

## PATENTS IN MEDICINE AND HEALTH AS AN INTEGRAL HUMAN RIGHT

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*ABSTRACT: This article focuses on the relationship between medical patents and the right to health as an integral human right. The divergent interests involved in this issue are evaluated from the perspective of international law, which seeks to reconcile conflict through treaties and agreements of international organizations to find the balance best suited to benefit humanity. This study highlights the tension between patent law covering medicines and vaccines and the health needs of vulnerable populations in areas affected by armed conflicts and pandemics. In today's globalized world, sometimes referred to as the knowledge society, conflicts between patent rights and the human right to health are best resolved using transparent international institutions designed to promote international cooperation.*

*KEYWORDS: Patents, Medicines, Vaccines, Right to Health, Human Rights, Social Policies, COVID-19, TRIPS.*

*RESUMEN: El presente trabajo se centra en establecer el vínculo entre las patentes médicas y el derecho a la salud como un derecho humano integral. Se analizan las posiciones divergentes en la materia desde la perspectiva del derecho internacional, que busca conciliarlas a través de los tratados y los organismos internacionales, para encontrar un equilibrio que genere beneficios a la humanidad. En este estudio se destaca el choque entre las patentes de medicinas y vacunas contra la realidad de poblaciones vulnerables en conflictos armados y pandemias.*

*PALABRAS CLAVE: Patentes, medicamentos, vacunas, derecho a la salud, derechos humanos, políticas sociales, COVID-19, ADPIC.*

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## I. INTRODUCTION

In recent years, the number of inventions in the world has increased due to the competitiveness of global markets. However, this upswing has left developing countries behind as their current policies have not yet achieved a sufficient harmonization between government structures, scientific-technological structures, and production.<sup>1</sup> This lack of harmonization not only inhibits innovation but can also impede the importation of necessary technology or lead to the purchase of obsolete technology.

Competitiveness in technology implies the empowerment of industry, which ultimately generates a conflict between industrial property rights and the societal need for the development of national healthcare systems to protect the population. The protection of patent rights can be at odds with the demand of doctors and patients for certain medicines that, because of excessive costs, are effectively unattainable. Therefore, these two rights, patents rights and the right to health, are often in conflict.

This conflict directly impacts the quality of life of people whose right to health is officially protected by various international instruments. The Universal Declaration of Human Rights of 1948, the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social, and Cultural Rights of 1966, and the Declaration on the Right to Development of 1986, all protect health as a human right and promote increasing access to health care.

The pharmaceutical industry, which conducts extensive research on its own, is understandably attracted by important discoveries in the field of science. It is also the focus of significant investment and innovation. This is a worldwide phenomenon, and Mexico is no exception. As one might expect, Mexico displays some characteristics resulting from the conflict identified above. The

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<sup>1</sup> Jorge Sábato & Natalio Botana, *Science and Technology in the Future Development of Latin America*, 146 (575) *ARBOR* 21 (Nov 1, 1993).

right to health as a human right is established in the Mexican Constitution.<sup>2</sup> Mexico is also part of one of the most dynamic commercial regions in the world through its membership in the United States-Mexico-Canada Agreement (USMCA). The USMCA superseded the North American Free Trade Agreement (NAFTA).<sup>3</sup> The new agreement strengthened patent protections and led to increased foreign investment in the health sector.<sup>4</sup>

According to the National Institute of Statistics and Geography (INEGI) and the National Chamber of the Pharmaceutical Industry (CANIFARMA),<sup>5</sup> Mexico is considered to be one of the main markets for health supplies in the world and is classified as a solid and highly competitive industry at the regional level. Their study indicates that in 2021, the pharmaceutical industry's gross domestic product (GDP) grew 8.4% compared to 2020, and that from 2003 to 2021, the number of pharmaceutical industry establishments had increased from 480 to 908. The numbers had increased due to the restructuring of international value chains.

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<sup>2</sup> CONSTITUCIÓN POLÍTICA DE LOS ESTADOS UNIDOS MEXICANOS [CPEUM] [POLITICAL CONSTITUTION OF THE UNITED MEXICAN STATES] Feb. 05, 1917, article 4 states: "Every person has the right to health protection. The Law will define the bases and modalities for access to health services".

<sup>3</sup> THE UNITED STATES-MEXICO-CANADA AGREEMENT [USMCA] Jul. 01st, 2020, is an updated version of the NORTH AMERICAN FREE TRADE AGREEMENT [NAFTA], that includes major changes in intellectual property protections. The Agreement extends the terms of copyright to 70 years beyond the life of the author (up from 50).

<sup>4</sup> In the NAFTA and the USMCA, the chapter on intellectual property recognizes the Geneva, Bern, and Paris Conventions signed on various dates, all aimed at the protection of rights derived from intellectual property, including producers of phonograms, literary, and artistic works, as well as industrial properties (patents, brands, models, industrial secrets, and industrial designs). Under the USMCA, parties may grant greater protection to intellectual property rights through domestic legislation, that is, more protection than is granted in the Treaty. National treatment is granted for protection and defense, except for the obligation to submit to the procedures established in the multilateral agreements issued by the World Intellectual Property Organization [WIPO] on the acquisition and conservation of intellectual property rights. On August 24, 1994, in the Official Journal of the Federation [D.O.F.], Mexico published a Decree to Reform, Add, and Repeal Provisions of the Law on the Promotion and Protection of Industrial Property. Its purpose was to improve the national industrial property system through greater protection of industrial property rights. It granted to the Mexican Institute of Industrial Property the powers necessary for the exercise of administrative authority in this area and the harmonized Mexican law with the provisions of international treaties to which Mexico is a party. Later, on January 1, 2020, Mexico published the new Federal Law for the Protection of Industrial Property, which repealed the previous law. The new law protects industrial property through the regulation and granting of invention patents (among other things) and, in the case of natural persons, grants them exclusive and temporary rights to exploit the patents for their own benefit or to allow others to do so with the consent of the patent holder. LEY FEDERAL DE PROTECCIÓN A LA PROPIEDAD INDUSTRIAL [LFPPPI] [LAW FOR THE PROTECTION OF INDUSTRIAL PROPERTY] Jul. 07, 2020.

