessary to develop new drugs to fight global epidemic and can also be used to seek price levels below what a given national market is capable of supporting. In this way, it further concentrates the burden of financing pharmaceutical innovation on developed country consumers and discourages the development of drugs targeted at the disease burdens of countries using such licenses.

Essentially, India uses patents to develop commercial pharmaceutical industries that produce products directed at local diseases and available at price that patients in those countries can afford. These efforts are supported by foundations and non-profit organizations such as the Bill and Melinda Gates Foundation and One World Health and highly suggest that developing countries have the capacity to build research-intensive pharmaceutical industries capable of operating profitably in the conditions of the local market. However, for such local industries to take root and grow, effective patent protection must be made available, the commercialization of publicly funded research must be encouraged, and compulsory licensing must be kept to a minimum.

Life-saving drugs demonstrate incredible medical advances that can be achieved through R&D. As such, they do not come cheaply and are often unaffordable to patients as pharmaceutical companies expect high returns from their successful drugs and rely on profits generated through patents to recoup the sunk costs of R&D.

In an effort to make essential medicines more affordable to the people, India has worked within its domestic patent laws to mount oppositions to patent applications by pharmaceutical giants. Advocates such as the Indian Network for People Living With HIV/AIDS and UNITAID have also sought to negotiate lower prices for ARVs. Yet, despite these achievements, medications remain out of financial reach to those who need them most. Although the effects of pharmaceutical patents under

120 Sampat, see note 114 above, 414
TRIPS cannot be fully prevented, it is possible to press for a judicious application of the new laws with public health priorities in mind.

**Decisions by the Indian Courts**

Recent rulings by Indian Courts have changed the rules of the game, forcing several pharmaceutical giants to put health interests before profits. India previously did not award any patents at all and gave generic drug companies free licenses to copy essential drugs at affordable prices. However, the enforcement of TRIPS effectively handed multinational companies patents in all markets. Yet, numerous western pharmaceutical companies have struggled to patent their drugs in India and have vigorously argued against the decisions of Indian courts.

The Novartis Case:

The Glivec case raises important issues that are essential to the future of intellectual property law and the innovative pharmaceutical business in India. After a tedious 6-year battle, the Indian Supreme Court ruled against Swiss pharmaceutical giant Novartis and decided that its altered leukaemia drug, Glivec, did not deserve a new patent. It was found to be a clear case of “evergreening” by Novartis, a process whereby the company makes minor alterations to existing drugs in order to secure a new patent and to extend its monopoly. The engagement in this process is a global trend as several pharmaceutical companies argue that without recognition of incremental innovation, pharmaceutical companies will lose the incentive to invest in R&D of patented drugs and that patients will be denied new and better medicines. Although breakthrough innovations are important, they are rare and hence, it is through incremental innovations that many important advances are made.

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Incremental innovation is seen as a major means for improving medicines in the industry as it provides benefits beyond enhanced efficacy in terms of patient safety and compliance, manufacturing efficacy, product stability during storage and transport and new formulations of the product aimed at specific patient groups. On the other hand, compulsory licenses withdraw a patent from a drug company if it is deemed prohibitively expensive to a domestic market and a vital public health need.

Additionally, it is argued that without strong patent protection, the Indian pharmaceutical industry will be unable to transform from a generic leader into an innovator.

Novartis India’s managing director Ranjit Shahani argued that the decision discourages innovative drug discovery essential to advancing medical science for patients and is a setback for patients. John Castellani, chief executive of US trade organisation PhRMA, also expressed his dismay as he felt that the protection of intellectual property is fundamental to the discovery of new medicines. He opined that it is critically important that India promote a policy environment that supports continued R&D of new medicines for the health of patients locally and globally, in order to solve the real health challenges. On the other hand, the decision is welcomed by humanitarian organisations like Médicins Sans Frontières (MSF), which said that the decision is a ‘major victory’ for patient access to affordable medicines.

