World Health Organization

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CHAIR LETTER

Dear Delegates,

Welcome to WHO! My name is Karina Holbrook and I am your chair for this committee. I am from Washington, DC, but I grew up in both the US and Japan. I am currently a third-year at the University of Chicago studying Public Policy and Russian Studies. Aside from this committee, my other MUNUC experiences include chairing a committee at MUNUC 33 and being an assistant chair at MUNUC 32 and 31. I am also a crisis director at ChoMUN 24, the collegiate MUN conference at the university of Chicago. Finally, I am also a tutor of MUNUC's MUN tutoring program.

Outside of Model UN, I work for Moda, the University's fashion magazine, as well as working as a researcher for the Slavic Department on campus. I am also a radio DJ and a member of the University's table tennis club.

I'm very glad that you are in this committee! I am passionate about pharmaceutical development, and I hope that you are too. Sustainable drug developments through the lens of technology is an incredibly topical and important issue that has wide-reaching implications throughout the globe. There is no one right answer - we all come from different backgrounds, with different points of view. The best solution is one that takes into account this diversity of opinion and is mindful of the topic's importance on the global scale. During this conference, I hope to see plenty of well-researched ideas, good debate, and most importantly, collaboration! We are stronger together, whether that be on the debate floor or in real life.

Please do not hesitate to reach out with any questions, comments, song suggestions, or concerns at cso@munuc.org. See you in committee!

Best,

Karina Holbrook

HISTORY OF THE COMMITTEE

The World Health Organization (WHO) was established on 7 April 1948, as a member of the United Nations Development Group (UNDG) dedicated to the promotion of global health.[1] WHO followed the Health Organization of the League of Nations, which was chartered in Article 23 of the Covenant of the League 2. While the League of Nations failed with the onset of World War I, the horrific events of World War II demonstrated to the United Nations, successor to the League, that protection of fundamental health was an international priority critical to social, economic, and political recovery and progress. Thus, a new institution, the WHO, created in the spirit of the Health Organization, was tasked with the responsibility of not only assuming the earlier responsibilities of the Health Organization but also addressing the growing threats and potential benefits to health from developing science and technology.

Since its founding, WHO has been regarded as the supreme directing authority in the sphere of public health. The World Health Organization is the first inter-governmental institution to include the term "world" in its title. This addition to the name of the predecessor agency, the League of Nations Health Organization, reflects how the new United Nations wished to stress that international problems, must not be solved merely by the actions of a nation or a single alliance, but by the actions of a global community. In particular, the protection of fundamental human health transcends all borders and treaties, and disease affecting a single member state has the potential to undermine the health in all other member states. Thus, the WHO possesses neutral status and nearly universal membership, resulting in almost unparalleled convening power.

The Constitution of the WHO is considered to be the fundamental health doctrine of the post-World War II world that defines health in a modern context. Previously, health was generally considered to be a physiological state. However, health for the WHO was defined in the Preamble to the Constitution as a multidimensional "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."[2]

[1] "WHO | History of WHO," *WHO*, accessed October 22, 2016, http://www.who.int/about/history/en/.
[2] Ibid.

Additionally, the Preamble underscores the importance of health as "fundamental to the attainment of peace and security," as the need for "fullest cooperation of individuals and States." This revised definition of health set a comprehensive international standard that was reflective of scientific and medical developments of the mid-twentieth century. Furthermore, this comprehensive definition of health was stated as a fundamental right in the Universal Declaration of Human rights, issued by the United Nations General Assembly in 1948.

TOPIC: INTELLECTUAL PROPERTY RIGHTS OF PHARMACEUTICALS

Statement of the Problem

Understanding Intellectual Property Rights

The term intellectual property refers broadly to any creations of the mind. Although this definition appears generic, *the Convention establishing the* ***World Intellectual Property Organization*** (1967) provides a list of specific subject terms that fall in the category of intellectual property. Under the convention, intellectual property can take the form of literary and artistic works, symbols, names and images used in commerce, as well as invention.[3] However, what is special about intellectual property is its intangible nature. The chemical composition of a drug, for instance, is a creation of the mind and fits perfectly into the domain of intellectual property. Yet, in the absence of government regulation, multiple manufacturers can produce the same drug with the formula at little or no cost without contributing to the research of the particular drug. Therefore, the notion of intellectual property rights, defined as rights given to persons over the creations of their minds, comes into the picture. However, despite the fact that intellectual property rights are analogous to any other property rights by theory, its intangible nature makes the protection of intellectual property rights a particularly challenging endeavor.

Why is Intellectual Property Protection important?

To understand the importance of intellectual property rights protection, it is crucial to extrapolate the underlying rationale and the objectives for intellectual property rights policies. By allowing creators or owners of copyrighted works to benefit from their creations, intellectual property rights protection rewards individuals for the efforts and resources they devoted into the scientific, literary or artistic productions in order to optimize human, economic and social relations.[4] The motif to

[3] "What Is Intellectual Property?," accessed May 9, 2016, http://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo_pub_450.pdf.
[4] Ibid.

enforce intellectual property rights can be summarized into three main needs.[5] The first is the need to stimulate creativity and innovation in the society as a means to promote social, economic and cultural development of nations. Intellectual property rights are granted in exchange for the inventor or developer disseminating how the product was created.[6] This dissemination, put into a bigger picture, can further benefit the society at large as it serves as a basis for further creative and inventive work. The second motif is the need to protect the considerable financial investment which is necessary for the creation of works.[7] For instance, complicated pharmaceutical products typically require a large amount of investments to go into the development process. Therefore, the second basis provides financial compensation that can be considered as an incentive to further motivate **research and development**. Lastly, the third rationale for intellectual property protection is to give recognition and protection for the moral investments of creators and inventors, preventing external parties' misuse or exploitation of the intellectual properties.[8]

Who grants a Patent?