<sup>5</sup> INSTITUTO NACIONAL DE ESTADÍSTICA Y GEOGRAFÍA, *Conociendo la Industria farmacéutica*, (Colección de estudios sectoriales y regionales, 2022), available at: <https://www.canifarma.org.mx/uploads/descargables/inegi.pdf>

However, this has divided the markets in the search for new niches for producing medicines or promoting imports. Therefore, on the one hand, GDP growth is good, but not about the increase in imported medicines. They determined that 83.2% of all imports came from eight countries. The principal source of these imports was the United States, at 42.3%. In 2020, imports were at 81.4% and came from nine countries. The country with the highest percentage in that year was, again, the United States, at 30.7%, followed by China, with 14.2%.<sup>6</sup>

Regarding drug patents, there has historically been a tension between the pharmaceutical industry's desire to recover their investments and the government's need to control health costs. Moreover, the cost of developing new medicines will always be more expensive than merely reproducing those that already exist. Thus, the intellectual property regime encapsulates the ongoing struggle between protectionist and liberalizing forces on both a national and international scale.<sup>7</sup>

Thus, there is an antagonism between the empowerment of the pharmaceutical industry and the population's access to healthcare. One example of the empowerment of the pharmaceutical industry is the excessive protection granted to intellectual property rights in biomedical research, which has led Heller and Eisenberg to make use of the "tragedy of the commons"<sup>8</sup> phenomenon in their article on the subject. The tragedy of the commons problem results from the fact that a given limited resource quickly becomes overused when each of the owners is permitted to use it but is unable to exclude others from using it. The "tragedy of the anticommons", according to Heller and Eisenberg, results when a resource has many owners, each of which has the right to exclude all the others. This can result in a situation where no one, in fact, has use of it.<sup>9</sup>

In these types of cases, what usually occurs is that the government uses its regulatory powers to implement national policies that prioritize access to healthcare. The Mexican government, for example, promotes health as a human right. The National Health Program 2007-2012 promoted universal access to quality medical services through a functional and programmatic integration of the various public institutions under the Ministry of Health. The program contained the following five central concepts aimed at achieving this social policy: 1) improve the health conditions of the population; 2) provide efficient health services, with quality, coziness, and safety for the patient; 3) reduce health inequities through targeted interventions in marginalized commu-

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<sup>6</sup> *Ibid.* at 7.

<sup>7</sup> Karen van Rompaey, *Salud global y derechos humanos: propiedad intelectual, derecho a la salud y acceso a los medicamentos*, 15 ANUARIO DE DERECHO CONSTITUCIONAL LATINOAMERICANO 497, at 500 (2009).

<sup>8</sup> Michael Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 (5364) *Science* 698, (1998).

<sup>9</sup> *Ibid.* at 698.

nities and vulnerable groups; 4) prevent impoverishment of the population due to health issues through universal medical insurance, and 5) to guarantee that health contributes to improving poverty alleviation and human development in Mexico.<sup>10</sup>

Additionally, on November 29, 2019, the Mexican government reformed the General Health Law by enacting the Health Sector Program 2020-2024, which implemented a new policy offering free health services and medicines designed to progressively expand access to health services to people not covered by the country's employment-related social security program. To achieve this, the government promoted improving and strengthening all systems involved in the production, purchasing, and supply of medicines as an integral part of the therapeutic process and not merely as merchandise to which universal access must be granted. The government recognized that the production of medicines, vaccines, and medical equipment derives from commercial interests, which often make pharmaceutical products more expensive. As a result, the government directed the Ministry of Economy to review the commercial and productive activities of the pharmaceutical sector. The government is laying the foundation for adequate, universal, and free access to health care, continuing improvement of the quality and capacity of the National Health System, and achieving a differentiated and culturally relevant, rights-based approach promoting both regular monitoring and epidemiological care to improve the health and well-being of the population.<sup>11</sup>

As we can see, the State is the ultimate guarantor of healthcare for the people. However, there is a contradiction in a liberal state. On the one hand, State is thinning on economy, while on the other, the State maintains paternalistic policies. The policy mentioned above was, in fact, the first time that a government in Mexico promoted a policy of universal access to quality health care through universal health insurance.

However, this exposed the contradiction inherent in a liberal state, that is, while the government promotes the reduction of its influence on the economy, it also maintains policies that do not sufficiently address true distributive justice to secure the right to health. Even though the government does seek to help the most vulnerable, the regulations only operate at the national level, leaving the economic interests of international pharmaceutical companies relatively unaffected. Thus, there appears to be an opposition between the protection of patent rights and the right of the population to adequate health services.

The COVID-19 pandemic of 2020-2022 highlighted the significant gap between developed and developing nations in managing public health crises. While developed countries possess the necessary financial resources and scien-

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<sup>10</sup> PROGRAMA NACIONAL DE SALUD 2007-2012, [NATIONAL HEALTH PROGRAM 2007-2012], Jan. 17, 2008, D.O.F., (Mex.).

<sup>11</sup> PROGRAMA SECTORIAL DE BIENESTAR 2020-2024, [SECTOR WELFARE PROGRAM 2020-2024], Aug. 17, 2020, D.O.F. (Mex.).

tific expertise, as well as the robust pharmaceutical industry, necessary to combat the pandemic, developing countries faced severe difficulties in attempting to mitigate its effects. In addition, countries such as Ukraine, India, Iraq, Libya, Pakistan, the Philippines, Thailand, and Yemen,<sup>12</sup> were all simultaneously facing unprecedented humanitarian crises involving ongoing armed conflicts or other forms of violence, all of which exacerbates the already existing disparities in access to essential medical supplies and vaccines. National health policies in a globalized world must be able to respond more effectively to this novel global phenomenon. Moreover, there needs to be an international model for patent development that emphasizes cooperation.