The ability to rely on patents in India benefits government, industry and patients alike because research-based organizations will know if investing in the development of better medicines for patients in India is a viable and sustainable long-term option. For pharmaceutical companies, the real issue is the R&D costs associated with drug creation. Novartis stated that "only one out of 10,000 experimental compounds in development will reach the marketplace". Thus each successful product needs to cover the costs used to make the other failed products. Without patents, investment

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127 Ibid, 163
129 Ibid.
130 Bhaven N. Sampat, “Academic Patents and Access to medicines in Developing Countries” (2009) 99 Health Policy and Ethics 9, 12
in R&D will plummet as foreign investors are less attracted to invest in an environment where they will not be able to recover their losses in. Simply put, weak patent protection leads to insufficient discoveries of new medicines and the lack of new generics for untreated diseases.

As mentioned, Section 3(d) of the Act, which bars patents on drugs that are not deemed to be sufficiently novel, is at the heart of discussions questioning India’s compliance with TRIPS. Due to its vague and potentially limited meaning, pharmaceutical companies like Novartis rely on this section to challenge the rejection of its patent applications by Indian Courts by arguing that it is contrary to both Indian law and TRIPS standards. According to this provision, a known drug cannot be patented unless the ‘known efficacy’ for a substance has been enhanced.\(^{131}\) However, the Act does not provide any test or guidelines for determining this enhanced efficacy. One of the primary purposes was for preventing evergreening of a patent. India has used the “enhanced efficacy” concept to differentiate genuine innovation from evergreening. Despite strong arguments against India’s current interpretation of section 3(d), India’s treatment of patent applications is unlikely to change unless Switzerland complains successfully to the WTO.

Pharmaceutical patent advocates argue that the outcome of the case will not hinder the supply of essential medicines because of the presence of safeguards in TRIPS. Although the Novartis case does not challenge these safeguards, pharmaceutical companies claim that even with those safeguards in place and 98% of the WHO essential drugs available at off-patent prices, more than a third of the world population still lacks access due to political, economic and logistical barriers.\(^{132}\)

Furthermore, currently available generic drugs launched in India before 2005 such as generic versions of Glivec will continue to be available regardless of the legal outcome of the case. Novartis strongly supports the contribution of generics to


improving public health once drug patents expire, but also recognizes that many patients need further assistance to gain access to the medicines they need. It has set up the Glivec International Patient Assistance Program (“GIPAP”) that is currently helping more than 31,000 patients in 80 countries and more than 16,000 patients in India receive Glivec free of charge. Since it began in 2002, more than 37,000 patients have been helped through GIPAP. Novartis has also designed an expanded new access program, Novartis Oncology Access (NOA) that provides access to eligible Glivec patients in India.

India has revoked, or denied in one form or another, multiple drug patents, which lets Indian companies produce cheaper, generic versions for sale in the South Asian nation. While many of these brand-name drugs would be too expensive to sell in big numbers in a developing country such as India, pharmaceutical companies and US officials say they never could have been developed without American investment and research. Given India’s role as an economic leader among emerging countries, there is concern that India’s strict patent policies may have a spillover effect to other countries. India’s approach, while lucrative for some of its big businesses, may end up doing more harm than good to its people and its overall economy. Foreign investment is beginning to dry up as seen through the drop in foreign direct investment from $35 billion in 2011 to $22.4 billion in 2013.

However, it is unlikely that the Novartis decision will curb investment in India. Firstly, firms have approached India with caution since the 1970s and although the recent Novartis case justifies such cautious attitudes, it also signals to firms the direction in which India plans to take its new patent law. With this knowledge, pharmaceutical companies will be able to tailor their investments to maximize the benefit they can extract from India while minimizing their risk.

It is important to view India in the context of its past patent history. When the Indian Patent Act was amended in 1970, many foreign companies left due to the lack of

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134 Ibid, 755

patent protection. Following the 2005 changes to patent law, companies are once again considering India as a viable option for investment. Although the Novartis case have kept investors cautious, many drug makers have formed research-based partnerships with Indian companies. For instance, the pharmaceutical giant, GlaxoSmithKline has recently teamed up with a local Indian company Ranbaxy to conduct early-stage drug development.\textsuperscript{136} In fact, GSK has consistently increased the number of clinical studies it has conducted in India, going from 3 leading up to 2005 to sixteen in 2006, to approximately 31 in 2007.

