SIMULATION GUIDE:

INTELLECTUAL PROPERTY RIGHTS:

GENETICALLY MODIFIED ORGANISMS AND PHARMACEUTICALS

GENERAL ASSEMBLY
THIRD COMMITTEE

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Introduction

Intellectual Property Rights (IPR's) are rights given to persons to protect and provide them with control over the creations of their minds. They establish ownership over these ideas and give creators the right to prevent others from using their creations without permission (and potential compensation). In practice, IPR's give the owners a monopoly over their work under international law. These laws are designed to promote incentives for investment and innovation by allowing the creators to share their work or extend control over the use of these inventions for a specified period of time. Some common types of IPR's are trademarks, copyrights, patents, industrial design rights, integrated circuits, and often trade secrets. These works extend protection over music, literature, and art; discoveries and inventions; as well as words, phrases, symbols, and designs.

Proponents of IPR's argue that without international legal protection, there would be little incentive to invest capital and time into developing new products and processes since interlopers could use these creations for their own profit without paying any development costs. The creation of new drugs to combat disease or new crops that increase yield while limiting constraining factors (insects, water access, disease, and other barriers) takes years to invent, test, and distribute at a cost of millions of dollars. Not every approach is viable and these false starts result in lost funding. IPR's are critical for manufacturers to cover these investment costs and make a profit for their shareholders. Critics, on the other hand, condemn IPR's because these laws favor wealthy and powerful corporations and Western nations. These laws give the wealthy a monopoly over products, technology, and critical knowledge. Using IPR's as a shield, multinational corporations (MNC's) are able to charge exorbitant prices for their products, which developing countries cannot afford nor do they have the industrial infrastructure to develop their own pharmaceutical or Genetically-Modified Organism (GMO's) industries to compete with the developed states. As a result, capital streams to the West from the underdeveloped South.

Normally, the World Trade Organization (WTO) is responsible for establishing guidelines for the sharing and use of IPR's. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) establishes global trade rules for IPR's to encourage cooperation and limit conflict over the treatment and use of intellectual property. Under the TRIPS Agreement, all member states of the WTO are required to enforce intellectual property rights, although not all members are enthusiastic about this provision of the treaty. The situation has been compounded by the failure of WTO delegates to achieve progress in reconciling these issues during the current Doha Round over the past few years due to gridlock in the negotiations. As a result, the General Assembly Third Committee has decided to address some of these critical issues. This committee seeks to reach an agreement on the availability and distribution of pharmaceutical supplies and the sale of GMO's to developing nations. In both cases, Western MNC's own the IPR's on a wide range of pharmaceuticals and GMO crops that can help reduce disease and hunger in underdeveloped countries.

Historical Background

While the concept of intellectual property emerged during the Renaissance and evolved over centuries, the term did not emerge until the 18th century. The British government recognized patent and copyright law in 1710 and during the Industrial Revolution, Britain, the United States, the North German Confederation, France, Belgium, and Switzerland extended protection to intellectual property. This era represented a period of innovation and competition between countries that sought to increase their economic and political power. The issue of standardization of Intellectual Property Rights was complicated by a lack of consistency in the enforcement of national laws between nations. IPR owners in Great Britain, for example, had to apply for protection in France, Belgium, Germany, and other countries if the owner wanted to control the use of his property in these states. To address this situation, delegates negotiated the Paris Convention of Industrial Property of 1883 and the Berne Convention for the Protection of Literary and Artistic Works of 1886 to set minimum standards for the protection of IPR's between the member states. The administrative secretariats of the Berne Union and the Paris Convention merged in 1893 and established the United International Bureaux for the Protection of
Intellectual Property, with its headquarters in Berne, Switzerland. These two treaties established the foundation for modern intellectual property law. By 2015, 168 countries were members of the Berne Union and 176 states had ratified the Paris Convention. This organization eventually relocated to Geneva in 1960, and was succeeded in 1967 by the World Intellectual Property Organization (WIPO), which became a specialized agency of the United Nations in 1974. WIPO entered force in 1970 with the objectives of international protection of intellectual property and the administration of multilateral intellectual property unions (such as the Berne and Paris Conventions).