In the situation described above, the premise of the theoretical model referred to as the “Sábato triangle”<sup>13</sup> has been broken. This model identifies the main actors as the government, the productive system, and the academy. The government oversees managing the scientific and technological community’s ability to respond to the needs of industry. However, those needs are not sufficiently linked to the other actors involved. This results in benefits accruing to industry because of the exploitation of patents, but without any balancing of these benefits against the possible adverse impacts on the nation’s healthcare system.

Undoubtedly, economic incentives promote research in science and technology in the private sector. If they were to be abolished, it would discourage research and lead to the deterioration in overall social health and compromise the effectiveness of the government as the guarantor of the right to health. In this regard, international organizations and institutions such as the World Intellectual Property Organization (WIPO) and the United Nations Development Program (UNDP) are working to create an international normative framework that focuses on both the rights of industrial property and people’s standard of living.<sup>14</sup>

This paper will focus on the relationship between medical patents and the right to health as an integral human right. The divergent interests involved in this issue are evaluated from the perspective of international law, which seeks

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<sup>12</sup> Tobias Ide, *COVID-19 and armed conflict*, 140 WORLD DEVELOPMENT (2021).

<sup>13</sup> In the field of science, technology and society, literature has existed since the 1960s, what we call today academic-scientific knowledge. Theoreticians such as Marcos Kaplan emerged in the development of a scientific policy, who in the 1980s would define this as a set of measures or decisions, interventions or activities carried out by different institutions of a specific society and whose main and ultimate objective is to encourage, stimulate or inhibit the progress of research, such as the application of products for socioeconomic, political, cultural or military purposes, delimiting what, who and for what. In this definition, Kaplan goes back to the ideas of J. Sábato and his theory of the “triangle of development” later baptized as a “triple helix” theory by Henry Etzkowitz, which precisely links government, universities, and industry through investment in this field. Specifically in scientific research and technological development, that are generators of growth and changes in diverse orders. Alvin Toffler would later establish in *The Third Wave*, in relation to the transfer of power and the knowledge society as is currently known through the value of the information that is possessed.

<sup>14</sup> This issue can be explored through the UNDP Human Development Index (HDI) study.

to reconcile conflict through treaties and agreements of international organizations in order to find the balance best suited to benefit humanity. This study will focus on how changes regarding the fundamental concepts of human rights and medical patents affect the lives of ordinary citizens. Considering the rapid evolution of scientific knowledge in the field of medicine, specifically regarding vaccines, nations need to create policies that promote the so-called knowledge society by using approaches that emphasize international cooperation.

Theoretical bases emerge from the conception that scientific knowledge is a strategic task in our modern society. Information and knowledge have become a vital instrument for economic growth and social development.<sup>15</sup> This is typical of contemporary society,<sup>16</sup> constituting a source of well-being and wealth for the majority of the most developed countries, that left behind the philosophical approach of ancient Greeks on the science as a contemplative way, towards an interpretation of value of the knowledge and its practical applications from the scientific innovation, in which the three main actors are the government, universities, and industry, which some authors considered the triangle of innovation.<sup>17</sup>

According to Hohfeld's theory,<sup>18</sup> the right to health may be deemed a human right due to the presence of "correlative concepts" that entail reciprocal notions, such that when asserting that X (a person with a disease) has a right over Y (the owner of the patent) with regard to a given action, it implies that Y has a duty towards X regarding that action; therefore, stating that X is competent vis-à-vis Y concerning a normative action denotes that Y is subject to X regarding that normative action. Conversely, utilizing Hohfeld's theory in relation to what he calls "opposite concepts" or contradictory concepts, such as maintaining that X has a right to and Y has a non-right concerning a given action, is tantamount to stating that X possesses a legal power over Y with respect to that normative action. In either case, the consistency of the legal systems must be ensured. Kelsen highlights the distinguishing features of legal norms to examine the functioning of legal systems understood as collections of norms with such characteristics. Hence, the classification of the right to health as a human right necessitates a review according to the distinct legal systems.

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<sup>15</sup> See MANUEL CASTELLS AND PEKKA HIMANEN, *THE INFORMATION SOCIETY AND THE WELFARE STATE. THE FINNISH MODEL* (Oxford U. Press, 2011). Cite on the subject: "We live in a time characterized by the rise of the information society in its diverse reality. The foundation of this society is informational, which means that the defining activities in all realms of human practice are based on information technology, organized (globally) in information networks, and centered around information (symbol) processing".

<sup>16</sup> Understood as post-World War II.

<sup>17</sup> ANTONIO PULIDO AND EMILIO FONTELA, *INNOVACIÓN Y POLÍTICA CIENTÍFICA* (Instituto LR Klein/Ceprede/IBM, 2008).

<sup>18</sup> Wesley Newcomb Hohfeld, *Some Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 23 (1) *YALE LAW JOURNAL* 16, 30 (1913).



## II. INTERNATIONAL PROVISIONS THAT ESTABLISH A CORRELATION BETWEEN INDUSTRIAL PROPERTY RIGHTS AND HUMAN RIGHTS

Under the Economic and Social Council (ECOSOC) authority, Intellectual Property and human rights are under discussion through various international mechanisms, whose considerations seek to raise awareness and eliminate actual or potential contradictions between scientific progress and economic, social, and cultural rights.