A **patent** is an exclusive right granted for an invention that provides a new way of doing something, or offers a new technical solution to a problem.[9] It is designed to provide incentive for individuals or corporations to continue innovation by recognizing their creativity and offering possible material reward for their marketable inventions.[10] These incentives encourage innovation, which in turn triggers positive ripple effects that ultimately enrich human life. National patent offices or regional offices that hold administrative control over a body of nations, such as the European Patent Office (EPO) and the African Intellectual Property Organization (OAPI), generally serve the role of reviewing and granting patents, which is the primary form of intellectual property that pharmaceutical products belong to.[11] If an applicant requests a patent status for a particular invention in one or more countries, then each individual country will determine whether to accept

[5] "Intellectual Property In A Knowledge- Based Society: The Role Of Copyright And Future Challenges To Creators, Industry, Legislators And Society At Large; Inventors' And Creators' Rights As Basic Human Rights," Accessed May 9, 2016, Http://Www.Wipo.Int/Edocs/Mdocs/Innovation/En/Wipo_ Inv_Bei_02/Wipo_Inv_Bei_02_2.Pdf.
[6] Ibid.
[7] Ibid.
[8] Ibid.
[9] "What is Intellectual Property?"
[10] Ibid.
[11] Ibid.

the application request and offer protection, unless a regional body is in place to make collective decisions for the nations in which it has administrative power upon.[12] Furthermore, the Patent Cooperation Treaty (PCT), administered by the World Intellectual Property Rights Organization, eases the process by allowing the applicant to submit a single international application and request the protection from as many signatory nations as he or she may wish.[13] However, the current mechanism for patent rights can be insufficient when dealing with cross-nation disputes, as unilateral revocation of patent rights has incurred complaints under many instances.

When securing a patent, the first step is to file a patent application.[14] In the application, the applicant is required to provide the title, background and description of the invention. To obtain a patent, the description must be precise and clear to an extent that a reader who does not have a background of the patent's respective industry can comprehend the patent. Furthermore, the application should also provide effective claims that testify the uniqueness, authenticity, and necessity of the desired patent.

The Economics of Pharmaceutical Industry

Since we have established the importance of intellectual property protection, it is interesting to examine why the pharmaceutical industry has been considered as a challenging case in the enforcement of intellectual property rights protection. Compared with the food or textile industry, the pharmaceutical industry is the most intellectual property-intensive industry and yields the most benefits.[15] From 2000 to 2004, an average worker in the pharmaceutical industry produced more than $425,000 in value annually, with their peers in other less intellectual property-intensive industries producing an amount of less than $106,000 under the same metrics.[16] In addition, it was found that when manufacturing jobs were decreasing between 2000 and 2004, the labor force in the pharmaceutical industry was actually increasing, implying a significant level of economic well-being within the industry despite the suboptimal external conditions.[17] In fact, the economic influence is so

[12] Ibid.
[13] Ibid.
[14] Ibid.
[15] "Economic Effects of Intellectual Property-Intensive Manufacturing in the United States," accessed May 9, 2016, http://www.sonecon.com/docs/ studies/0807_thevalueofip.pdf.
[16] Ibid.
[17] Ibid.

significant that the pharmaceutical industry, in addition to many other industries that are also intellectual property- intensive, has a large role in determining the productivity of the United States as a nation.[18] Therefore, many pharmaceutical companies, citing their economic influence, argues that government policy should lean towards protecting and promoting the creation and adaptation of new products, patents and inventions since they are crucial to the nation's economic growth and well-being.[19] In addition, due to the economic impact of the pharmaceutical industry, the interest of pharmaceutical companies has been given great attention, and has motivated governments to undertake many actions to protect their interest, as is seen in the case of U.S. v. Brazil, which will be introduced later in this background guide.

In addition to the economic impact of the industry as presented above, the pharmaceutical industry also possesses the characteristics that apply to some intellectual property- intensive industries. The research and development process of drugs is lengthy, costly, and risky since it is not rare for an elaborate research initiative to collapse. As a matter of fact, compared to the cost associated with the invention of an innovative drug, its cost of production is indeed trivial.[20] The sharp contrast then explains the equally drastic discrepancy between the manufacturing cost of most innovative drugs and their actual retail prices. The relatively low cost of production means that the cost of producing more units of drugs is small, yet the cost of research inputs forces the manufacturers to drive up the price in order to compensate for the investments they have made towards the research and development of their products.[21] To do so, pharmaceutical companies rely heavily on the current patent system, which grants a period of market exclusivity that provides the holder of a patent with the freedom to be the only eligible seller of the patented product in the market.[22] Under the period of market exclusivity, the market for the particular drug is monopolized, and therefore the patent holders are given the freedom to maximize their profit by setting high prices of their products. Thanks to the profit yielded by the high market price of the drugs, the period of exclusivity grants patent holders the opportunity to make up for their research and development costs, and thereafter, continuing the innovation process. Yet, the economic mechanism revolving around the sales of

[18] Ibid.
[19] Ibid.
[20] "PharmaPricingF.pdf," accessed May 21, 2016, https://www.pacificresearch.org/fileadmin/documents/Studies/PDFs/2013-2015/PhamaPricingF.pdf
[21] Ibid.
[22] "What Is Intellectual Property?"

patented drugs may prove to be problematic when implemented in the real world, as the high market price may make the drugs unaffordable to the patients who need them the most, causing social inequity concerns. Such consequences can be found in numerous cases in which overwhelmingly high prices are charged for patented drugs and will be presented in the latter part of this background guide.