India’s workforce is perhaps its greatest asset in attracting foreign pharmaceutical investment. It has a large number of English speaking engineers and scientists who are willing to work for relatively low wages. Also, investors can look into India’s thriving generics industry to provide well-educated workers with highly relevant experience. The new patent laws will encourage firms to utilize India’s educated workforce as the skills and process knowledge required is directly applicable to the discovery process.

The Novartis case presented the Indian Court with an opportunity to defy the cultural and political trends toward weak patent protection. Instead of paving the way for a new era of strong patent protection, the Court maintained the Indian tradition of protectionism. Despite the controversy surrounding section 3(d), it is unlikely that the WTO would find India in violation of TRIPS because of the wide discretion given to member countries by the language of TRIPS.

(c) Bending the Rules: Making the Best of TRIPS Flexibilities

In March 2012, India’s Intellectual Property Appellate Board upheld the country’s first compulsory license to an Indian generic drug manufacturer, Natco Pharma Ltd., to make cheaper versions of German pharmaceutical company Bayer Corporation’s drug, Nexavar.\textsuperscript{137} Seeing that Bayer took no adequate or reasonable steps to the drug accessible the Indian people, Natco applied for a compulsory license. Bayer argued

\textsuperscript{136} Ruth Gana, “Prospects for Developing Countries Under the TRIPS Agreement” (1996) 29 Vanderbilt Journal of Transnational Law 735.

that it could not maximize the distribution of the drug in the country as another pharmaceutical company, Cipla, is selling a similar drug. According to the decision, Natco must pay a quarterly royalty at 6% of the net sales of the drug, lower than Bayer’s asking royalty of 15% of net sales. The royalty of 6% is in line with the United Nations Development Program recommendation of a 4% royalty. Under the terms of the compulsory license, Natco shall provide the drug for free to at least 600 needy and deserving patients every year, sell the drug at no more than 8,880 Indian rupees (US$178) for 120 tablets and is prohibited from outsourcing the manufacturing of the drug. MSF opines that the ruling ends Bayer’s monopoly in India on the drug and could set precedent for making more expensive patented drugs available for compulsory licensing. This incidence offers hope to the possibility of patented new drugs being produced by generic makers at a fraction of the original price with royalties being paid to the patent holder. This compensates patent holders while at the same time ensures that competition can bring down prices.

Another health concern in India is that drug companies in the West have no incentive to develop treatments for many of the health problems that affect India. Diseases like malaria and leprosy are not major concerns in the West, so pharmaceutical companies lack an incentive to research possible cures. If a Western drug company does not invent a treatment, Indian companies, while adept at copying, will not have the capability to invent the drugs.

Indian pharmaceutical companies have begun trying to build technology muscle. A prime example is Ranbaxy Lab Incorporated which signed a $90 million joint venture with Eli Lilly & Co. to collaborate for drug research and development. In recognizing the problems with its patent system, India is attempting to modernize and join the developed world.

Other signs of change can be observed from the establishment of an aggressive program to commercialize the research of the scientists working in its laboratories by

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138 Ibid.
the Indian Council for Scientific and Industrial Research (CSIR).\footnote{Barnes, see note 139 above, 922-923} This program involves identifying useful inventions and patenting them not only in India, but in big markets like the United States as well. From 1991 to 2002, CISR received a substantial increase in the number of patents from the United States Patent & Trademark Office.\footnote{Ibid.} Many of these patents involve pharmaceutical products arising out of research based on traditional knowledge and the local ecosystem of India. One of the most successful examples is Asmon, a polyherbal medication for the relief of bronchial asthma.\footnote{Alka Chadha, “TRIPS and Patenting Activity: Evidence from the Indian Pharmaceutical Industry” (2009) 26 Economic Modelling 499, 503.} The product is now on the market in India and is available to asthma sufferers in that country at a price they can afford.