There are several important documents on this subject, such as the Venice Declaration on the right to enjoy the benefits of scientific progress and its applications, adopted in 2009, the Universal Declaration on Bioethics and Human Rights, adopted by the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 2005, the Recommendation on Science and scientific researchers, adopted by UNESCO in 2017, the report of the Special Rapporteur on cultural rights on the right to enjoy the benefits of scientific progress and its applications (A/HRC/20/26) and General Comment No. 17 (2005) of the Committee on the right of every person to benefit from the protection of the moral and material interests derived from any scientific, literary or artistic production of which he is the author. In addition, applications of scientific progress are under intellectual property regimes, which struggle between the economic benefit for the patent owner and the right to health. Even though in the World Trade Organization Doha Declaration on the TRIPS Agreement and Public Health (2001), the intellectual property regime should be interpreted and implemented in a manner supportive of the duty of States “to protect public health and, in particular, to promote access to medicines for all”.<sup>19</sup>

The right to health is considered to be a human right and is characterized by: *a*) universality; this right is inherent to all men, is for the benefit of all, and cannot be restricted to a particular class of individuals; *b*) unconditionality; it is not subject to any condition beyond the guidelines and procedures that determine the limits of that right; *c*) inalienability; it cannot be abrogated or transferred because it is inherent to the idea of human dignity; *d*) internationalization; its expansion has had an impact on all countries, whether through their own efforts or as a result of pressure from the international community; and, *e*) progressiveness; the needs of both the individual and society must be taken into consideration while keeping in mind the dynamic and changing character of these needs.

Today, human rights are universal. It is widely accepted that there should be no limitations on these rights due to political boundaries, beliefs, or race. This universal validity is based on a general recognition of their fundamental

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<sup>19</sup> UN CESCR, General comment No. 25 (2020) on science and economic, social, and cultural rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights), April 30, 2020, UN Doc. E/C.12/GC/25; WORLD TRADE ORGANIZATION, Trade-Related Aspects of Intellectual Property Rights Jan. 01, 1995.



importance. Human rights limit the sovereignty of the state but are respected due to this belief that they are essential for the optimum and harmonious development of the individual in society.

In the international sphere, the universalization of human rights began with two specific events. The first was the “Four Freedoms” speech given by President Roosevelt before the US Congress in 1941, and the subsequent signing of the Atlantic Charter, which was an effort to codify into a single text those rights that all nations should protect. The second was the signing of the Universal Declaration of Human Rights in 1948, which occurred largely due to the combined efforts of non-governmental organizations and a number of smalls, primarily Latin American countries, that had fought to include a solid commitment to human rights in the United Nations Charter. At the Pan-American Conference held in Mexico in February and March 1945, Latin American countries expressed their determination to see those human rights included in the Charter of the United Nations. It was at this conference that the concept of human rights acquired its new international legal status, which would lead to its universalization. The UN Charter states in Article 1:

The Purposes of the United Nations are... To achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language or religion.

This idea of universal applicability, although often thought to have been inspired by the liberal revolutions of the eighteenth century, originates in the thought of one of the vital enlightenment writers on legal and political philosophy, Immanuel Kant. Kant places the idea of universality at the center of his moral philosophy, and he uses the term “categorical imperatives” for universal rules that everyone must follow. Thus, Kant points out that reason, through informant characteristics, reveals humankind’s essential trait. Each person with a rational tendency can be considered a member of a great ideal family that manifests in sociability. Kant would further develop this thesis in his work, *Perpetual Peace*, where he advocates universal citizenship and cosmopolitan hospitality as necessary foundations for peace between men and nations.

Today we see that interdependence supposes the defense of these rights from a more radical conception of their own needs and interpretations, subjecting human rights to scenarios of such particularity that often fragment this sense of universality in defense of specific societal and community ideas, which refutes the abstract meaning of such universality. In the absence of a social economic framework that allows fully to satisfy all human rights in a universal or complete way and which underlies the international community by allowing the creation of international mechanisms for the peaceful coexistence of States, leaving aside cultural pluralism, or the recognition of a plural reality of political and cultural traditions and institutions.

In international law, the regulatory framework regarding the right to health is based primarily on the following international conventions: (1) The Universal Declaration of Human Rights (1948); (2) the International Covenant on Civil and Political Rights (1966), which expanded the rights set forth in the Universal Declaration; (3) the International Covenant on Economic, Social and Cultural Rights (1966); and (4) the Declaration on the Right to Development (1986), whose main purpose was to harmonize the civil, cultural, economic, political, and social rights identified in the previous three documents. The right to health is also referred to in Articles 10, 12 and 14 of the Committee on the Elimination of Discrimination Against Women (CEDAW), Article 24 of the Convention on the Rights of the Child, and the Alma-Ata Declaration on Primary Health Care of 1978.

The relationship between the right to health and industrial property rights also appears in the above-mentioned international instruments. Specifically, Article 17 of the Universal Declaration of Human Rights states, “Everyone has the right to own property alone as well as in association with others”, and “No one shall be arbitrarily deprived of his property”. Article 27 states:

Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits... Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author.<sup>20</sup>

The International Covenant on Economic, Social and Cultural Rights follows the tone of the Universal Declaration of Human Rights. Article 15 of that document states:

1. The States Parties to the present Covenant recognize the right of everyone:
  - (a) To take part in cultural life;
  - (b) To enjoy the benefits of scientific progress and its applications;
  - (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.
3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.
4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.<sup>21</sup>

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<sup>20</sup> U. N., UNIVERSAL DECLARATION OF HUMAN RIGHTS, Dec. 10, 1948, available at: <https://www.un.org/en/about-us/universal-declaration-of-human-rights>.

<sup>21</sup> U. N., INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS, Dec. 16, 1966, available at: <https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights>.

