PAMUN XVII RESEARCH REPORT— Measures setting limits to medical intellectual property

Introduction of Topic

With the advent of new technology and increased dependency on human creativity, intellectual property (IP) has become the driving force of modern societies. Progress has built its foundation upon the human intelligence and innovation, and it has become more evident that this trend will only continue in the coming years. Ergo, the United Nations finds the protection and encouragement of intellectual property crucial to our development, which is further stressed by Article 27 of the Universal Declaration of Human Rights (UDHR), which proclaims the right of the individuals to benefit from the scientific advancements and 'protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.'

Intellectual property in the field of medicine covers great extents: from pharmaceutical drugs to research and development, and biotechnology. It seeks to incentivize human creativity and innovation to foster greater progress in ensuring global health and wellness. However, limitations appear as we see that medical IPs have become commercial products heavily motivated by the demand of a selective group of people. Consequently, it is common that these medical products are often denied to populations in need.

Yet, the objective of this agency isn't to eradicate all intellectual property rights (IPR). UNESCO recognizes the crucial role that IP plays in various aspects of our society, one of many being the medical industry. Rather, it seeks to strike a balance between rewarding the achievements of the creators and ensuring public access to the necessary goods and services.

Definition of Key Terms

Intellectual Property (IP)

The World Intellectual Property Organization (WIPO) defines 'intellectual property' as "creations of the mind: inventions; literary and artistic works; and symbols, names and images used in commerce." It refers to products of human intelligence and innovation, whether it be an invention or process, whose author or creator may hold ownership of.

The WIPO divides intellectual property into several categories, the two main being industrial property and copyright. The former consists of patents, trademarks, industrial designs and geographical

indications while the latter covers literary works and artistic creations such as films, novels, paintings, music, drawings, etc.

Intellectual Property Rights (IPR)

As the word conveys, intellectual property rights are protections granted to creators or owners of an intellectual property from unfair competition such as exploitation or illegal copying and pirating of their work.

Medical intellectual property

Medical IPs indicate all IPs found in the field of medicines, such as pharmaceutical drugs, biotechnology, bioengineering, etc.

Patents

Patents are exclusive rights granted for an invention; however, the phrase ‘invention’ does not limit patentability to mere physical objects; instead, it can also apply to new technical processes. Patents grant the owner or creator with the control over the production, sale, distribution and consumption of his/her invention for a limited period, generally 20 years. Patents are registered by the national or regional patent offices – an international patent does not exist. Instead, one has to file for a patent to multiple offices of regions where they wish to acquire protection for their inventions.

Once a patent expires, the terms of protection are terminated and the invention goes off-patent, meaning that it is now a part of the public domain. The owners are no longer entitled to the rights that the patent previously conferred.

Trademarks

The World Intellectual Property Organization (WIPO) defines trademarks as ‘a distinct sign that identifies certain goods or services produced or provided by an individual or a company’. Trademarks help consumers identify goods or services with its source or quality. Unlike patents, the period of validity for trademarks varies and can be renewed.

Compulsory and Voluntary Licensing

Voluntary licenses are grants that the patent holder endows a third party with rights to produce or manufacture the patented good or process. The terms of the license is arranged between the patent holder and the contractor, who negotiate on how they would distribute the profits.

Compulsory licenses are grants issued by the government to allow a non-patent holder to produce the patented product. The TRIPS agreement (see under ‘Background Information’) permits this but only under certain circumstances. National or regional offices are allowed to issue compulsory licenses if ‘unsuccessful attempts have been made to acquire a voluntary license on reasonable

terms and conditions within a reasonable period of time'. For example, when the patent holder of a pharmaceutical drug refuses to put his/her product on the market, the patent offices can grant compulsory licenses to generic manufacturers to produce it at a cheap cost for the consumers. In exchange, the office would pay the patent holder a royalty free. Although compulsory licenses aren't permitted or legalized in some countries, this is often practiced by key industrialized countries, such as the United States.