2. Stepping up: Efforts by External Groups

**Indian Generic Manufacturers**

In addition to the pharmaceutical companies’ duty to supply, there is also hope that generic drug manufacturing companies in developing countries will assume some of this responsibility to supply essential medicines and will invest more in R&D instead of simple reverse engineering. This will allow developing country drug manufacturers to develop original low cost medicines on their own. Indian companies such as Cipla, one of India's largest generic drug manufacturers, has already begun assuming some of this responsibility by taking advantage of the fact that they are able to make a variety of different drugs from many competing pharmaceutical companies.\footnote{David R. Downes “How Intellectual Property Could be a Tool to Protect Traditional Knowledge” (2000) 25 Columbia Journal of Environmental Law 253, 277.} These companies combine various ARVs into a one-a-day, easy-to-take fixed dose combinations that would be very difficult to manufacture in developed countries due to patent protection, but that are essential to HIV-AIDS treatment in developing countries due to their simplicity. Therefore, such efforts have significantly improved the access to essential medicines in developing countries to individuals suffering from HIV-AIDS.
Cipla has also cut the price on its cancer medicines by up to 75%, a move likely to further complicate efforts by big Western pharmaceutical companies seeking to develop their businesses in India.\(^{145}\) Its decision to slash prices comes only weeks after India's patent authority forced Germany's Bayer AG to grant a license to another Indian generic drug producer for its kidney and liver cancer medicine, Nexavar.

As compared to Bayer's patented Nexavar at 280,000 rupees (US$5,234) a month, Cipla is offering its generic version at a much cheaper price of 6,840 rupees (US$128) a month.\(^{146}\) Y. K. Hamied, Cipla's chairman and managing director, cast the move as an attempt to bring cheap cancer medicines to the world, just as the company became a champion of HIV patients in Africa a decade ago by using its cheaper manufacturing base to sell AIDS drugs at a deep discount.\(^{147}\)

Foreign companies are likely to be concerned that medicine prices could fall further in India if patent offices and local courts continue to challenge patents recognized elsewhere. Other countries in the past have forced foreign drug companies to issue licenses for drugs patented elsewhere. In 2007, Thailand revoked a patent for U.S. firm Abbott Laboratories blockbuster AIDS medicine to allow generic producers to make cheaper versions.\(^{148}\)

Big pharmaceutical companies want to sell in India, a country of 1.2 billion people with an economy growing at over 6% per year. But these companies argue that – unlike generics producers, who typically copy drugs that come off patent – they need intellectual-property protection to fund the high cost of research. The drug industry says new medicines can take a decade and cost more than $1 billion to develop.\(^{149}\)


\(^{147}\) Journeyman Pictures, Patents and Patients – India, (3 January 2008) <http://www.youtube.com/watch?v=dyvojfrfYnrI> at 15 September

\(^{148}\) Jena, see note 146 above, 339

Richard Bergstrom, director general of the European Federation of Pharmaceutical Industries and Associations, said that compulsory licenses should only be the ‘last resort’ and that India should seek other ways to work with foreign companies to get the drug to poor people. Many foreign producers have pushed tiered-pricing, in which they offer the drug at different costs depending on a country's level of development.

India has declined to defend patents on a number of occasions previously, contending that the Indian system fosters a competitive environment that keeps prices low so that the country's vast and mostly poor population can afford medicines.

3. Other developments: South Africa and Brazil

South Africa: The trade dispute in South Africa in 1998 is a matter that has shaped the debate on TRIPS and access to medicines. In that case, the South African Pharmaceutical Manufacturers Association and 40 mostly multinational pharmaceutical manufacturers, brought a suit against the government of South Africa, alleging that the Medicines and Related Substances Control Amendment Act No. 90 of 1997 violated TRIPS and the South African constitution.

The Amendment Act introduces a legal framework to increase the availability of affordable medicines in South Africa and includes provisions regarding the generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines.