To address the reestablishment of a post-World War II international capitalist economic system, Allied delegates met in Bretton Woods, NH in 1944 to create the International Bank for Reconstruction and Development (known today as the World Bank, it was tasked with the rebuilding war torn economies after the conflict); the International Monetary Fund (designed to address international currency problems); and the International Trade Organization (assigned to promote global trade). Intellectual Property Rights emerged as an important component of the new post-war world economy and would have come under the purview of the proposed ITO. However, disagreements between the United States and the British Commonwealth between 1945 and 1950, over colonial preferential tariffs, killed the new organization. Instead, in 1947, delegates formed the General Agreement on Trade and Tariffs (GATT), which was formed to promote economic recovery by reducing barriers to trade, focusing on cutting tariffs, subsidies, and quotas. As a result, GATT emerged as a de facto international organization as a multilateral institution for trade promotion and became the focus for international cooperation in trade matters. Under GATT, member states sent delegates to negotiate the gradual elimination of trade barriers in a series of “rounds,” which were conducted over several years.

During the 1980’s, deep divisions began to emerge between the interests of developing countries and the United States and the West. During the Diplomatic Conference for the Revision of the Paris Protection for Industrial Property Rights, which WIPO sponsored from 1980 to 1984, developing nations declared that the terms of the Paris Convention undermined their national goals. Through the protection of patent monopolies and inequalities in power and wealth held by Western nations, developing states demanded preferential treatment under international law which would allow them to discriminate against direct foreign investment (DFI) as well as issue compulsory licenses for patent protected technology when IPR owners did not make available such properties in sufficient quantity or at affordable prices. The United States rejected this proposal and countered that stronger IPR protections were needed to curb the trade of counterfeit products and other intellectual property law infringements (the International Trade Commission estimated that these violations cost American companies from $43 to $61 billion a year in lost revenue).

In an effort to protect American interests, the United States turned to bilateral trade agreements and sanctions to force IPR compliance by developing countries, and initiated the Uruguay Round (the eighth and final round of the GATT) in 1986, placing IPR’s on the official agenda for the first time. These negotiations led to two important outcomes: the formulation of Trade Related Intellectual Property Rights (TRIPS) and the establishment of the World Trade Organization (WTO), which went into effect in 1994, to oversee the implementation of TRIPS. This agreement extends IPR protections granted by the Berne and Paris Conventions, sets standards, enforces measures and compliance, and provides processes for settling trade disputes. Least Developed Countries received a transitional period before they had to comply with TRIPS standards, which was extended to 2021 or until a country ceases to meet the least developed standard if such a condition occurred before that time. Article 27 of the agreement allows for exceptions and exclusions such as protecting public order or morality; protecting human, plant, or animal life or health; and avoiding serious prejudice to the environment. This provision has become very controversial since it has been used by developing countries to justify the exclusion of certain pharmaceutical products and technology related to agriculture from IPR protection.
Pharmaceuticals

Pharmaceuticals are drugs that are used to diagnose, cure, treat, or prevent disease. Drug therapy (pharmacoptherapy) is a critical part of medical science and relies on the science of pharmacology for continual advancement. Drug discovery and development are complex and expensive undertakings that are conducted by pharmaceutical companies, academic scientists, and governments. In many cases, governments regulate what drugs can be marketed, how they can be marketed, and at what prices. There have been considerable controversy regarding the distribution of drugs and their pricing under IPR laws.

The use of plant substances to treat all kinds of diseases and medical conditions may date back to prehistoric medicine. Ancient Egyptians, Babylonians, and Hindus used a variety of plants and herbs to treat diseases and infections. Arab scholars recorded their discoveries regarding drug treatment in the 9th century AD, which were well known in the Islamic world. While advances were made in medicine during the Medieval era in Europe, especially in surgery, truly effective drug discoveries were limited to opium and quinine. Even by the 19th Century, drugs were not highly effective in treating or preventing disease. However, after the First World War, the drug industry began to achieve a number of successes. Scientists developed sulpha antibiotics in 1932 and World War II led to Anglo-American cooperation in developing penicillin, new “wonder drugs” that limited the growth of bacteria and other micro-organisms. New discoveries led to aspirin, codeine, and morphine for pain; digitalis, nitroglycerin, and quinine for heart problems; and insulin for diabetes. Today, pharmaceuticals are used to treat gastrointestinal (digestive) problems; cardiovascular (heart and blood pressure) issues; central nervous system disorders, pain; musculo-skeletal issues; eye problems; ear, nose, and oropharynx ailments; respiratory complications; endocrine problems; reproductive or urinary system disorders; contraception prevention; obstetrics and gynecological problems; skin ailments; infections; immune deficiencies; allergic disorders; nutritional issues; neoplastic illnesses; and euthanasia (physician-assisted suicide, which is illegal in many countries).