Generic medicines

The word 'generic' is used to label a product that does not have a trademark. Generic medicines are copies of patented drugs. Manufacturers of generic medicines usually sell their goods under the name of the chemical ingredient or another brand name from the patented drug. Generic medicines are generally considered legal if they're made after the patent expires or when under certain circumstances such as voluntary or compulsory licenses. However, generic medicines are considered illegal if they are pirated or counterfeited products.

Research and Development (R&D) or Research and Technological Development (RTD)

Research and Development (R&D) refers to activities between corporate powers or governmental bodies to improve or innovate products and procedures.

Background Information

Brief History of IP & IPR

The origins of intellectual property traces back to Venice during the Renaissance of the 15th century. Despite its primitive nature, the Venetian Patent Statue of 1474 well incorporates the modern principles of intellectual property. Its objective was to attract inventors and discoverers to their economic hub by enticing them with protections – patents – for their 'new and ingenious devices.' The socioeconomic concept of intellectual property was later solidified with the Statue of Monopolies in 1624 and the Statue of Anne in 1710. The two statues are considered to be the very origins of patent and copyright laws.

Although with common purpose and intention, patent laws were initially limited to the sphere of national and regional laws. Technical differences in patent laws were observed across borders, partially owing to the diverse social, economic and political backgrounds. In extreme cases, certain countries denied the existence of intellectual property, such as the absolutist states who claimed government ownership over all individual properties. Nevertheless, with few exceptions, the consensus was that intellectual property rights indeed contributed to economic growth and technological advances. In fact, the United States included a clause recognizing intellectual property in its constitution of 1787 while France adopted its very first patent system during its Revolution in 1791. Eventually in the 1880s, patent and copyright laws were recognized internationally by the Paris Convention (1883) and the Berne Convention (1886), the underlying documents of the modern intellectual property rights.

As intellectual property evolved throughout the centuries, its domain expanded to various industries and commerce such as but not limited to engineering, art, literature, food, and – rather recently – medicine.

Medical IPR

Objectives

As outlined by the WIPO, intellectual property rights 'allow creators, or owners, of patents, trademarks or copyrighted works to benefit from their own work or investment in a creation.' (http://www.wipo.int/about-ip/en/) IPRs reap many benefits, one of which being that legal protection granted by IPRs encourages more resources to be invested for further innovation in the field of technology or art that it pertains to. For instance, the reward guaranteed by the protection of IPRs vitalizes the R&D in the medical industry. Moreover, consumers can be assured of the reliability of the medical products, such as drugs, through patents issued by the national or regional offices.

Patents

The main form of IP found in the medical industry is patents. Patents are often issued for new pharmaceutical drugs, medical engineering, and others.

In exchange for the guarantees of the patent, owners are obliged to disclose information on their inventions. They're held to provide a written description of the invention, and the manner and process of making and using it in clear terms that any individual skilled in the pertaining art may make and use the same methods. The purpose of this is to enhance the general knowledge of the industry that it pertains to.

International Agreement on Medical IP

Over the past few decades, several international treaties have been negotiated on the issue of medical intellectual property. These treaties established international minimum standards for patents, industrial designs, etc., in effort to maximize its benefits.

One of the most notable treaties on IP is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), administered by the World Trade Organization (WTO) in 1995. Its signatory states consist of all 162 members of the WTO. The agreement endorsed much of the content of the Paris and Berne Conventions and provided for enforcement mechanisms. It included key agreements such as national treatment, right of priority and most-favored nation treatment:

National treatment refers to the equal treatment of foreigners and locals in a territory or region. The TRIPS agreement bound its signatory states to guarantee protections granted by IPRs to its citizens and non-citizens alike.

The right of priority allows a patent applicant to efficiently apply for admission to various states and regions. Under the right of priority granted by Article 2 of the TRIPS agreement, the filing date of its very first submission, regardless of the office or governmental body, is to be considered as the submission date for all other patent bodies and thus hold priority over other applications.