Generic Drugs

A **generic drug** is a replication, in biological terms, of a brand name drug that matches the original product in terms of "dosage form, safety, strength, route of administration, quality, performance characteristics and intended use" by the definition of United States Food and Drug Administration.[23] Although generic drugs are highly identical to their branded prototypes, generic drugs are typically priced at a significantly discounted rate. According to the Congressional Budget Office, choosing generic drugs can save consumer an estimated $8 to $10 billion a year collectively at retail pharmacies, not to mention the potential savings if hospitals also opt for generic drugs.[24] The presence of generic drugs is typically considered beneficial for both sides engaged in the manufacturing. Generic drug companies can gain greater access to the market for the previously patented drugs, while patent holders will not have to face the moral dilemma of choosing between their profits and their social responsibility when impoverished patients cannot afford their highly-priced products.[25] Since the patent grants the company the right to be the exclusive seller of the drug in a given period of time, the generic version of the drug can only be produced after the period of exclusivity expires. However, given that the patented drug has already undergone the approval process conducted by the authority, the Abbreviated New Drug Application (ANDA) process, required for the production of generic drugs, does not require the applicant to go through the elaborate and costly process of drug approval, further driving down the cost for generic drugs.[26]

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[23] Center for Drug Evaluation and Research, "Understanding Generic Drugs - What Are Generic Drugs?," WebContent, accessed May 9, 2016, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm.

[24] "Effects of Using Generic Drugs on Medicare's Prescription Drug Spending," accessed May 21, 2016, https://www.cbo.gov/sites/default/files/ cbofiles/ftpdocs/118xx/doc11838/09-15-prescriptiondrugs.pdf.

[25] Research, "Understanding Generic Drugs – What Are Generic Drugs?"

[26] Ibid.

Although the idea of generic drugs appears benevolent, it may trigger a conflict of interest between nations in which the patent is still under its period of exclusivity and nations in which the patent is not protected, as is seen in the case between Netherlands and India. While it is evident that nations in which the patent is protected will not permit any sale of generic versions of the drug within its border, nations have applied the same logic as a reasoning to confiscate generic drugs that ship across their ports.[27] For instance, between 2008 and 2009, Dutch authorities confiscated several shipments of generic drugs bound for various developing countries in South America and Africa.[28] The shipments contained generic versions of drugs that despite still being protected by the Netherland, were not protected by neither the destination countries for which they were bound, nor their production country: India.[29] After they were seized, some of the shipments were destroyed, some were returned to India, and a few were eventually allowed to continue on to their destinations.[30] Thus, the question of administrative authority becomes particularly important in examining the global trade of generic drugs, which may prove to be a good strategy in order to promote access to pharmaceuticals in impoverished areas, as this study guide will discuss in detail in the latter parts.

[27] "Why Are Generic Drugs Being Held Up in Transit?," accessed May 9, 2016, https://saudeglzobaldotorg1.files.wordpress.com/2014/06/ rosina-shaver-2012.pdf.
[28] Ibid.
[29] Ibid.
[30] Ibid.

History of the Problem

The history of intellectual property rights has differed among nations and time periods. While concrete legal codes have been implemented to safeguard intellectual property rights in nations such as Belgium, which has advanced pharmaceutical technology, other nations, such as China and India, are still in the early stage of establishing such codes. One possible reason for such a discrepancy in legal progress is the lack of awareness regarding intellectual property rights in nations that are considered behind in the research and development of intellectual properties. For example, in China, roughly 95% of the registered pharmaceuticals that are authorized to be produced in the nation are generic drugs, meaning that little effort has been dedicated to the research and development of pharmaceuticals in China.[31] Meanwhile, the research-based pharmaceutical industry in Europe and U.S.A bears a sharp contrast to their colleagues in China, as they invested heavily in the development of new drugs, which plays a critical role in ensuring their sustainable growth and competitiveness. Therefore, the differentiated focus of pharmaceutical industry in different nations has resulted in few consensus regarding the governance of intellectual property rights across borders.[32] The lack of consensus can be reflected through lawsuits that foreign companies file in local courts, as is seen in Bayer AG's case in India, and more broadly, disputes that are brought to the international platform, such as the cross-nation dispute between the United States and Brazil.