The United States, where Big Pharma is from, had put pressure on South Africa by withholding trade benefits and threatening further trade sanctions, aiming to force the South African government to repeal the amendments. Outrage and strong demands from demonstrators and several governments around the world caused the pharmaceutical companies involved to withdraw from the case. The case brought out

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two key issues into the international arena.  

Firstly, the interpretation of the flexibilities in TRIPS and their use for public health purposes needed clarification to ensure that developing countries could use its provisions without the threat of legal or political challenge. Secondly, it became clear that industrialized countries that exercised trade pressures to defend the interest of their multinational industries could no longer exert pressure without repercussions from the wider international community.

Brazil: Since the 1990s, Brazil has offered comprehensive AIDS case, including universal access to AVR treatment. On an estimate, it is purported that close to 600,000 people are suffering from HIV in Brazil but only half of the cases are reported to the Ministry of Health. Brazil has set up the Brazilian AIDS programme that has assisted in reducing AIDS-related mortality by more than 50% and the country has also saved US$472 million in hospital and treatment costs under this initiative.

At the core of the success of this programme is Brazil’s ability to produce medicines locally, just like India. It has also managed to negotiate lower prices for patented drugs by using the threat of production under a compulsory license as allowed for under Article 68 of the Brazilian patent law. However, the US took action against Brazil at the WTO Dispute Settlement Body over Article 68 and argued that the Brazilian law discriminated against the US owners of Brazilian patents, that it curtailed patent holders’ rights and violated certain articles in TRIPS. The US action came under fierce pressure from the international Non-Governmental Organisation (“NGO”) community. Brazil has been vocal internationally in the debates on access to medicines and has offered support to developing countries to help them increase manufacturing capacity by the transfer of technology and knowledge. Hence, the NGO community feared that the US action would have a

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152 Ibid, 42
155 Ibid.
detrimental effect on Brazil’s successful AIDS programme and that this would in turn negatively impact on other countries that receive assistance from Brazil.

The Brazilian AIDS programme serves as a model for some developing countries for the production of generic ARV drugs. In addition to the success story of India, it is also shown that other developing countries like Brazil do not have to bear the brunt of strong patent protection under international agreements. It is possible for them to benefit from the changes in the international landscape and at the same time, offer a helping hand to other developing countries in adapting to the changing environment.

8. Actions of Global Players

Many international institutions and UN agencies have also contributed to the debate on the access to medicines and looked into the consequences of stronger intellectual property protection as a result of TRIPS for developing countries.

The public health community first raised concerns about the consequences of globalization and international trade agreements with respect to drug access during the 1996 World Health Assembly. A resolution on the Revised Drug Strategy (RDS), which set out the World Health Organization (“WHO”) medicines policy requested the WHO to report on the actions of the WTO with respect to national drug policies and essential drugs.156 The resolution gave the WHO the mandate to publish the first guide with recommendations to Member States for implementing TRIPS while limiting the negative effects of higher patent protection on drug availability.

At that time, the WHO’s involvement in trade issues was highly controversial. The emphasis on public health needs over trade interests was seen as a threat to the commercial sector of the industrialized world. However, the US and some European countries unsuccessfully pressured the WHO in an attempt to prevent the publication of the guide.157 The WHO subsequently adopted two resolutions that addressed the need to strengthen policies to increase the availability of generic drugs and the need to evaluate the impact of TRIPS on access to drugs. At present, the WHO’s work


programme on pharmaceuticals and trade includes provisions of policy guidance and
information on intellectual property and health to countries for monitoring and
analyzing the effects of TRIPS.

In 2001, the EU also adopted the Programme for Action, which accelerates action on
diseases such as HIV/AIDS and malaria in the context of poverty reduction. The EU
programme recognized the potential problem of TRIPS and the need to rebalance its
priorities with a shift towards a more pro-public health approach to TRIPS.\textsuperscript{158} In
acknowledging the concerns of developing countries, European company, DG Trade
dropped its objections to the use of compulsory licensing to overcome patent barriers
to medicine access and became an advocate for a global tiered pricing system for
pharmaceuticals.

