World Health Assembly (WHA)

INTELLECTUAL PROPERTY IN PHARMACEUTICAL DEVELOPMENT

Research Report

Leiden Model United Nations 2023

"Let us sing songs of freedom together."

Forum: World Health Assembly

Issue: Intellectual Property in Pharmaceutical Development

Position: Deputy Chair

Introduction

The pharmaceutical sector plays a vital role in present-day healthcare, persistently aiming to innovate and provide novel treatments to enhance human health and welfare. The pharmaceutical sector relies heavily on intellectual property (IP) as a crucial factor in stimulating imaginative thinking, safeguarding investments in research, and promoting healthy competition.

The area of intellectual property within the pharmaceutical industry involves a range of legal mechanisms, including patents, trademarks, copyrights, and trade secrets. These mechanisms are designed to protect the special procedures, formulations, and research discoveries of pharmaceutical companies. These protective measures enable corporations to recover significant investments in pharmaceutical research and development, thereby guaranteeing a consistent supply of novel treatments to the industry.

Definition of Key Terms

Intellectual Property:
Intellectual property (IP) refers to conceptual creations such as inventions, literary and artistic works, designs, and commercially used symbols, names, and images.

Pharmaceutical Development:
Pharmaceutical development covers the comprehensive process of designing, developing, manufacturing, and optimizing medicinal products intended for utilization in clinical studies and subsequent commercialization.

Clinical Trials:
Clinical trials are scientific investigations that evaluate the effectiveness and safety of medicinal, surgical, or behavioral interventions in human subjects. Clinical trials serve as the principal method by which researchers ascertain the safety and efficacy of novel treatment or preventive measures, including but not limited to pharmaceuticals, dietary interventions, and medical devices such as pacemakers in human subjects.

Patent:
A legally binding document that grants to inventors the exclusive entitlement to their inventions for a specified time frame, commonly lasting 20 years. This prevents third parties from engaging in the manufacture, use, commercialization, or importation of the patented product.

Parallel Importing:
The unauthorized importation and selling of patented drugs between countries, without the consent of the patent owners, is frequently justified by the notion of intellectual property rights exhaustion.

TRIPS Agreement:
The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a globally recognised treaty overseen by the World Trade Organisation (WTO). Its primary objective is to establish a baseline of intellectual property (IP) protection norms, including many aspects such as pharmaceutical patents.

Research and Development (R&D):
Research and development (R&D) is an essential tool for business growth and improvement. Research and development entails conducting market and customer requirements research and developing new and improved products and services to meet these needs.

General Overview

Intellectual property (IP) incorporates a wide range of original creations generated by the human intellect, including artistic, literary, technical, and scientific works. Intellectual property rights (IPR) include the legal entitlements bestowed upon inventors or creators, serving as a means to safeguard their inventions or creations for a specified duration. Among various technological areas, medications and pharmaceuticals exhibit the most prominent characteristics of globalization, thereby requiring an effective intellectual property (IP) framework. Considering the significant financial investment required for the introduction of a new pharmaceutical treatment onto the market, along with all of the risks involved with the developmental phase, it is understandable that companies are unwilling to expose their IP to the chance of becoming publicly accessible without comparable monetary rewards. The combination of activities related to the creation, acquisition, safeguarding, and administration of IP should be treated as an essential corporate function, similar to the processes involved in acquiring resources and cash.

Patents

Patents serve as a major motivation for the promotion of research in the field of novel pharmaceuticals. The purpose of its design is to offer a finite duration of exclusive rights to inventors, allowing them to monetize their ideas regardless of the technological area. This approach aims to stimulate investment in the advancement of research and technology. Patents are exclusively awarded to innovations and creations that possess originality, form a non-obvious inventive element, and demonstrate potential for industrial use.

A patent confers the privilege of preventing others from engaging in commercial exploitation of their innovation for a specified duration of 20 years from the date of filing. This duration commences after research demonstrates the viability of the invention. In exchange for exclusivity, the creator is required to make public the particular details of the invention, so facilitating the widespread distribution of scientific and technological knowledge. This in turn aids in accelerating further advancements in innovation.