The internationalization of health care emerged in the early 20th century after World War I. The World Health Organization (WHO) is a specialized agency of the United Nations and has achieved considerable success in combating disease around the world since it was founded in April 1948. Its roots date back to the Health Organization, formed in 1923 as part of the League of Nations. The organization has been active in epidemic control, health research, vaccinations, health conferences, and aid to developing countries. Today WHO consists of 194 member states with its headquarters in Geneva and its primary objective is “the attainment by all people of the highest possible level of health.” The organization’s greatest success was the eradication of smallpox around the world by 1979, with the collaboration of scientists and pharmaceutical companies. This was the first disease in history to be eliminated solely by human effort. WHO has implemented a number of vaccination projects since 1950 to eliminate tuberculosis, measles, whooping cough, tetanus, polio, cholera, and diphtheria. Today, WHO is concentrating on the eradication of malaria, HIV/AIDS, and polio as diseases that can not only be treated but ultimately eliminated. While WHO’s budget is one of the largest in the UN Organization, it suffers from the lack of financial support, limited numbers of health care personnel, and inadequate planning. The ability of WHO to tackle these diseases, especially in the developing world, relies heavily on working with pharmaceutical corporations to increase global access to lower cost drugs. It is an important tool for UN delegates in combating epidemics.

One of the most contentious issues surrounding IPR’s is its application to pharmaceutical patents and technologies, especially in response to public health concerns. The HIV/AIDS epidemic has been at the center of this debate. By the end of the 20th century, medical authorities reported that one in eight South Africans were infected with HIV, yet the cost of the treatment of one patient was estimated at $12,000 per year, well beyond the means of most patients. However, in countries where HIV drugs are not protected by patents, treatment costs are significantly less expensive; in 2001, the UN Commission on Human Rights estimated that the HIV drug AZT cost $48 per month per patient in India. Although the TRIPS Agreement allows nations to issue compulsory licenses in the case of public health crises, there is
a great deal of ambiguity over what constitutes a crisis. These challenges have made life-saving drugs inaccessible to many patients in the developing world and has created a thriving international black market for the illegal sale of pharmaceutical medications.

WHO has defined essential medicines as "those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford." Recent studies have found that most of the medicines on the WHO essential medicines list are not patented in the developing world, except for HIV medication. The lack of widespread access to these drugs arise from the problems of underdevelopment, the lack of infrastructure and widespread poverty. The non-governmental organization, Médecins Sans Frontières, runs the “Campaign for Access to Essential Medicines,” which includes demands for greater resources to be invested to diseases that are currently untreatable and occur primarily in the developing world. The “Access to Medicine Index” measures how well pharmaceutical corporations make their products available to developing countries.

WTO negotiations in the 1990’s, based on the TRIPS Agreement and the Doha Declaration, have focused on international trade in pharmaceuticals and IPR’s. Western states seek strong intellectual property rights to protect their corporate investments that were expended to develop, test, and process new drugs. On the other hand, developing countries seek to develop and promote their own domestic pharmaceutical industries to make medication more available to their people through compulsory licenses. A number of ethical questions have emerged regarding pharmaceutical patents and the high costs for drugs charged by Western corporations, which poor people around the world are unable to afford. Detractors question the rationale that exclusive patent rights and resulting high prices are required for Western pharmaceutical companies to recoup the large investments they claim for research and development. These critics also argue that the marketing expenditures for new drugs often double the cost allocated for research and development. However, Western experts point out that patent settlements, where pharmaceutical companies turn over the drugs they develop without adequate compensation, are costly for patients, national health care systems, and developing countries because these suits will delay these consumers access to lower cost generic medications and could constrict future development of new drugs.