Under the most-favored nation treatment, highlighted in Article 4 of the TRIPS agreement and several other trade-related treaties, countries cannot discriminate between their trading partners. With regard to protection of intellectual property, the TRIPS agreement holds its signatory states to give all other member states equal and unconditional advantage, favor, privilege or immunity in trade.

Prior to the TRIPS agreement, a diverse range of perception for 'patentability' existed between member states. It was a common case that pharmaceutical drugs weren't granted patents by the state legislatures who claimed the 'right of access' of its natives. The TRIPS agreement extended patentability to any types of inventions excluding three key types: inventions that are 'contrary to the public policy doctrine (*ordre public*) or morality of the group', diagnostic, therapeutic and surgical inventions, and biological processes for the production of plants and animals (further explored under 'main issues') The TRIPS agreement goes further to say that the moral grounds that a state can object to a patent by can only be based on health issues concerning the life of humans, animals or plants and the environment. They may not, however, object based on their regional or national laws.

However, as major health issues surrounding medical intellectual property became increasingly palpable, the debate on the overall impact of IPRs intensified. A negotiation was reached in the Doha Ministerial Conference (2001) hosted by the World Trade Organization (WTO). The Doha Declaration proclaimed that 'international trade rules could and should not undermine legitimate rights to countries to protect public health.', thus allowing some flexibility for governments in dealing with public health issues and medical IPRs.

Major Countries and Organizations Involved

World Intellectual Property Organization (WIPO)

The WIPO is a specialized agency of the United Nations who serves to promote activities related to intellectual property around the world. Created in 1974, it currently has 189 member states and is based in its headquarters in Geneva, Switzerland. The WIPO plays a key role in shaping international policies or agreements on IPRs to ensure remuneration of individual talent.

World Trade Organization (WTO)

The WTO is a branch of the United Nations that sets provisions on policies regarding world trade. It administered the TRIPS agreement and the Doha Declaration. The WTO is heavily involved in issues

surrounding medical IP, as it mainly concerns itself with harmonizing national or regional laws on industrial properties such as patents to facilitate trade. It seeks to uphold the rights of the creator or owner but also serves to ensure the basic human rights, such as access to medicine, of individuals are preserved.

World Health Organization (WHO)

The WHO is a specialized agency of the United Nations that works to promote international public health. Regarding the issue of medical IP, its main objective is to ensure that the principles of the Doha Conference are upheld. Currently, the WIPO, WTO, and WHO have formed a trilateral agreement to cohesively respond to issues surrounding medical IPs.

Pharmaceutical companies

The major pharmaceutical companies include Johnson & Johnson, Novartis, Roche, Pfizer, Sanofi, GlaxoSmithKline, etc. As R&D generally requires great amount of capital, it is often the case that these companies are the inventors and the owners of patents of new drugs and pharmaceutical products, thus allowing them to exert significant influence over the medical industry.

Timeline of Events

Date	Description of event
1474	Venetian Patent Statute
1624	Statue of Monopolies
1710	Statue of Anne
1883	Paris Convention for the Protection of Industrial Property
1886	Berne Convention for the Protection of Literary and Artistic Works
1970	Indian Patent Act
1977	Formation of the European Patent Office
January 1978	Patent Cooperation Treaty (PCT)
December 12th 1980	Bayh-Dole Act
January 1995	Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)
1998	Medicine Act of South Africa
November 2001	Doha Ministerial Conference
October 2004	Madrid Protocol for the International Registration of Marks

Relevant UN Treaties and Events

- Revised drug strategy, 24 May 1999, **(WHA52.19)**
- HIV/AIDS: confronting the epidemic, 20 May 2000, **(WHA53.14)**
- Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action, 27 May 2006, **(WHA59.24)**
- Intellectual property rights, innovation and public health, 28 May 2003 **(WHA59.26)**
- Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS, 22 May 2004 **(WHA57.14)**
- Global Strategy and plan of action on public health, innovation and Intellectual Property, 24 May 2008 **(WHA61.21)**

Main Issues

Despite its good intention to incentivize the market and push for further progress in its field, medical IPRs has frequently been the source of contention in the national, regional and international level. The side effects relating to global health, trade, economy, etc. has prompted concerns on the current institution of IPR laws.