Supplementary Protection Certificates (SPCs)

In contrast to numerous other businesses, approximately half of the typical 20-year patent duration in the pharmaceutical sector is allocated to the thorough conduction of clinical trials. These trials serve the purpose of substantiating the safety and effectiveness of the medicine, hence ensuring its suitability for administration to patients. In response to this drawback, the European Union (EU) implemented supplementary protection certificates (SPCs) as a means to mitigate a portion of the patent term reduction and guarantee the provision of adequate protection, thereby sustaining the promotion of sustainable and suitable funding for future advancements in biopharmaceutical research

and development. In practical use, the Supplementary Protection Certificate (SPC) reaffirms a portion of the patent protection for a duration of up to 5 years, subject to individual determination in each situation. The combined duration of patent and supplementary protection certificate (SPC) safeguarding, commencing with the authorization of marketing, must not exceed a maximum of 15 years.

Regulatory Data Protection (RDP)

Pharmaceutical businesses are required to provide comprehensive data concerning preclinical and clinical trials in order to acquire a marketing license. This data serves to substantiate the quality, productivity, and safety of the medicine seeking approval. Regulatory data protection (RDP) serves as a safeguard for creative businesses, protecting their investment in the creation of a substantial collection of data. This protection entails a restricted duration of exclusivity on the data, commencing from the moment of marketing authorization

After the RDP period, generic manufacturers are authorized to utilize the originator's data in order to seek clearance for their goods via an "abbreviated" application. The implementation of time-limited protection is of utmost importance in order to provide motivation for the substantial expenditure required to establish the safety and effectiveness of novel pharmaceuticals. Simultaneously, this approach allows other companies to eventually register their own drugs based on the facts mentioned above.

Research & Development in the Pharmaceutical Sector

Research and development (R&D) is the basis for the discovery of innovative medicines and vaccines that improve the lives of patients.

In general, the R&D process comprises basic and translational research, as well as the development of medicines and vaccines:

- Primary research: investigates the biological bases of disease and potential therapeutic targets. Often performed in close collaboration by academic research centers, government agencies, and the private sector.

- Translational research connects new knowledge about a process or compound to a practical medical application or therapy. Typically carried out by bio-pharmaceutical firms.

- Medicine and Vaccine development: Clinical trials are used to investigate the safety and efficacy of new medications and vaccines. Typically carried out by bio-pharmaceutical firms.

Investing in Medicines for specific populations

Medicines for children: The adoption of the Paediatric Regulation in 2007 aimed to enhance the facilitation of the creation and accessibility of high-quality pharmaceutical products that are appropriate for the pediatric group. The implementation of the Regulation has played a significant role in integrating pediatric research into the broader field of pharmaceutical development. It has placed responsibilities on pharmaceutical companies to conduct research and advance their products not just for adult populations but also for children.

Orphan Medicines: According to the European Union (EU), a rare disease can be defined as a medical condition that impacts less than five individuals per 10,000 population. There exists an

extensive number of more than 6,000 distinct rare diseases, with an estimated 30 million individuals in Europe being affected by them. The EU Orphan Medicinal Products (OMP) Regulation incorporates various strategies to promote the advancement of pharmaceuticals for rare diseases. These strategies encompass protocol assistance, which entails regulatory guidance on the development of programmes, as well as a 10-year period of market exclusivity following the initial authorization for marketing. Additionally, the regulation offers fee reductions specifically targeted towards small and medium-sized enterprises (SMEs).

Major Parties Involved

World Trade Organisation (WTO)

The World Trade Organisation (WTO) is responsible for the administration of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement holds significant importance in the facilitation of trade in knowledge and innovation, the resolution of trade disputes related to intellectual property, and the provision of flexibility for WTO members to pursue their domestic goals. The Agreement represents the legal acknowledgment of the substantial connections existing between intellectual property and trade. The TRIPS Agreement of the World Trade Organisation (WTO) aims to reduce inequalities in the protection and enforcement of intellectual property rights globally, while establishing uniform worldwide regulations for such rights. The agreement sets forth a set of minimal requirements for the protection and enforcement of intellectual property rights, which must be provided by each government to safeguard the intellectual property held by citizens of other World Trade Organisation (WTO) member countries.

World Intellectual Property Organisation (WIPO)

The World Intellectual Property Organisation (WIPO) is a specialized organization of the United Nations that is dedicated to the promotion and protection of intellectual property. The platform facilitates worldwide collaboration, advocates for the protection of intellectual property rights, and provides valuable resources and recommendations for the effective management of intellectual property in several industries, including the pharmaceutical sector. Although WIPO's jurisdiction includes more than only the pharmaceutical sector, it significantly contributes to the intellectual property (IP) industry. The organization establishes a connection between their intellectual property (IP) management practices and the United Nations' sustainable development goals, as well as other significant global concerns under discussion.