India

When India changed its patent law to enforce patents on the chemical formula of pharmaceutical products and conform to the intellectual property rights system that is analogous to those employed in the United States and Europe, as mandated by the World Trade Organization, in early 2005, the response and consequence were mixed.[33] Before the change, India employed a pharmaceutical patent law that only grants patents to the manufacturing process used to produce drugs, but not on the end products themselves, meaning that the sale of marketable drugs is not subject to direct

[31] "The Pharmaceutical Industry in Figures," accessed May 9, 2016, http://www.efpia.edu/uploads/Figures_2014_Final.pdf.
[32] Ibid.
[33] "India Changes Patent Law to Meet WTO Treaty, Making New Medicines Less Available to Most Citizens, Other Countries," accessed May 9, 2016, http://www.aidsnews.org/2004/12/india-patent.html.

coverage of intellectual property rights.[34] Consequently, the original Indian patent law was considered encouraging for companies to compete in low-cost manufacturing, and thus influenced India's pharmaceutical industry to focus heavily on making widely-available, low-cost medicines. Under the original system, 60,000 generic brands in 60 therapeutic areas were available in India prior to early 2005, which in terms of monetary value, only accounted for 1% of the pharmaceutical market, but constituted 8% of the total volume sold, demonstrating the affordable nature of such products.[35] However, the large volume share of Indian's generic drug industry also highlighted the consequence that the change of patent law may incur. At the time of the change, many non-governmental organizations estimated that at least 15% of the drugs, many essential to the patients' survival, would have to be withdrawn from the market under the new legislature, further hampering access to pharmaceutical products in India and other poverty-stricken regions around the world.[36]

While U.S.-European pharmaceutical corporations such as Bayer AG welcomed the change, the new law also received negative criticisms. Many believed that the real incentive for the World Trade Organization to push India into adopting the new patent law is not to better regulate the Indian pharmaceutical market, or many other markets that relied predominantly on Indian-exported drugs, since the economic revenue from these markets are financially small. Instead, it was believed that by regulating the Indian pharmaceutical market and enforcing more restrictive qualifications to generic drug production, many U.S.-European pharmaceutical corporations would have an easier time persuading their targeted consumers who are able to afford the market prices of such drugs, mostly residing in developed countries, to purchase the highly-priced drugs, without having the possibility to purchase lower-priced alternatives from India. In addition, since the mass production and circulation of generic drugs in India and other poor nations may not be contained in these markets themselves, there has always been concerns regarding how the robust generic drug industry in India may influence the pharmaceutical market in Europe and the United States.

Even though India's Patent Act of 2005 has theoretically conformed to an intellectual property rights system that is in compliance with the standards set by the World Trade Organization, India's history with generic drug production makes disputes revolving the practice of India's patent law somewhat

[34] Ibid.
[35] Ibid.
[36] Ibid.

inevitable. In February 2010, the German pharmaceutical firm Bayer AG filed and subsequently lost an appeal to the Delhi High Court to prevent a local competitor from producing a generic version of its cancer-fighting drug, Nexavar.[37] Since by definition, patent protection can only be extended to drugs that are considered "new combinations" and possess significantly different disease-fighting efficacy from the original chemical substances used to produce the drug, the Indian government denies many patent applications on the ground of ruling the particular drug as a "known substance".[38] Since the line between a "new combination" and a "known substance" tends to be blurred, Indian patent officials have had broad discretion over the ruling of patent applications, and in some cases, denied patients to novel and valuable pharmaceutical inventions such as Bayer AG's drug, Nexavar.[39] Even with similar legal codes governing intellectual property rights, the different attitude towards the issue has still led to fundamentally different decisions regarding intellectual property rights between India and U.S.- European nations such as Germany, where Bayer AG is based. However, the negative consequences of a series of rulings in favor of copying had started to emerge and demonstrated a concerning trend. Multiple foreign pharmaceutical companies have expressed reluctance to introduce their latest and most advanced products to the Indian market in fear of losing their patents. In addition, many Indian drug companies that don't rely on mass-producing generic drugs for low-budget patients have also leaned in favor of more rigorous patent protection. Therefore, Indian government has taken actions to tackle the current issue, including setting up a government fund to provide a list of essential medicines that are provided free of charge to those in need.

South Africa

When Nelson Mandela became the president of South Africa in 1993, he found the healthcare system of his country to be as segregated as the nation was back then. Approximately 20% of the population, mostly white, was covered by private health care, while the others rely on public sector care that was beyond inadequate.[40] Given that the public sector care was significantly under-

[37] Ronald A. Cass, "Does India Want Drug Innovation or Not?," *Wall Street Journal*, February 22, 2010, sec. Opinion, http://www.wsj.com/articles/SB 10001424052748704804204575070381023034458.
[38] "What Is Intellectual Property?"
[39] Cass, "Does India Want Drug Innovation or Not?"
[40] "The South Africa AIDS Controversy A Case Study in Patent Law and Policy," accessed May 9, 2016, http://cyber.law.harvard.edu/people/tfisher/ South%20Africa.pdf.

resourced, many South Africans did not have access to health care at all, making healthcare reform an urgent item on the new government's agenda. To identify the probable causes for the failure of public sector care, the committee on national drug policy, chaired by Dr. Nkosazana Zuma, soon raised concern about the nation's lack of equality in access to essential drugs, the comparatively high prices for pharmaceuticals in the private sector, and the theft of drugs due to poor security from the public sector.[41] The price gap between private and public sector was so significant such that the private sector yielded 80% of the nation's expenditure on drugs, while only roughly 30% of the total volume of pharmaceuticals were sold to the private sector.[42] In addition, 50% of the drugs in public hospitals, purchased to serve patients in the public sector care, were stolen and subsequently sold to the private sector.[43] Therefore, the National Drug Policy was introduced in 1996, aiming to lower drug prices, support the development of local pharmaceutical industries for the local production of essential drugs, by promoting the prescription of generic drugs in both the public and private sectors.[44]