Lack of access to medicine in developing countries due to high cost

The WHO deems the access to essential medicines as one of the fundamental human rights. However, in developing countries, a significant portion of the population do not have the necessary access to the drugs and medication whose high cost easily surpass their standard cost of living. These drugs are patented by pharmaceutical companies who own the exclusive rights over the production, sale and distribution of the drug, which greatly eliminates competition and naturally raises the price.

In developed countries where the demand meets the supply, a majority of the population have the access to these vital drugs. However in developing countries where demand is low due to several factors such as poverty, there is no incentive in the market, failing to stimulate the development and supply of goods. Consequently, the price of the drugs are high and in several cases, the patent holder is reluctant to sell his/her drugs in the developing regions, thus greatly restricting the access to medicine of many. As the World Health Organization reports, an estimated 1/3 of the global population are currently

deprived of regular access to essential drugs. Communicable diseases, such as HIV/AIDS, are rampant in LDCs due to the lack of antiretroviral medicines supplied to the population. In the poorest parts of Africa and Asia, the count may rise to over 50 percent.

Moreover, data collected over the decade reveals a global trend in rising health care costs. As key medical products such as drugs and medicine are subjected to extreme competition in modern societies' markets, healthcare becomes a rare commodity enjoyed by a limited number of people.

However, the high prices of medicine is not solely determined by its manufacturer. In many countries, implemented taxes or tariffs, port charges, importer's margin, and others adds significant additional cost to the basic prices of the drugs. A study in 2003 conducted by the European Commission found that countries that currently apply the highest tariffs are Nigeria, India, Pakistan and China where its markets and economy greatly profit from the locally produced generic medications.

10/90 gap

As a study from the Global Health Forum indicates, less than 10% of worldwide resources were used for research towards health in developing countries, where over 90% of preventable deaths worldwide occurred.

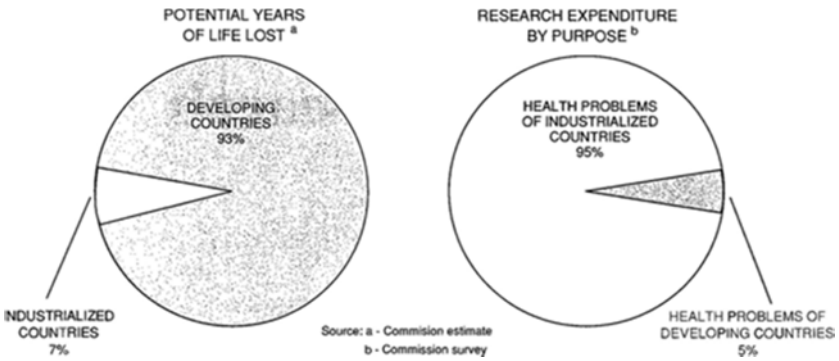


figure from the report of the Commission on Health Research for Development

As the chart on the left reveals, much of the capital invested in research purposes are dedicated to finding cures for 'health problems of industrialized countries', which is mismatched by the overwhelming years of life lost in the developing countries.

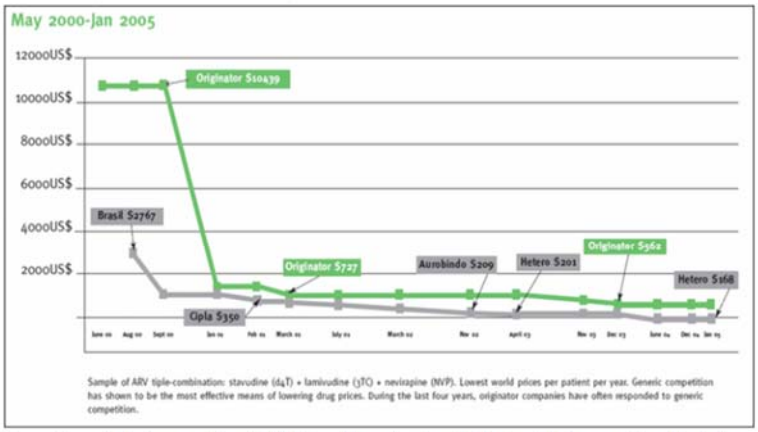
The discrepancy in the data is caused by the fact that when pharmaceutical companies invest in R&D of new drugs or medical products, they tend to target those with the purchase power, mainly found in developed countries.