\textbf{PART V: ADVOCATING A MULTI-LAYERED SYSTEM}

A potential and viable solution to attaining harmonization between the
pharmaceutical industry and the public health request exists as shown by success
stories of developing countries like India in adapting to strong patent protection
requirements under TRIPS. Despite controversial arguments against pharmaceutical
patents, there is an intricate connection between the promotion of public health and
promotion of pharmaceutical inventions. Patents are a critical component in the
development of new drugs for treatment of the world’s health as they provide great
incentives to the pharmaceutical industry to engage in R&D and production of new
medicines. However, it is necessary to take measures to prevent the abuse of patent
protection by pharmaceutical companies that attempt to secure a monopoly and set
drug prices at a level that is way out of reach of patients.

A balance between medical innovation and public affordability can be achieved
through the development of realistic and practical solutions offered by both the
pharmaceutical industry and public interest groups. This calls for the development of
a multi-layered system that may include stricter patent approval procedures, the use
of patent pools, more extensive use of TRIPS flexibilities such as compulsory
licensing, the promotion of regionally produced drugs and state compensation from

\textsuperscript{158} Tvedt, Morten Walloe, “One Worldwide Patent System: What’s in it for Developing Countries?”
developing countries to medical companies in developed countries. The effectiveness of some of these components has already been assessed in earlier parts of the paper and they have shown to produce positive results in the real world. It is necessary to further promote these existing efforts and to inculcate new ones on a broader and more comprehensive scale in order to solve the lack of access problem that is plaguing the world.

TRIPS has significantly shaped the landscape for pharmaceutical patents and made great impact upon the availability of affordable medicines that has threatened a possible violation of the right to health. It is important that the open-textured language of the provisions is interpreted in a manner that reflects the need to place the public interests ahead of the economic pursuits of pharmaceutical companies.\textsuperscript{159} A proper treaty interpretation helps by possibly eliminating reducing or providing mechanisms to resolve seeming conflict between them.

Like India, many developing countries possess the capacity and capabilities to build robust and profitable pharmaceutical industries that provide products directed to the diseases common to their own nationals and that can be supported by the local market. However, for such local industries to be established, it is imperative to have effective patent protection, the commercialization of publicly funded research, and the minimal use compulsory licensing. This development process can be assisted by wealthy developed through subsidies on the local markets for the purchase of drugs through the Global Fund and other direct assistance programmes.\textsuperscript{160} Consumers in all countries can then share the burden of drug development equitably and pay for medicine at a price level that is within their means.

The future the role of public agencies and private players in delivering healthcare should also be defined more clearly. Pharmaceutical companies can take steps to alter their policies or adopt a more accommodating system towards public affordability whereby a sustainable profit-making business may co-exist with the

\textsuperscript{159} Alan O. Sykes, “TRIPS, Pharmaceuticals, Developing Countries and the Doha “Solution” (2002) 3 Chicago Journal of International Law 47, 76

effective and affordable provision of medicines to the poor. To ensure sustainable success, corporate responsibility activities have to be professionally managed, with clearly defined objectives, cost-effectiveness, performance monitoring and accountability, as well as transparent communication.\(^{161}\)

There is presently insufficient research done for the development of medicines needed to treat tropical diseases due to the lack of incentives for pharmaceutical companies. In order to increase the strength of these incentives, action by the local governments and pharmaceutical companies themselves, are crucial. Firstly, there should be a uniform public policy that recognizes the need for drug discovery along with modification of anti-trust laws that impede collaboration between the US companies. Instead, companies should be encouraged to work together on humanitarian projects. Last summer, the Director General of WHO spoke at a Conference on Pharmaceuticals for Developing Countries and encouraged the pharmaceutical industry to focus more attention on the development of drugs for diseases of developing nations.