Médecin Sans Frontière (Doctors without Borders)

Médecins Sans Frontières (MSF) is a globally recognised international humanitarian organization that was established in 1971. Médecins Sans Frontières (MSF) provide medical care and humanitarian aid to people impacted by various crises, covering armed conflicts, natural disasters, epidemics, and other emergent situations. One of the primary areas of focus for Médecins Sans Frontières (MSF) is the promotion of access to vital medications. To accomplish this goal, they actively engage in efforts to challenge the intellectual property practices of pharmaceutical companies. Médecins Sans Frontières (MSF) is recognised for its proactive involvement in addressing the intellectual property (IP) practises of pharmaceutical corporations that limit the availability of vital medications. Frequently, they are faced with challenges related to patents, pricing, and monopolistic practices maintained by pharmaceutical corporations. They argue that the adoption of rigorous patent protections has the potential to result in increased prescription prices, rendering essential medications financially

unavailable to a significant number of patients, particularly those residing in low- and middle-income nations. This can potentially lead to needless instances of human suffering and death.

United States of America

The United States plays a significant role in pharmaceutical research and development, and its influence on global intellectual property (IP) policies and regulations is widespread and complex. The United States is home to a substantial pharmaceutical industry, which consists of numerous multinational corporations, research-intensive biotechnology firms, and prestigious academic institutions. The prevalence of these entities promotes innovation and propels global pharmaceutical research and development (R&D). They are a pioneer in biotechnology, an essential sector for the development of advanced therapies such as biologics and gene therapies. American biotechnology innovations have had a significant impact on global healthcare. In addition, the U.S. pharmaceutical market is among the largest in the world, and its purchasing power has a significant impact on drug pricing and commercialization strategies. How pharmaceutical companies price their products in the United States frequently serves as a model for international pricing. As a significant global player, the United States holds considerable influence over international IP agreements and trade negotiations. For instance, it played a pivotal role in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) negotiations.

India

India is an active producer of generic pharmaceuticals, and as a result, it has a substantial impact on drug access and pricing globally. The country possesses a flourishing and fiercely competitive sector dedicated to the production of generic pharmaceuticals. The primary objective of this sector is the production of unbranded pharmaceuticals, both patented and off-patent, at reduced costs compared to their branded equivalents. Indian pharmaceutical businesses have made significant investments in advanced manufacturing facilities and methods, which have empowered them to manufacture generic medications of superior quality that adhere to global standards. Their businesses are able to create medicines at a more affordable price due to the cost advantages associated with manufacturing in India, which include lower labor and production expenses. This results in reduced pharmaceutical costs for global consumers. Indian civil society organizations and advocacy groups strive to enhance the availability of pharmaceuticals and lobby for reasonable pricing. They actively participate in legal and regulatory campaigns to guarantee that intellectual property (IP) safeguards do not hinder access. India is commonly recognised as the "pharmacy of the developing world" because of its significant contribution in providing cost-effective pharmaceuticals to nations with lower economic statuses. The Indian generic pharmaceutical industry has significantly contributed to the reduction of global health concerns, namely in the context of HIV/AIDS and tuberculosis.

China

In the pharmaceutical industry, China's growth as a powerhouse in pharmaceutical research, production, and its expanding position in global drug development and intellectual property (IP) is a significant development. The pharmaceutical business in China has experienced significant growth. The region hosts an extensive variety of pharmaceutical companies, containing both prominent state-owned enterprises and innovative startups. They actively participate in the field of biotechnology, involving gene therapy, cell therapy, and precision medicine. It has made substantial progress in several domains and is actively involved in the advancement of breakthrough therapeutic approaches. China has emerged as a key global hub for conducting clinical studies. The presence of a sizable and varied patient groups, along with an increasing number of clinical trial locations and scientists, renders it an appealing destination for international pharmaceutical corporations.