In each of the above articles, a contradiction between the protection of a right to culture and the protection of the material interests of the producer is evident. The tension arises between the norms that guarantee the use of information and the norms that guarantee the diffusion of information. On the one hand, there is the right “freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits”. On the other hand, we have regulations designed to protect the creators of information, that is, to protect “the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author”.<sup>22</sup>

The Inter-American Court of Human Rights refers to the TRIPS Agreement and its relationship to the right to health, especially in Title 3.2 which addresses access to medicines and the right to health, and Article 3.3 which addresses amendments to the TRIPS Agreement. However, this instrument has rarely been invoked since it fails sufficiently to clarify the relationship between the protection of intellectual property rights and the right to health. The instruments emanating from organizations such as the WTO have all tended to prioritize intellectual property rights over the right to health.

### III. THE FRAMEWORK OF TRIPS AND RECONCILING PATENT LAW WITH THE RIGHT TO HEALTH

The TRIPS Agreement permits compulsory licensing. Compulsory licensing allows governments to use patents without the explicit authorization of the patent holder, albeit with conditions designed to protect the interests of the patent holder. These conditions are contained in Article 31, which states that granting of such licenses may only occur after an unsuccessful attempt has been made to acquire a voluntary license on reasonable terms and conditions within a reasonable period of time. There is also a requirement that adequate remuneration be paid based on the circumstances of each case and taking into account the economic value of the license. A requirement that decisions be subject to judicial or other independent review by a higher authority is included as well.

These conditions may be relaxed in situations where compulsory licenses have been employed in response to practices determined to have been anticompetitive following a legal process. All these conditions should be read together with the related provisions of Article 27.1, which require that patent rights shall be enjoyable without discrimination as to the field of technology or whether products are to be imported or locally produced.<sup>23</sup>

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<sup>22</sup> WORLD INTELLECTUAL PROPERTY ORGANIZATION [WIPO] & NATIONAL PATENT AND REGISTRATION OFFICE OF FINLAND [NPRF], *Foro sobre Creatividad e Inventiones. Un mejor futuro para la humanidad en el siglo XXI*, OMPI/IP/HEL/00/17, oct. 5 to 7, 2000 (Finland).

<sup>23</sup> WTO, *Overview: the TRIPS Agreement*, available at: [https://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm).

The use of compulsory licenses and the use of a patent by a government without the patent holder's authorization is only allowed if the conditions established in Article 31 have been met, particularly the conditions which protect the legitimate interests of the patent holder. The person or company that requests such a license must have tried, unsuccessfully, to obtain the license voluntarily from the patent holder under reasonable terms and conditions (Article 31(b)). If the license is obtained, adequate compensation must be paid to the patent holder (Article 31(h)).

However, there are several exceptions related specifically to the topic of the right to health. Some of the phrases outlining the circumstances that permit these exceptions are: "in the case of a national emergency or other circumstances of extreme urgency"; "in the case of public non-commercial use... by or for the government"; and, "to correct anti-competitive practices". Under these circumstances, it is not necessary to make any effort to obtain a voluntary license under Article 31(b). The compulsory licensing permitted in these cases, in accordance with the TRIPS, is not an exclusive grant to the licensee, so the patent holder still retains the possibility of receiving benefits from it. It is generally understood that these compulsory licenses should only be granted to supply a country's internal market. Article 31 itself does not identify what specific circumstances qualify as "a national emergency", "other circumstances of extreme urgency", or "anti-competitive practices".

According to the Doha Declaration, the criteria are to be established by the state that invokes this provision in response to a particular situation.<sup>24</sup> This lack of specificity has generated uncertainty even though some states have implemented mechanisms for the granting of compulsory licensing, often due to pressure from pharmaceutical companies. The conflict between intellectual property rights and the protection of the right to health during a national emergency has not yet been resolved by any international agreement. The lack of agreed upon criteria can lead to a situation where the governments of different countries are required to negotiate directly with each other to resolve issues affecting the rights of patent holders when a conflict arises. Such a conflict arose between the United States and Brazil over the interpretation of Brazil's Industrial Property Law.

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<sup>24</sup> The Doha Declaration, in paragraph 5, establishes the commitment of the TRIPS Agreement and recognizes existence of coercive economic measures, and the freedom of action that include the following: "(b) Each Member has the right to grant compulsory licenses and the freedom to determine the basis on which such licenses are granted. (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics may represent a national emergency or other circumstances of extreme urgency. (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4". WTO, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/W/2, (2001).

Brazil's Industrial Property Law of 1996<sup>25</sup> established the requirements under which "local exploitation" of exclusive patent rights will be permitted. The United States stated that such "local exploitation" could only be met if Brazil produced the patented material itself and did not merely import the patented material from another country. The Brazilian position regarding "local exploitation" includes a provision making a patent subject to a compulsory license if the patented material has not been put to use in Brazilian territory. That is, Brazil defines "lack of exploitation" as "the non-production of the product or its incomplete production", but also, the "non-utilization of the patented procedure in a complete manner".

For the United States, this provision was incompatible with Brazil's obligations under Articles 27 and 28 of the TRIPS, and Article III of the GATT (1994). On July 5, 2001, following direct discussions between representatives of the governments of the two countries, the parties to the dispute notified the Dispute Settlement Body (DSB) that they had reached a mutually beneficial solution and that Brazil would grant the compulsory license regarding the patents held by United States companies. Nevertheless, in the agreement, the United States emphasized that Brazil had never used this provision to grant a compulsory license.<sup>26</sup>

Another provision that impacts the right to health is the "Bolar" provision,<sup>27</sup> which appears in Article 30 of the TRIPS. This provision is intended to promote scientific and technological advances by allowing researchers to use patented inventions in their research. Some countries, like Canada, allow producers of generic medicines to use the patented invention to obtain an authorization for commercialization of those products without having to obtain the permission of the patent holder, and before the protection period has expired. As a result, producers are able to market such medicines as soon as the patent expires.<sup>28</sup> Generic medicines are typically more affordable than patented medicines because their price is closer to the actual cost of production, especially when several generic versions of the same medicine are available as competition between producers will lower prices.<sup>29</sup> Unfortunately, the Bolar provision is very difficult for developing countries to take advantage of since they often do not

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<sup>25</sup> LAW NO. 9.279 of 14 May 1996 (Bra.) (Regulating rights and obligations related to industrial property).