However, the law was widely conceived as a threat to the patent rights of foreign and local pharmaceutical companies, since it essentially granted the health minister the freedom to invalidate a patent and mass produce generic versions of the drug with almost no restriction.[45] One of the major arguments against the new policy is that the trade of drugs will undermine the ability of pharmaceutical companies to charge different prices in different parts of the world. Therefore, the National Drug Policy, which was intended to benefit the poverty-stricken patients in South Africa, may indirectly become a venue for patients in the developed world, those who are able to pay the patent fee, to obtain drugs without paying the market price in their local pharmaceutical market.[46] In addition, many lobbyists against the law also raised the possibility that since the manufacturing of generic drugs is less exclusive under the new policy, many ineffective drugs that contain no active ingredients, produced by unlicensed manufacturers, may enter the market.[47] It was further argued

[41] "National Drug Policy for South Africa," accessed June 20, 2016, http://apps.who.int/medicinedocs/documents/s17744en/s17744en.pdf.
[42] Ibid.
[43] Ibid.
[44] Ibid.
[45] Donald G. Mcneil Jr, "South Africa's Bitter Pill for World's Drug Makers," *The New York Times*, March 29, 1998, sec. Business, http://www.nytimes. com/1998/03/29/business/south-africa-s-bitter-pill-for-world-s-drug-makers.html.
[46] Ibid.
[47] "The South Africa AIDS Controversy A Case Study in Patent Law and Policy."

that these inferior drugs may indeed harm the patients, causing drug resistance and messing up the treatments as prescribed by the doctors.[48] Yet, all of the concerns above were discarded by Dr. Zuma, who was the Minster of Health of South Africa, as she argued that the loss in price due to mass production can be made up by the increase in volume, which may eventually increase the profit of drug companies, even for those who could charge patent fee before the new law was introduced.[49] As she stated, "The lives of South African people override everything else. All we want to do is to give health services to the people who are poor in this country, and to the people who have been denied these health services for centuries."[50] Today, the dispute between South African government and foreign pharmaceutical companies are gradually being settled. In a settlement reached by Boehringer Ingelheim, a German pharmaceutical company, the company stated that it will allow selected generic manufacturers to produce and sell some of the company's drugs in the nation in return for a relatively low royalty (5%) that is proportional to the net sales relevant products.[51] While the settlement allows the prices for relevant drugs to drop by 90%, it does provide reasonable compensation for the research and development of drugs by its original company. The settlement marks the start of a new chapter in the battle between the South African government and foreign pharmaceutical companies, as both parties begin to compromise and seize the best of its own interest.

United States v. Brazil

In early 2001, the Brazilian government introduced an AIDS control program that endorsed a similar principle as South Africa's medical act. The program, based on Brazil's ability to manufacture affordable drugs, allowed the government to grant compulsory licenses, which is a legal instrument that allows a nation to manufacture or buy generic versions of patented drugs while paying the

[48] Sabin Russell and Chronicle Staff Writer, "World Trade Showdown / Activists, Industry Split Over AIDS Drugs /Manufacturers Fight Affordable Access," *SFGate*, accessed June 20, 2016, http://www.sfgate.com/health/article/World-Trade-Showdown-Activists-Industry-Split-2894099.
[49] "The South Africa AIDS Controversy A Case Study in Patent Law and Policy."
[50] "South Africa's Health C'tee Rejects MRSCA Bill Change - Pharmaceutical," accessed June 20, 2016, http://www.thepharmaletter.com/article/ south-africa-s-health-c-tee-rejects-mrsca-bill-change.
[51] "Deal Paves Way for Generic HIV Drugs - Drug Companies to Allow Sales in Sub-Saharan Africa | Business & Human Rights Resource Centre," accessed June 20, 2016, https://business-humanrights.org/en/deal-paves-way-for-generic-hiv-drugs-drug-companies-to-allow-sales-in-sub-saharan-africa.

patent holder only a small royalty.[52] Under the legal framework, the Brazilian government has the right to override patents if it deems that the drug is needed in resolving a health emergency, or if the pharmaceutical industry is using abusive pricing on the drug.[53] In addition, it also permits local companies to manufacture a product, developed by foreign companies, if that company fails to initiate production of the drug in Brazil within three years of obtaining the patent. For instance, President Luiz Inacio Lula da Silava of Brazil issued a "compulsory license" that bypassed the patent on the AIDS drug efavirenz, which was given to the U.S. pharmaceutical company Merck & Co. in 2007. The license would allow Brazilian manufacturers to produce generic versions of the drug despite the active patent held by Merck & Co.[54] Fearing that the gains of its pharmaceutical companies may be at loss, the United States responded by filing a complaint to the World Trade Organization (WTO) against the Brazilian legislation on the grounds that it allows the Brazilian government to coerce foreign pharmaceutical companies to reduce prices unreasonably and is biased towards Brazilian pharmaceutical companies. However, neither the United States nor Brazil seemed to be interested in the WTO proceedings. When the WTO acceded to the United States' request to establish a panel to rule on its complaint against Brazil, the United States refrained from seeking the appointment of three panelists to participate in the panel, mirroring its reluctance to actually pursue the case through international arbitration panels. In addition, Brazil's ambassador to WTO Celso Amorim also warned that if the United States insisted on resolving its issue with Brazilian law through international platform, its political consequence might be disastrous.[55] Eventually, in a joint statement released by the United States and Brazil, both parties conceded and agreed that it was in the interest of both nations to settle the matter through bilateral negotiation.[56] While international negotiation may appear to be a convenient way to settle bilateral disputes involving patent rights, the diplomatic relations between nations can sometimes trump the dispute on hand, making nations less likely to opt for international ruling when facing a patent conflict.