Consequently, there is a significantly less research devoted to Neglected Tropical Diseases (NTD) such as malaria, tuberculosis and helminthiasis commonly found in developing countries. Instead,

much of the investments in R&D go to improving drugs treating diseases such as diabetes and cancer to target the buyers in Europe and United States. The drugs that reap high profit for the companies are known as “blockbuster drugs”. “Me-too” drugs are developed primarily for lifestyle and not predominating medical needs.

Generic medications and litigation issues

In order to reduce the costly price of the corporate drugs, countries often encourage local generic manufacturers to produce cheaper versions of the patented product. Either through permit from voluntary or compulsory license, generic manufacturers reduce the gap for access to medicine. It becomes the source of competition, significantly lowering the prices. For example, the cost of triple drug therapy for HIV/AIDS in the US developed by a drug corporation was $10,000 per patient per year, but when an Indian generic manufacturer offered the same therapy in February 2001, the cost lowered to $350 per patient per year. By January 2005, the lost was reduced to $168.



Source: Campaign for Access to Essential Medicines. Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries. 7th Edition. Geneva: Medicins sans Frontieres. 2005.

However legal clashes have often arose between pharmaceutical companies and these generic manufacturers on the grounds of IPRs. Although the TRIP agreement loosely provides for conditions when compulsory licenses are permitted, the terms are vague and patent laws also differ by countries or regions, making litigation on such issues even more complicated. While others argue that generic manufacturers provide people with the vital medicines, some refutes this by claiming that they are flagrant violations of patent laws and thus create unfair competition and deter progress and innovation. Moreover, it is often the case companies producing these generic medications aren’t strictly regulated and therefore sell substandard or counterfeited products to the public, engendering other health consequences.

Impact on biotechnological innovation

As previously mentioned under ‘background information’, the TRIPS agreement gives the member states the right to exclude patentability to certain products and technology. By Article 27 2&3 of the document, member states can refuse patents to: inventions that are contrary to their moral standards, ‘diagnostic, therapeutic and surgical methods for the treatment of humans or animals’, and ‘plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes’.

Essentially, while the TRIP allows exceptions to biological processes and innovations in production of plants and animals, the exception does not extend to cover inventions of micro-organisms (a microscopic organism eg. bacteria, fungus), non-biological processes and micro-biological processes. In other worlds, a patent should be allowed to new innovations based on non-biological processes such as genetic engineering and gene transfers, whereas inventions based on substances existing in nature should not be granted the same privileges. The purpose of these provisions was to prevent drastic health consequences and to emphasize the idea that inventions from preexisting substances or organisms should not be considered as new forms of technology or innovation.

However, given the rapid development of biotechnology and its related fields such as biomedical engineering, and its increased application in medicine, new challenges are posed. Indeed, a patent may only be given under the condition that the invention is new, inventive and capable of industrial application, and not for discovery, but many of the new biotechnological inventions currently find their origin in organisms existing in nature and have subsequently lost the right to patents in several regions. Many countries, mainly identified as developing states, who currently possess the natural resources that may lead to great developments in biotechnology, has not invested in its full potential due to the lack of incentive. Therefore, it is greatly recommended that one either reviews on what terms can a patent can be granted or attempt to redefine ‘biotechnology’ and ‘invention’ to provide for these flaws.