Developing and delivering appropriate, affordable, well-adapted medicines remains an urgent challenge but there have been significant developments by public interest groups to counter the effects of strong patent protection. In July 2008, the UNITAID Executive Board approved the plan to create a patent pool to increase the access to more appropriate and affordable medicines to patients in developing countries. The pool is intended to avert a ‘tragedy of the anti-commons’ in which people are unable to make use of knowledge because of the tangle of property rights that can block them.\(^{162}\)

The Patent Pool Initiative established by UNITAID is the first medicines patent pool and it aims to help solve world health problems through an innovative initiative for the collective management of intellectual property rights by establishing a patent pool for HIV medicines. The idea behind a patent pool is to facilitate the availability

\(^{161}\) Anant Patil and Viraj Rajadhyaksha, “Evolving role of pharmaceutical physicians in the industry: Indian perspective” (2012) 3 Perspectives in Clinical Resolution 35

of new technologies by making patents and other forms of intellectual property of pharmaceutical companies and governments. These bodies voluntarily offer the intellectual property related to their inventions to the patent pool and any company that wants to use the property to produce or develop medicines for developing countries can seek a license from the pool and pay royalties to produce medicines for developing countries listed by the World Bank. The success of the patent pool largely depends on the willingness of pharmaceutical companies to participate and commit their intellectual property to the pool.

The pool will help to speed up the availability of lower priced, newer medicines because there will be no need to wait out the patent term of 20 years, a substantial period of time that patients cannot afford to lose. In exchange for the payment of royalties to the patent owners through the pool, any producer would be allowed to manufacture the patented medicines and sell them in countries well before the expiration of the patent term. With licenses covering both low and middle-income countries, the geographical scope of the market would be attractively large, thereby encouraging multiple generic producers to come forward and access the patents. In order to maintain competitiveness, producers will reduce the prices of medicines, making them more affordable to the people.

The pool has the potential to provide benefits not only to pharmaceutical companies when they are rewarded for their investments into R&D but also to generic companies are able to access the intellectual property more easily and quickly and patients in developing countries get faster access to better and more affordable treatments. Gilead is the first pharmaceutical company to agree to put specific drug patents in the pool. This will allow generic companies in India to make cheap copies of them for use in poor countries with major Aids epidemics. Even more importantly, the generics companies will also be allowed to make combinations of drugs from different companies. Mohga Kamal-Yanni, Oxfam senior health policy adviser, urged other companies to follow Gilead into the pool and that those that

163 Ibid.
have not done so should be ‘ashamed of themselves’.\textsuperscript{166} His strong tone suggests the severity of world health problems and the belief that pharmaceutical companies have the power to change the circumstances.

Aside from these efforts, it has been shown that the flexibilities in TRIPS do stand as sufficient safeguards against the brunt of strong patent protection for developing countries. Developing countries like India have taken advantage of compulsory licensing in establishing its growing pharmaceutical industry. It is a successful example of a developing country that has sculpted its domestic patent laws in a manner that is in compliance with TRIPS requirements while maintaining its national interests as top priority. The recent court ruling reflects India’s continuing protectionist nature and the flexibility in interpretation of international agreements display the nation’s desire to advance internationally. In rejecting several patent applications by pharmaceutical companies so as to protect its own domestic industry, India has emerged as a power not to be trifled with. This suggests that with the right actions taken by the government and the right laws in place, other developing countries can also reap the benefits of a flourishing pharmaceutical industry. Cooperating with developed countries would help to create patent-protection systems that would fulfill both nations' demands in protecting intellectual properties and fostering techno-economic growth.

Other options for accessing less expensive supply include trying to access differential prices of the originator’s product through ‘access’ programmes, pooling demand for bulk purchasing, tapping in to less expensive sources of the originator’s product through parallel importing, issuing a TRIPS compliant compulsory license, or in eligible countries, ensuring that domestic legislation allows the country to take advantage of the TRIPS extension for least developed countries until 2016.