<sup>26</sup> Dispute Settlement by United States, *Brazil – Measures Affecting Patent Protection*, WTO Doc. WT/DS199/1 (May 30, 2000).

<sup>27</sup> *Roche Products v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984) (inspiring in this case).

<sup>28</sup> WTO, *Obligations and exceptions. Under TRIPS, what are member governments' obligations on pharmaceutical patents?* (September 2006) available at: [https://www.wto.org/english/tratop\\_e/tripos\\_e/factsheet\\_pharm02\\_e.htm#dohadecl5b](https://www.wto.org/english/tratop_e/tripos_e/factsheet_pharm02_e.htm#dohadecl5b).

<sup>29</sup> Brigitte Tenni, et al., *What Is the Impact of Intellectual Property Rules on Access to Medicines? A Systematic Review*, 18 GLOBALIZATION AND HEALTH, at 35 (2022).

have the resources or economic capacity to develop new patents derived from previously patented material as the Bolar provision presupposes.

A substantial change took place in 2017. In that year, an important modification was adopted that directly affects the right to health. Although problems regarding the economic issues that affect developing nations still remain, this modification expands the range of possible solutions regarding the right to health. This change was the Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights, which became effective as of January 23, 2017. On December 6, 2005, WTO members approved changes to the WTO's intellectual property agreement (TRIPS), making permanent a prior decision on patents and public health that had originally been adopted in 2003.

In the Amendment, "WTO members assigned further work to the TRIPS Council to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can obtain supplies of copies of patented drugs from other countries without the authorization of the patent holder".<sup>30</sup> Without this flexibility, countries lacking the productive capacity in this area would not have been able to take advantage of the compulsory licensing system. This is often referred to as the "Paragraph 6" issue because it appears in the sixth paragraph of the Doha Declaration on the TRIPS Agreement and Public Health.<sup>31</sup>

Further, article 31(f) of the TRIPS Agreement states that compulsory licensing must be "predominantly for the supply of the domestic market". This applies to countries that are able to manufacture drugs and limits the amount they can export even, when the manufacture of the drug has been permitted under a compulsory license. This also has an impact on countries that are unable to manufacture their own medicines and need to import generic medicines. For countries in this situation, finding third countries that are permitted to supply drugs produced pursuant to compulsory licensing rules can be difficult.<sup>32</sup> Specific qualifications were included, such as "reasonable measures within their means" and "proportionate to their administrative capacities" in order to prevent the conditions becoming overly burdensome or impractical for importing countries.

Developed country members are obliged to provide technical and financial cooperation on request, and on mutually agreed terms, to assist countries using the system in order to avoid trade diversion away from the intended beneficiaries.<sup>33</sup> All WTO members are eligible to export under this plan, but developed countries have committed themselves to not using this system to import medicines. Some members have pledged to only use the system to import medicines during a national emergency or other circumstances of extreme urgency.

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<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

#### IV. THE DIFFERING CRITERIA AFFECTING DEVELOPED AND LESS DEVELOPED COUNTRIES

There is a contradiction within the capitalist system which seems to be consistent with the rules of free competition but opposing to the vision and need to extend human rights and medicine patents with respect to the right to health in the international arena. It is difficult to resolve this contradiction due to the secrecy inherent in the pharmaceutical sector and the patent system on which it relies, as well as other factors that hinder the availability of medicines. In this regard, the World Health Organization (WHO) points out that some of these barriers to “availability of medicines” are to be evaluated in terms of “(a) physical availability and (b) economic availability, or affordability. Moreover, physical availability assumes the supply of quality, effective and safe medicines to consumers. Affordability covers the State system to regulate pricing and the system that shapes demand for medicines”.<sup>34</sup>

To deal with these barriers, the WHO suggests countries enact legislation specifically targeted towards:

- Improving the regulatory framework for the circulation of medicines (regulating the quality required of medicines placed on the market and preventing the use of counterfeit medicines).
- Improving coordination of the activities of all relevant ministries and agencies.
- Strengthening controls on the import of medicines.
- Strengthening the personal responsibility of distribution network staff.
- Mobilizing international cooperation on medicine quality control.
- Providing information on advances in medicines.
- Developing measures to support pharmaceutical manufacturers.<sup>35</sup>

The failure of the current system to satisfy the demand for medicines has led to the proliferation of so-called miracle products, which are, at best, merely generic products, and at worst, ineffective or even dangerous counterfeit drugs. These types of products are poorly regulated in many countries, and the scale of their proliferation has resulted in overwhelming damage to national health care systems.<sup>36</sup> Nevertheless, the indicated recommendations, despite the problems they face regarding their implementation, are oriented towards a

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<sup>34</sup> SCP 19th Session, *Patents and Health: Comments Received from Members and Observers of the Standing Committee on the Law of Patents*, WIPO Doc. SCP/19/REF/SCP/18/INF/3 (April 11, 2012) available at: [http://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=226050](http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=226050).

<sup>35</sup> *Id.*

<sup>36</sup> It is not only regulation that has required them to avoid these practices, which constitute crimes in some jurisdictions, but harmonization with international legislation to effectively combat international proliferation and commercialization. Much of this activity is already in the hands of actual criminal organizations.



more equitable balance between the property rights of medical patent holders and the right to health.