[52] Splash News, "Brazil to Break Merck AIDS Drug Patent," *Msnbc.com*, May 4, 2007, http://www.nbcnews.com/id/18490388/ns/health-aids/t/ brazil-break-merck-aids-drug-patent/.
[53] Ibid.
[54] Ibid.
[55] "United States Drops WTO Case Against Brazil Over HIV/AIDS Patent Law," accessed May 9, 2016, http://www.cptech.org/ip/health/c/brazil/ bna06262001.html.
[56] Ibid.

Past Actions

World Intellectual Property Organization (WIPO)

Established in 1969, the World Intellectual Property Organization (WIPO) is a self-funding agency of the United Nations that aims to lead the development of a balanced and effective international intellectual property system that enables innovation and creativity for the benefit of the broader society.[57] As a global organization, the WIPO provides a platform for intellectual property services, policy, information and cooperation. Among its many intellectual property services includes the International Trademark System in Madrid, Spain, the International Design System in Hague, Netherlands, and the WIPO Arbitration and Mediation Center, which was part of the WIPO in Geneva, Switzerland.[58] Through the WIPO Arbitration and Mediation Center, private parties are able to efficiently settle domestic or international intellectual property disputes without taking the controversies to court.[59] Because the dispute resolution procedure offered by the Center to resolve commercial and private disputes does not involve court litigation, it is also called the **Alternative Dispute Resolution.** When resolving a dispute, the Alternative Dispute Resolution of the center includes three forms: Mediation, Arbitration and Expert Determination. In a Mediation procedure, a neutral intermediary, regarded as the mediator, strives to help the parties reach a mutually satisfactory settlement of their dispute, and eventually arrive at a settlement that is legally binding and recorded as an enforceable contract.[60] However, although the settlement itself is an enforceable contract, the Mediation procedure is a non-binding one itself, meaning that the parties involved in the mediation does not have to accept the settlement if it is not to the party's satisfaction at the conclusion of the Mediation procedure.[61] Should the mediation fail or the parties involved in the dispute opt not to mediate, then the Arbitration procedure can also be used to resolve the dispute. With the agreement of both parties involved, the Arbitration procedure submits the dispute to one or more neutral arbitrators who will make a binding decision on the dispute.[62] However, as a form of the Alternative Dispute Resolution, the Arbitration procedure bears the important characteristic of

[57] "WIPO – World Intellectual Property Organization," accessed June 30, 2016, http://www.wipo.int/portal/en/.
[58] Ibid.
[59] "Alternative Dispute Resolution," accessed July 1, 2016, http://www.wipo.int/amo/en/.
[60] "What is Mediation?," accessed July 1, 2016, http://www/wipo.int/amo/en/mediation/what-mediation.html.
[61] Ibid.
[62] "Alternative Dispute Resolution," accessed July 1, 2016, http://www.wipo.int/amo/en/.

providing a private dispute solution instead of resorting to court litigation. Thirdly, the expert resources that WIPO have given birth to the third form of Alternative Dispute Solution: Expert Determination. Under Expert Determination, parties can submit a specific matter, such as valuation of Intellectual Property assets or technical questions to one or more WIPO experts who will make a determination on the matter.[63] Expert Determination greatly supplements the former two procedures of Mediation and Arbitration, which altogether constitute the Alternative Dispute Resolution that WIPO currently has in place for intellectual property disputes between small scale private parties.

The Doha Declaration on the TRIPS Agreement and Public Health

The Word Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (**TRIPS**) is WTO's first attempt to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term goal of promoting access to pharmaceuticals to those who need them.[64] However, TRIPS failed to establish a well-defined relationship between intellectual property rights and access to medicines in operational terms, incurring concerns and critics about its implementation. Therefore, designed to respond to such concerns of TRIPS, Doha Declaration on the TRIPS Agreement and Public Health (**Doha Declaration** in short), adopted in 2001, reaffirmed flexibility of TRIPS member states in circumventing patent rights for better access to essential medications for their citizens, and stipulated the criterions needed for a nation's government to take advantage of the TRIPS Agreement and use it to combat a public health crisis.[65] One of the most important statements that the Doha Declaration made was its statement regarding compulsory licensing, which was discussed in the *U.S. v. Brazil* case in this study guide. The Doha Declaration made it clear that members can grant compulsory licenses on the grounds of protecting public health, which by Article 31 of the TRIPS Agreement, can be summarized into national emergency, public non-commercial use, and anti-competitive practices.[66] The determination of national emergency, in particular, was discussed in detail in the Doha Declaration. According to the Doha Declaration, each member has 'the right to determine what constitutes a