Today, the outbreak of the Ebola virus in West Africa and progress made by Western pharmaceutical companies in developing potential cures and vaccines against the illness offers great promise for the disease’s future containment and eradication. But these benefits will only pay off if the medications can be made available to Africans at low prices and sufficient dosages. Currently, the Zika virus threatens people, especially pregnant women, across the tropics from Africa, the Pacific Islands, and Central and South America. Researchers are seeking new medication to address this growing medical crisis. A solution to the cost and supply challenges for people in the developing world and protecting the IPR’s and investments of Western pharmaceutical companies is critical for global health.

Genetically Modified Organisms (GMO’s)

A Genetically Modified Organism is any organism (plant or animal) whose genetic material has been altered using genetic engineering techniques. GMO’s are used in the production of medicines and especially in genetically modified foods. The Cartagena Protocol on Biosafety, which regulates international trade in living GMO’s, defines “living modified organisms as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.” A more specific type of GMO is the “Transgenic Organism,” whose genetic composition has been altered by the addition of genetic material from another, unrelated organism. Most GMO’s are organisms whose genetic makeup has been altered without the addition of genetic material from an unrelated organism. The goal of genetic engineering is to improve particular traits and qualities of plants and animals to enhance desired qualities.
Since 12,000 BC, humans have domesticated plants and animals to produce superior quality offspring using selective breeding or artificial selection techniques (opposed to natural selection where nature alone determines the development of new breeds). The process of selective breeding, by which organisms with desired traits (and thus desired genes) are bred to produce the next generation while organisms lacking this trait are not bred, is the precursor of the modern concept of genetic modification. Gregor Mendel, an Austrian scientist and Augustinian friar, became the founder of the modern science of genetics in the mid-19th century. His experiments with pea plants resulted in the establishment of many of the rules of heredity and laid the basis for 20th century genetic engineering. Advancements in genetics allowed scientists to create new hybrid organisms and eventually directly alter DNA, or the genes of organisms.

Genetics took on an important role in increasing world food supplies between the 1930’s and 1970. The “Green Revolution” was a movement based on research, development, and technology transfers that increased agricultural production globally, especially in the developing world. Norman Borlaug, who became known as the "Father of the Green Revolution" received the Nobel Peace Prize for leading this initiative and was credited in saving over a billion people from starvation. This was achieved through the expansion of irrigation networks, modernization of agricultural management, synthetic fertilizers and pesticides, distribution of hybridized seeds, and, most importantly, the development of high-yielding varieties of cereal grains. Borlaug worked closely with the Ford Foundation and Rockefeller Foundation to introduce new breeding lines of crops which helped to reduce or eliminate famine in Mexico, the Philippines, India, and Brazil to the point where these countries became major food exporters (especially in wheat, rice, beef, and poultry). In 1970, the World Bank began to support and develop Green Revolution initiatives to developing countries, which led to greater investment in these new crops, irrigation, fertilizers, and pesticides to reduce world hunger.

With the success of the Green Revolution in increasing crop yields, scientists turned to a new field, genetically engineered organizations. In 1972, Paul Berg created the first recombinant DNA molecule when he combined the DNA of a monkey with the lambda virus. In 1973, Herbert Boyer and Stanley Cohen used genes from different species of bacteria to form the first genetically modified organism. In the same year, Rudolf Jaenisch created the first transgenic animal when he introduced foreign DNA into a mouse embryo. This breakthrough allowed scientists to follow with the first transgenic livestock in 1985. Progress was also achieved in plants. Michael Bevan, Richard Flavell, and Mary-Dell Clinton developed the first genetically engineered plant in 1983. They infected tobacco with Agrobacterium that had been transformed with an antibiotic resistance gene; they were able to grow new plants which contained the resistance gene. In 2000, scientists developed Vitamin A-enriched golden rice, which was the first plant GMO with increased nutritional value. This rice promised to become an important new food staple in developing countries. In terms of medical advancements, Herbert Boyer and Robert Swanson formed the first genetic engineering company in 1976, Genetech, and produced insulin two years later. With the advent of GMO corporations, new adaptations were developed to improve crops. The first genetically modified crop, an anti-biotic-resistant tobacco plant was produced in 1982. China was the first country to commercialize transgenic plants, introducing a virus-resistant tobacco plant in 1992. Since that time, genetically modified tomatoes, potatoes, corn, soybeans, cotton, sugar beets, canola and other crops have been produced in the U.S. and Europe that were resistant to herbicides, insects, and other agricultural scourges.