In the knowledge society, such a balance may be achievable when we consider a country such as Switzerland, which, despite having limited natural resources, has achieved the highest standards in the areas of human rights and the delivery of health services due to its enormous scientific and technological potential. This demonstrates that the patent system could be an instrument that could contribute to the full realization of the human right to health.<sup>37</sup>

However, the debate between developing and developed countries, or poor and rich countries, reveals a conflict. While the interest of developing countries is to increase access to patented medicines, the interest of developed countries is to protect inventors and proceed cautiously. This conflict of interests and positions was on display during the sixteenth session of the Standing Committee on the Law of Patents (SCP),<sup>38</sup> where South Africa, the African Group, and the Development Agenda Group (DAG), presented a work program on the topic of patents and health (SCP/16/7) that stated:

The proposed work program seeks to enhance the capacities of Member States, and particularly developing countries and least developed countries (LDCs), to adapt their patent regimes to make full use of the flexibilities available in the international patent system to promote public policy priorities related to public health. This work program is composed of three interlinked elements that are to be pursued simultaneously...

These three elements are respectively: (i) the elaboration of studies to be commissioned by the WIPO Secretariat, following consultations with the Member States at the SCP, from renowned independent experts; (ii) information exchange among Member States and from leading experts in the field; and (iii) the provision of technical assistance to Member States, and particularly developing countries and least developed countries (LDCs), in relevant areas, and building upon work undertaken in the first two elements of the work program.<sup>39</sup>

The above position, which was laudable and would have operated to the benefit of a large part of the international community—particularly the least developed or less developed countries—was opposed by the United States. The proposal offered by the United States (SCP/17/11) claimed that the

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<sup>37</sup> The 2019 Human Development Report presents the 2018 HDI (values and ranks) for 189 countries and UN-recognized territories, along with the Human Development Index (HDI) for 150 countries, the Gender Development Index (GDI) for 166 countries, the Gender Inequality Index (GII) for 162 countries, and the Multidimensional Poverty Index (MPI) for 101 countries. Switzerland's HDI value for 2018 is 0.946—which put the country in the very high human development category—positioning it at 2 out of 189 countries and territories. Between 1990 and 2018, Switzerland's HDI value increased from 0.832 to 0.946, an increase of 13.7 percent.

<sup>38</sup> *Supra* note 34.

<sup>39</sup> SCP 16th Session, *Proposal by the Delegation of South Africa on Behalf of the African Group and the Development Agenda Group*, WIPO Doc. SCP/16/7 (May 20, 2011) available at: [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_16/scp\\_16\\_7.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_16/scp_16_7.pdf).

South African proposal would not only weaken patent protection but would result in little benefit since most essential medicines are not protected by patents and insufficient delivery of medicines is the result of factors not related to patents. The proposal by the United States stated:

Weakening patent protection for innovative medicines is not a productive approach to improving availability of health care, because many other factors other than patents more directly affect the availability of medicines. It is known that patent protection has expired or was never sought for the vast majority of medicines on the WHO's List of Essential Medicines. As stated by the WHO,<sup>40</sup> in many countries, especially LDCs, there is no evidence of patent activity for medicines added to the EML, and for those countries where patents have been identified, the patents may not be valid, may be expired or may not be relevant. In fact, only about 4% of the medicines on the EML are presently protected by patents.

Many of the medicines on the EML once were protected by patents and were originally developed in large part due to the protection afforded to their developers by the patent system. This fact further highlights the large volume of important medicines that were developed under intellectual property protections and that subsequently became available from other manufacturers upon the expiration of the relevant patents...

By analyzing the reasons why unpatented, [*sic*] medicines do not reach the intended patients, it is possible to determine what are the factors not related to patents that impede their availability. These factors would naturally affect the availability of all medicines.<sup>41</sup>

The United States made three specific proposals directed at identifying all barriers, including non-patent barriers, to the availability of medicines in less developed countries. These proposals were:

- a) Inviting the WHO to make a presentation to the SCP on the availability of generic medicines in DC/LDCs, on the non-patent barriers to the availability of safe and effective medicines that are encountered in many countries, and on the effect of falsified medicines, both generic and patented, on the availability of proper medicines. This presentation would help to put in context the potential effect of patents, as compared to the effect of other factors, on the availability of medicines.
- b) Conducting a comprehensive study on the positive impact of patent systems on providing lifesaving medicines to developing countries. The study would evaluate the role of patent protection in providing incen-

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<sup>40</sup> WHO/WTO/WIPO Technical Symposium, *The patent status of medicines on the WHO model list of essential medicines*, Comments by Richard Laing (February 2011) (this is the referenced article in cited material).

<sup>41</sup> SCP 17th Session, *Patents and Health: Proposal of the United States of America*, WIPO Doc. SCP/17/11 (December 7, 2011) available at: [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_17/scp\\_17\\_11.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_17/scp_17_11.pdf).

tives for research and development leading to innovative medicines and in fostering the technology transfer necessary to make generic and patented medicines available in DC/LDCs.

- c) Conducting a comprehensive study to examine the availability of life-saving medicines that are not protected by patents and the reasons for their lack of availability.<sup>42</sup>

The proposed goals included not only an assessment of the availability of medicines in the various markets, but also the detection of counterfeit medicines, which evade law enforcement and endanger the health of the population.

Organizations such as Knowledge Ecology International (KEI)<sup>43</sup> criticized the US proposal.<sup>44</sup> KEI highlighted the monopolistic nature of the patent system, which increases the prices of, and inhibits access to, medicines, both of which adversely affect the right to health.

Previous proposals presented at the SCP were framed within the context of public international law. These proposals had been written in such a way that they not only remained within the scope of international negotiations in general, but specifically adhered to the requirements of the various international treaties that confer obligations on the relevant states and organizations. One example, mentioned in this paper above, is TRIPS which established uniform legal standards for the protection of intellectual property.