[63] Ibid.
[64] "WTO | Ministerial Conferences - Doha 4th Ministerial - TRIPS Declaration," accessed April 30, 2016, https://www.wto.org/english/thewto_e/ minist_e/min01_e/mindecl_trips_e.htm.
[65] "The Road to Doha and Beyond," accessed May 9, 2016, http://www.ejil.org/pdfs/15/1/335.pdf.
[66] "WTO | Ministerial Conferences – Doha 45h Ministerial – TRIPS Declaration."

national emergency or other circumstances of extreme urgency'.[67] It further specifies that 'public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency'.[68] However, the magnitude or the level of impact are still ambiguous under such definition. Therefore, TRIPS member nations are still given the freedom to grant compulsory licenses if they pronounce that the nation is under public health crisis. While the Declaration enables developing countries and less-developed countries to use compulsory licensing as a tool to protect public health in their nations, differences of interpretation and implementation difficulties still exist. Given that the declaration of national emergency or extreme urgency is a relatively subjective judgement from the nation's government and because WTO has not yet provided a concrete guideline that can be consulted when determining eligibility of public health crisis, disputes regarding the implementation of Doha Declaration arise as pharmaceutical companies challenge the legitimacy of national governments' claims regarding the extent of public health crises.

[67] Ibid.
[68] Ibid.

Possible Solutions

When crafting a solution, delegates should fully utilize the progress that the international community has made regarding intellectual property rights and stimulate careful consideration of each cases presented in this study guide. Altogether, it will be the committee's goal to reach a solution that builds upon existing frameworks regarding intellectual property rights and provides new solutions that effectively address the deficiencies or concerns in the past solutions. It is also important to note that the following possible solutions are just a starting point as you venture into your journey of crafting your own solutions to the issue. While it will be helpful to consider some of the issues discussed in this section, please do not hesitate to go well beyond the scope of discussion here.

One of the pressing issues that need to be addressed is the legislative flexibility that should be given to developing countries as they take advantage of the flexibility granted to them by international treaties such as the Doha Declaration. While developing countries may argue that compulsory licensing is an effective tool for them to enhance access to essential medications, pharmaceutical companies in the developed world would argue that such legislation would threaten the strength of their patents, and may render them unable to recoup the investments they have made to develop new products.[69] The conflict is evident in the South African litigation case that has been discussed in this study guide, which triggered global debate about what should be allowed and what should be prohibited under TRIPS in order to maintain its original mission of maintaining the incentive for research & development while ensuring access to essential medications especially under the circumstance of a public health crisis.[70] Due to the subjective nature of the definition of "public health crisis" and "national emergency", national governments currently have the sole discretion in pronouncing such states, which constitutes a clear legislative flexibility as drug patents can be easily discarded by a government statement stating that the drugs are essential to resolving a public health crisis within the nation. Therefore, it remains at the committee's discretion whether WHO should establish more explicit guidelines or standards in determining the severity of a nation's public health crisis. However, what complicates the problem on hand is the fact that such a standardized

[69] "The South Africa ADIS Controversy A Case Study in Patent Law and Policy."
[70] Ibid.

evaluation, if conducted, must also take into account the individualized circumstance of each nation, as factors such as climate, culture, and geographical features can all influence the severity of a disease outbreak. Furthermore, if WHO decides to conduct the evaluation completely independently, it will have to dispatch its own personnel to perform census and survey on site, incurring a significant associated cost that needs to be funded. However, if not, then the sole source of information that WHO officials use to evaluate the severity of a public health emergency will be the information provided by the nation's Department of Health or other relevant bureaus, giving another leeway for national governments to influence the evaluation process conducted by the World Health Organization.

In addition to the granting of compulsory license discussed above, it is also important to note that the TRIPS requires that the use of a patent for which a compulsory license has been granted be "predominantly for the supply of the domestic market."[71] In other words, the reasonably-priced drugs manufactured and sold under the compulsory license must only be sold in within the nation's market. The implication of such a policy is manifold. For developing nations that do not have the facility or resource to manufacture even the generic versions of pharmaceutical products, it will be impossible to take advantage of the flexibility that the TRIPS Agreement has to offer.[72] Thus, TRIPS's mission of promoting access to essential medications will fail for those particular nations. If this committee decides to issue an exemption and allow nations to export generic drugs to countries that do not have the manufacturing power to produce, then it might incur a greater risk that results from an inability to contain generic drugs within the nation that issues the compulsory license. Furthermore, it is also a concern that if such an exemption is made, generic drugs produced by developing countries may be traded into the pharmaceutical markets of developed nations, which were once secluded from such alternatives. Delegates must consider whether the risk of disrupting the pharmaceutical markets of developed nations outweigh the benefit of extending access to essential medications to those nations that originally have no manufacturing capabilities to produce them.

[71] Ibid.
[72] Ibid.