Division in patent laws

To reiterate, although some provisions have been established to provide a minimum standard or common grounds in IPRs, technical differences are easily detectable in the current framework of patent laws across the globe. These differences have caused quite a headache for patent applicants, governments, states, and various organizations at varying levels. Although there is the “world” patent application guaranteed under the PCT which makes the filing process of the patent applications quite efficient, patents are still being granted separately by national or regional institutions whose terms of admission and protection differ accordingly. For example, laws in all states that are part of the WTO require permission from the patent-holder not only not to use the patented technology or invention, but also not to import any products created through using the same technology. Therefore, while in one state the particular product may not be considered an infringement of their patent laws, it might be impossible to export it to other countries who may have patented the process. A recent example was in Europe where the import of soybeans grown in Argentina was stopped by similar laws, for although no patent laws were being infringed in Argentina, the process of producing those soybeans was patented in Europe. Similar predicaments are found with pharmaceutical products where such technical differences in patent laws prevent the drugs from being delivered to people in need.

Sometimes, the differences may not be based on technical basis, but on a philosophical one. This is well portrayed through the stark contrast of patent laws in India and the United States. Currently, India has implemented strict restrictions to inventions that are considered patentable in its territories, claiming that it is to ensure the social welfare of its population. A patent also cannot be renewed in India unlike in the United States. Meanwhile, the United States government pursues a more liberal policy on patent laws. However, this is not to say that one of the two approach is wrong and the other is right. The right direction would be to see a common agreement from both ends.

Previous Attempts to solve the Issue

Establishing minimum standards and consensus

Past treaties, such as the Paris Convention, Patent Cooperation Treaty (PCT) and TRIP agreement, established minimum standards and provisions regarding medical IP.

However, although to a small extent were such attempts successful in establishing international standards, there still exists numerous conflicts between states, organizations and companies regarding the patent laws, especially on compulsory licenses and patentability.

Cost-containment methods

Few nations who have opened itself to international tendering found that prices of drugs were reduced from 40% to 50%. However, the limitation is that this can only be sustained if the product comes from multiple sources and is not patented and the solution is short-lived.

In other cases, countries such as Brazil and Thailand found local state production also drastically lower costs and increases the government's negotiating power with other major pharmaceutical companies over price regulations.

Collaboration in Research & Development in private-public sectors

Over recent years, UN and other NGO branches have collaborated with major pharmaceutical companies to steer the development of medical products for NTDs towards a more sustainable direction. For example, since 2011, the WIPO worked with BIO Ventures for Global Health, leading pharmaceutical companies and other private and public sector research organizations to launch the WIPO Research. Its objectives were to provide royalty-free licenses for R&D and make products royalty-free to all Least Developed Country. Other collaboration initiatives include Access to Medicine Index and the Accelerating Access Initiative (AAI). However, although such attempts have brought some immediate results, the overall impact was negligible.

Possible Solutions

Many would think that pharmaceutical companies hold the moral responsibility to this controversy. However, these companies are bound to their shareholders and if deprived of the economic motivation, and would not be as productive or efficient despite its current flaws. Instead, the prudent approach to this problem would be to reform the patent system or reexamine the incentives in the market. Please keep in mind that the solutions proposed in this section does not in any way set limitations for debate.

Reexamining the incentives in the market

- increased public-private collaboration in R&D would ensure that a proper distribution of resources take place
- increased political and financial support for the implementation of national or international program for health research
- Sharing of knowledge and information across NGOs, UN branches, pharmaceutical companies, and others to provide for greater coordination between the various players

Patent Reform

- Patent pools: patent holders would patent their inventions but would make it available to the Patent Pool who would hold the authority to grant licenses. Generic manufacturers would sell them at much affordable cost and pay royalties to the patent holders in remuneration
- Fixed reward pool: a product registered for the system would be granted 10 years. The owner of creator would not patent its product and instead, be rewarded annually by a higher authority or system. The creator would not be rewarded based on the profit the product makes but rather on the health impact, evaluated by clear and established standards.

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Appendix

Patent Cooperation Treaty (PCT) - <http://www.wipo.int/pct/en/texts/articles/atoc.html>

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)— <https://www.wto.org/english/docs_e/legal_e/27-trips.pdf>