In addition to these, in order to reach the right to health as an integral part of current public policies, there is in Doha Declaration, which not only reflects previous positions but also points out in the TRIPS Agreement its ambit for members of the WTO in matters of public health and access to medicines, as mentioned in the Global Strategy and Action Plan on Public Health, Innovation, and Intellectual Property Rights of the World Health Organization of 2008.<sup>45</sup>

The United States proposal reveals the profound differences between the interests of rich and poor countries. In fact, it is in everyone's interest to health find a just and equitable model that can protect patent holders, expand the list of vital medicines, and increase accessibility to health care services for those most in need.

War, internal armed conflicts, and pandemics, such as COVID-19, aggravate the situation for people living in environments already affected by humanitarian crises. Through international organizations such as the United Nations, the international community makes efforts to direct humanitarian aid to areas suffering from armed conflicts and other disasters. In the case of the

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<sup>42</sup> *Id.*

<sup>43</sup> Thiru, *KEI submission to WIPO patent committee commenting on the US proposal on patents and health*, KNOWLEDGE ECOLOGY INTERNATIONAL (February 29, 2012), available at: <https://www.keionline.org/21803>.

<sup>44</sup> *Id.*

<sup>45</sup> *Supra* note 34.

COVID-19 pandemic, the United Nations, world health organizations, governments, businesses, scientists, the private sector, and civil society, all worked together to create a vaccine delivery mechanism called COVAX, which was designed to act as a “humanitarian buffer”.<sup>46</sup> This initiative was implemented to help distribute COVID-19 vaccines after global leaders had called for a solution that would accelerate the development and manufacture of COVID-19 vaccines, diagnostics, and treatments, and would guarantee rapid and fair access for people in all countries. Implementation of COVAX was necessary to promote access to medicines and vaccines for people who were not protected against deadly diseases such as COVID-19 and to minimize the number of deaths resulting from that virus. Additionally, COVAX guaranteed that the inability to pay would not be a barrier for vulnerable populations that need access to treatment. Nevertheless, COVAX has faced numerous political, legal, and operational challenges.

## V. CONCLUSIONS

As we approach the quarter of the 21st century, there is still a keen interest in expanding intellectual property rights, as it is a key component of the knowledge-based economy. Scientific and technological advances sometimes require legislative changes, but the ideal model would proceed by first establishing an international standard that national legislators could look to for guidance in adapting that standard to the local context. The same holds true for the international standardization of human rights, especially considering that these rights often depend on the protection of other related rights necessary for their full realization. Some of these other rights include the right to education, the right to technological advancement, and the right to food, medical care, and work, just to name a few. The goal should be to promote scientific and technological research, development, and innovation while simultaneously working to balance intellectual property rights with the people’s right to health. Ensuring access to necessary medicines is a fundamental component of a genuine right to health.

In times characterized by economic interdependence and globalization, the international system cannot function without international organizations capable of fostering peaceful coexistence between nations. WIPO plays a key role in intellectual property law, finding ways to reconcile property rights with human interests and needs, such as was done with the TRIPS Agreement. However, WIPO could go beyond the changes adopted in the Amendment to the TRIPS Agreement that allow less developed countries to obtain patented drugs from third countries without the authorization of the patent holder.

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<sup>46</sup> Security Council Resolution, February 26, 2021 U. N. Doc. S/RES/2565 (2021) available at: <https://documents-dds-ny.un.org/doc/UNDOC/GEN/N21/053/90/PDF/N2105390.pdf?OpenElement>.

WIPO could serve as a mediator between governments and patent holders to streamline access to patents for essential medicines, most importantly in emergency situations. This issue needs to be considered more in the Doha Declaration and the other instruments of international law. Special regimes could be designed allowing free access to medicine, a reduction of costs, and the temporary exploitation of medical patents, all of which would help the right to health attain its appropriate status as a genuine human right. This would be particularly important for developing countries.

The development and defense of both intellectual property rights and human rights depend on a solid educational system. Furthermore, the development of each individual's capacities depends on the genuine enforcement of human rights. The right to health, in fact, precedes all other human rights, since no one can achieve their optimal realization if they are not healthy. Intellectual property rights have their origins in traditional property rights. Intellectual property creates value, which invigorates the economy at the micro and macro levels, as well as at the national and international levels. The pharmaceutical industry demonstrates the ever-expanding reach of intellectual property. However, to the degree it does expand, access to life-saving medicines for the most vulnerable people living in less developed countries needs to expand as well.

Pharmaceutical companies should contribute to the realization of the right to health and help to generate conditions that permit access to essential medicines, especially in emergency situations. The pharmaceutical industry could also work with governments to fashion rules defining the circumstances under which a reduction of costs or the donation of certain essential medicines are warranted. This could include the donation of medical patents, in accordance with national and international laws, in a way that would not affect their cost or create unfair competition with regard to other companies.

Despite its importance, COVAX does not resolve the issue of monopoly control of knowledge related to medicines and vaccine patents. Currently, only compulsory licenses permit using patents for generic medicines. Alternatives to this system are only limited by the negotiating capacity of governments regarding the treaties they sign. One example might include creating "TRIPS-plus" clauses that mutually benefit all states parties in emergency situations.

The goal of international law should be to find ways to promote the recognition and enforcement of human rights in a globalized system that continues to privilege economic rights over human rights. Failure to do so will result in a continuation of the problematic circumstances in which we currently find ourselves, circumstances that led Stephen Hawking to sarcastically announce, "We think we have solved the mystery of creation. Maybe we should patent the universe and charge everyone royalties for their existence".<sup>47</sup>

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<sup>47</sup> *Stephen Hawking: Questioning the Universe*. YouTube: TED (2008) (accessed Feb. 19th, 2023) available at: <https://www.youtube.com/watch?v=xjBIsp8mS-c>.