The third issue that this committee can look into is an implementable international arbitration system that can be used to settle disputes regarding intellectual property, especially on pharmaceutical products, across nations. Through the *U.S. v. Brazil* case, it is easy to infer that the current dispute solution for cross-nation disputes can incur too big an impact that may be unnecessarily detrimental to the diplomatic relationship between the two disputed parties.[73] However, the Alternative Dispute Resolution, offered by the World Intellectual Property Organization, only deals with disputes between two private parties, and cannot resolve macro-scale disputes between national governments. Therefore, members of this committee are advised to consult other dispute resolution models and consider designing a model that is able to resolve the disputes revolving intellectual property rights of pharmaceutical products in a manner that does not do harm to the normal diplomatic relations between the parties involved. In addition, as an organization that is within the United Nations system, delegates of the World Health Organization are recommended to consider potential cooperation with other United Nations agencies or organizations. Such collaboration will allow this committee to build new solutions based on existing resources, such as the Expert Determination Procedure of the World Intellectual Property Organization, mentioned earlier in this study guide. Through examining the existing system governing intellectual property rights and adding the specialized resources that is unique to the WHO itself, delegates should develop a resolution that has a general vision for intellectual property rights protection, but focused extensively on the topic of this committee, that is, the Intellectual Property Rights of Pharmaceuticals.

[73] "United States Drops WTO Case Against Brazil Over HIV/AIDS Patent Law."

Bloc Positions

Australia, Belgium, Canada, France, Germany, Israel, Italy, Japan, Korea (Republic of), Spain, Switzerland, United Kingdom, United States of America

All nations in this bloc are developed countries that have a mature pharmaceutical industry that focuses on the research and development of drug products. These countries have a mature legal system enforcing the protection of intellectual property rights and emphasize on scientific innovation and invention. In most cases, the emphasis is due to the economic impact that intellectual property intensive industries, such as the pharmaceutical industry, can bring to these nations' economy. The market price for patented drugs is typically very high in these nations, although many patients are able to resort to government welfare or private insurance to offset a significant portion of the high drug cost. In international negotiation, these nations tend to be very protective of their domestic pharmaceutical companies, as is seen in the dispute that the United States filed towards Brazil. However, it remains a possibility for these developed nations to provide private aids or subsidies to nations in which the patent of drugs come in conflict with access to essential medications.

Argentina, Brazil, China (People's Republic of), Chile, Czech Republic, India, Indonesia, Pakistan, Philippines, Qatar, Russian Federation, Saudi Arabia, South Africa, Turkey, Viet Nam

Unlike the first bloc, this bloc is comprised mainly of developing nations that have an emerging pharmaceutical industry that is not yet fully developed. Some nations in this bloc, such as China and India, have technologies to mass-produce pharmaceutical products, but are still falling behind on research and development of drugs. Given that nations in this bloc have the technology and resource to produce generic versions of pharmaceutical products, they often come in conflict with developed nations, whose pharmaceutical companies hold patent rights, when they are trying to promote access to essential medications in their nations. Nations in this bloc often take advantage of the TRIPS agreement through compulsory licensing, and then authorize domestic manufacturers to produce generic versions. Yet, such practice often incurs disputes. However, these countries are also active in adopting more sophisticated and mature intellectual patent laws as a means to promote scientific research and development domestically.

Algeria, Bosnia and Herzegovina, Central African Republic, Djibouti, Egypt, Haiti, Honduras, Jamaica, Libya, Mali, Nicaragua, Nigeria, Rwanda, Sudan, Syrian Arab Republic, Tanzania, Zimbabwe

Nations in this bloc are relatively fallen behind in terms of scientific and economic development. The pharmaceutical industries in these nations are typically undeveloped and do not have the capacity to produce essential medications for the nations' citizens. Therefore, nations in this bloc cannot take advantage of the compulsory licensing under TRIPS as they don't have the resource to even produce the generic versions of pharmaceutical products. A typical approach for these nations to provide medical products to their citizens is through importation from the second bloc, although such trade is sanctioned by developed nations, who are concerned that such trade can undercut the interest of their domestic pharmaceutical companies. Many nations in this bloc would appreciate external support as they strive to improve access to pharmaceutical products within the nation.

Glossary

Alternative Dispute Resolution: Dispute resolutions such as mediation and arbitration that do not involve litigation in court.

Compulsory Licensing: A legal tool through which a government allows a domestic manufacturer to produce the patented product without the consent of the patent owner.

Doha Declaration: The abbreviation for the Doha Declaration on the TRIPS Agreement and Public Health, which was adopted by the WTO Ministerial Conference of 2001 in Doha in 2001.

Generic Drugs: Drugs that are identical--or bioequivalent--to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

Market Share: The percentage of an industry or market's total sales that is earned by a particular company over a specified time period. Market share is calculated in economic terms.

Market Volume Share: Similar to market share, but calculated in terms of the volume earned by a particular company or product over a specified time period.

Patent: A government authority or license conferring a right or title for a set period, especially the sole right to exclude others from making, using, or selling an invention.

Research and Development: The scientific research directed toward the innovation, introduction and improvement of pharmaceutical products.

TRIPS: The Agreement on Trade-Related Aspects of Intellectual Property Rights is an international agreement administered by the World Trade Organization that coins many forms of intellectual property (IP) regulation as applied to nationals of other WTO Members.[74]

[74] "WTO | Intellectual Property (TRIPS) – Gateway," accessed July 6, 2016, https://www.wto.org/english/tratop_e/trips_e/trips_e.htm#NegHist.

WIPO: The World Intellectual Property Organization, which was created in 1967 "to encourage creative activity, to promote the protection of intellectual property throughout the world."[75]

[75] "WIPO – World Intellectual Property Organization."

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