Developing countries should view the patent-protection system as a tool for economic development. If a developing country does not have the capabilities to develop an industry for pharmaceuticals, it can still diminish the impacts of strong patent protection by formulating more efficient local laws and policies that target specific groups of people or the government can seek to collaborate with pharmaceutical companies and public interest groups to improve the provision of

\textsuperscript{166} Ibid.
affordable medicines. The incorporation of new rules and regulations of TRIPS into the national patent systems of developing countries could be the initial step toward reforming patent protection systems. National leaders from developing countries should set up a committee for analyzing the pros and cons of reforming patent protection systems, and then move toward restructuring those systems to promote further development in their growing economies.\textsuperscript{167}

Initially, it may be costly initially for developing countries to adopt such a system but this should be offset with the possibility of long-term economic growth. With stronger patent protection systems in place, developing countries can assure appropriate rewards for pharmaceutical companies and help them invest into the local technological market. It may also help to generate an increased flow of FDI and R&D investments into developing country markets. Therefore, developing countries should reform their patent protection structures for their own technological and economic development.

CONCLUSION

In the past 60 years, innovation and technology have driven huge improvements in global health. Growth in life expectancy that took over 300 years to achieve in developed countries has been secured by developing countries in just half a century, thanks largely to innovations in medicine and other public health interventions. Intellectual property has played a key role in this progress.

This paper points out that patents on pharmaceuticals are a necessary “evil” for the development of new and improved medicines to treat the world’s health. In line with the historical notions on the justification of intellectual property, the drive to innovate is closely determined by the strength of protection offered by patents. Without the exclusivity and assurance, not only are inventors less willing to expend time and effort into discovering and creating new drugs, investors are also less inclined to pump substantial capital into an environment where they do not foresee

any profits. This jeopardizes the well-being of future patients and the innovation process itself. Financial capital is a critical component in the pharmaceutical sector as a large amount of money is needed in the development of new medicines for both the employment of skilled individuals and the tedious R&D process. This in turn ensures that products churned out by pharmaceutical companies are of a high standard, which brings positive benefits to patients such as fewer side effects and more effective treatment of diseases.

With regards to the high prices on drugs set by pharmaceutical companies that has made essential medicines out of reach of the poor, it is not a matter that cannot be solved as seen from successful examples set by developing countries like India. Although it is arguable that India has the infrastructure to build a robust pharmaceutical industry that other developing countries do not, its success should primarily be credited to the effective policies and actions by the Indian government. Through its adherence to traditional values of protectionism, India has emerged as a country not to be trifled with. Instead of being resistant to change, the nation has adapted well and built upon changes in the international landscape to bring prosperity to its economy.

As such, it is observed that the main responsibility for ensuring public health lies with local governments and national institutions. Governments have the duty to respect, protect and fulfill the right to health of its people progressively, within their means. In order to adapt to the changes in the international environment regarding patent laws, governments should do their best to ensure availability, accessibility, acceptability and quality of health services. Such actions may include reforming current healthcare systems to positively impact the health of the poor and collaborating with pharmaceutical companies to ensure the affordable and effective provision of medicine on both a local and international scale.

At present, the lack of access to medicines issue suggests that the right to health is not being effectively fulfilled. The pharmaceutical industry has a special responsibility to contribute to improving access to medicines. The primary function of the research-based pharmaceutical corporations is to create value by discovering and producing effective medicines that improve patients’ well-being. It is necessary for the pharmaceutical industry to keep in mind these wise words:
“Essential medicines are not a luxury whose availability can be left to private market forces only, but an essential component of the fulfillment of the right to health”.

With this mentality in mind, pharmaceutical companies should take a different approach in their business models and put public interests before profits. Innovative alliances, financing mechanisms and cost-sharing models are essential to ensure that patients worldwide can access existing medicines. This can include applying differential pricing strategies and market segmentation to make medicines more affordable for those with low purchasing power, provided there is political safeguarding to prevent diversion of medicines to mature markets. In order to fully cater to the interests of the society, pharmaceutical companies should also direct focus towards developing treatments for neglected, poverty-related diseases, which they deem to have little prospect of being profitable. Through the responsible use of patents, it is possible for the pharmaceutical industry to make a vital contribution in ensuring broad access to existing life-saving medicines.

Development is a gradual process and it is not impossible. This essay puts forth the idea that medical innovation and public affordability can and should co-exist. With the right policies and laws in places, coupled with strong support from wealthy developing countries and pharmaceutical companies, the lack of access issue can be solved to a large extent.
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