Timeline of Events

1960-1970s	TRIPS Agreement: During this time, negotiations for the General Agreement on Tariffs and Trade (GATT) established the groundwork for the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which later became part of the World Trade Organisation (WTO). The TRIPS Agreement established international standards for the protection of intellectual property, including pharmaceutical patents.
December 12th 1980	Bayh-Dole Act (U.S.): The United States passed the Bayh-Dole Act, which permits universities and research institutions to retain intellectual property rights for inventions funded by federal grants. This law facilitated the transfer of technology and the commercialization of research, including pharmaceutical discoveries.
January 1st 1995	Establishment of the WTO: With the establishment of the World Trade Organisation (WTO), TRIPS entered into force. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) required WTO members to provide patent protection for pharmaceuticals, affecting global access to medications.
November 14th 2001	Doha Declaration on TRIPS and Public Health: The WTO Ministerial Conference in Doha issued a declaration affirming public health's primacy over IP rights. It clarified that TRIPS should not prevent countries from implementing measures to safeguard public health, such as access to essential medicines.
2005	Access to Medicines via TRIPS Flexibilities: The WTO issued a decision allowing countries with insufficient manufacturing capacity to import generic versions of patented medicines during public health emergencies. This decision was intended to improve access to medications in developing nations.
2006	WHO's Global Strategy and Action Plan on Public Health, Innovation, and Intellectual Property: The World Health Organisation (WHO) developed this strategy to examine the connections between intellectual property (IP), innovation, and public health. It highlighted the need for a balanced approach to intellectual property rights in the pharmaceutical industry.
2012	Doha Amendment to TRIPS: The WTO adopted the Doha Amendment, which permits countries to import generic medicines for noncommunicable diseases, thereby facilitating access to essential medicines in developing nations.
2020	COVID-19 Pandemic: The pandemic emphasized the significance of worldwide access to medications and vaccines. The issue of intellectual property (IP) rights and equitable distribution of COVID-19 vaccines has become a focal point of discussion, with demands for temporary waivers of certain IP protections to increase vaccine production and distribution.

Possible Solutions

Voluntary Licensing Agreements:

Voluntary licensing agreements refer to the voluntary granting of licenses by pharmaceutical corporations to generic manufacturers, especially in low- and middle-income nations. These licenses let businesses to produce and distribute cost-effective versions of patented pharmaceuticals. The primary objective is to achieve a harmonious equilibrium between the safeguarding of intellectual property rights and the facilitation of availability and affordability of pharmaceutical products. Pharmaceutical corporations utilize this approach to maintain their intellectual property rights while simultaneously addressing the issue of accessibility to medications in regions where their affordability may be limited.These agreements have the potential to be negotiated either bilaterally or with the involvement of intermediate bodies such as the Medicines Patent Pool (MPP). The MPP serves as a facilitator in talks between patent holders and generic producers.

Various terms can be provided by companies in these agreements, including royalty fees, geographical reach, and duration. Certain agreements could additionally include the provision of technology transfer as a means to facilitate the development of industrial capabilities within economically disadvantaged nations.

Voluntary licensing agreements have the potential to enhance accessibility to vital medications in places that are lacking in adequate healthcare services. They facilitate collaboration between pharmaceutical corporations and generic manufacturers, fostering a heightened level of competition within the marketplace. Nevertheless, the obstacles involving the terms associated with voluntary licenses exhibit variation and may not always yield the most optimal medicine costs. The process of negotiations can exhibit a high degree of complexity and may not comprehensively address ensuring the inclusion of all essential medications or geographic areas.

Patent Pooling:

The practice of patent pooling involves the collaboration of numerous patent holders, typically pharmaceutical corporations, who combine their own patents that concern a particular field or disease into a single pool. Subsequently, generic manufacturers are able to obtain access to these patents via a unified license, thereby reducing the procedure involved in manufacturing and distributing generic versions of essential medications. Patent pooling programmes, such as the Medicines Patent Pool (MPP), primarily concentrate on important medications used in the treatment of diseases such as HIV/AIDS, TB, and hepatitis C. Low- and middle-income countries frequently experience a disproportionate burden of these diseases. Patent pools engage in the process of negotiating licensing arrangements with patent holders, thereby facilitating the production of cost-effective versions of certain pharmaceutical products by generic manufacturers, specifically tailored for designated geographical areas. Through the combining of patents, patent pools effectively shorten the licensing procedure, resulting in a reduction of administrative hassles and legal intricacies.

The practice of patent pooling has been shown to enhance the availability of essential medications, particularly in environments with limited resources. It facilitates cooperation between patent holders and generic manufacturers towards a shared objective of public health. Nevertheless, there are certain issues that need to be addressed. There may exist a lack of willingness among certain patent holders to engage in the participation of patent pools. The task of ensuring that the licenses given through patent pools contain a wide geographical and therapeutic scope that can present difficulties.

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