With the success of genetically modified crops through the alteration of the genetic basis of important food species, MNC’s have created new plants that have increased per acre crop yields, are resistant to pests and diseases, are no longer vulnerable to herbicides (which eliminates weeds), and require less water and fertilizer to flourish. These crops can reduce hunger in the developing world through greater crop yields and can make food-importing states into food exporters. With increased food supplies, agricultural prices fall making more food available to the poorest members of society.
GMO’s are not without their detractors, especially in regard to their use in producing food. While there is scientific agreement that food from GMO’s is not riskier than conventional food to human health, there are long term effects that may not have been adequately tested. They suggest that genetically modified foods have led to increased allergies in children to the development of tumors. There are strong demands that GMO food products be labeled to warn consumers of their potential danger, while harsher critics have called for a moratorium on their production and sale. There are also concerns about GMO’s from a biodiversity perspective; genetically modified plants may displace native crops and inadvertently alter the natural environment with harmful effects in a process known as “outcrossing.” In addition, by making crops herbicide resistant, they could become “super weeds” and may be difficult for farmers to eliminate if future problems are discovered with these plants. This will result in the use of more toxic herbicides in greater amounts to counter the threat.

While innovation in agriculture has played an increasingly important role in world food security, there is considerable controversy over GMO’s in regard to IPR’s. Investment in agricultural research and development are protected by intellectual property laws with regard to a wide range of information, materials, products, and processes. Multilateral trade agreements have also increased the distribution of GMO knowledge and farm products around the world. However, the benefits of agricultural innovation through the modification of genes are not equally distributed to all countries. Trade agreements limit the ability of some governments to protect their agricultural sectors, which have negative effects on farmer income and national food security. The privatization of this technology through multinational corporations has shifted the ownership of crop knowledge from local farmers to the private corporate sphere. For example, MNC’s often use Genetic Use Restriction Technology (GURT) to produce crops with traits that are controlled by external chemical processes, which require farmers to purchase these chemicals. Corporations using GURT technology also design and sell sterile GMO seeds, known as “terminator seeds,” that cannot reproduce and be used in the next planting season as farmer-saved seeds; this requires farmers to purchase a new stock of seed annually from corporations. These innovations make farmers dependent on MNC’s that have important implications for sustainability and food security in developing countries.

As the world’s population continues to grow, new ways to meet global food demands through the distribution of low cost foods is critical. The Food and Agricultural Organization, a UN specialized agency established in 1945, estimates that it will be necessary to grow 70 percent more food by 2050 to keep up with food demand. Will GMO’s be the panacea to world hunger or will it result in an even greater threat to global food security?

Summary and Directives

The growing challenges of global epidemics and world hunger and the failure of the WTO to move forward on these issues requires the General Assembly to take action to address and solve these issues. As members of the Third Committee, you will tasked with drafting resolutions that meet the Intellectual Property Rights of Western MNC’s while improving health care needs and promoting agricultural expansion in developing nations.

At this session, the General Assembly Third Committee must consider the evidence and address the following issues to ensure the availability of pharmaceuticals to eradicate global diseases and prevent epidemics as well as guarantee access of developing countries to genetically modified plants to end world hunger:

1. Should health care issues, especially communicable diseases that could result in global pandemics, supersede Intellectual Property Rights laws and, if so, what incentives can be offered to multinational corporations to continue their research and development in pharmaceuticals?
2. Should GMO corporations provide their genetic research, processes, and plants to developing countries to combat global hunger and, if so, under what conditions so as to ensure the continued development of enhanced food crops?

3. With deadlock in the WTO, should Intellectual Property Rights be renegotiated to achieve a balance between corporate profit (and continued research, development, and production of new intellectual goods) and an improved distribution and reduced costs for developing countries (what should be the framework for a new IPR code)?

The success of these deliberations will promote improved health and living standards in terms of drug and food availability to people living in developing countries as an important step to world peace.