Journal of Intellectual Property
Vol. 6 No. 2 Tahun 2023

INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND HEALTHCARE: HARMONIZING THE LEGAL PROVISIONS FOR HEALTHCARE AND PHARMACEUTICAL INDUSTRY

Dr. Bhupinder Singh
Proffessor
Sharda School of Law, Sharda University Greater Noida, India.

Contact: talwandibss@gmail.com

Diterima: 1 Agustus 2023
Direvisi: 5 Agustus 2023
Disetujui: 10 Agustus 2023
Halaman:

ABSTRACT

The healthcare sector is being impacted by information technology advancements in four key ways: first, a wide range of tasks that were previously performed manually can now be performed by computers; second, some tasks can be outsourced to other countries using affordable communications technology; third, longitudinal and societal healthcare data can now be analyzed in acceptable amounts of time; and fourth, the best medical expertise can sometimes be made available. The healthcare industry will increasingly employ a portfolio approach made up of three closely coordinated components that are seamlessly integrated together: healthcare tasks performed by humans on-site; healthcare tasks performed by humans off-site, including tasks performed in other countries; and healthcare tasks performed by computers without direct human involvement. The three-pronged healthcare services paradigm is discussed in this essay along with relevant legal and intellectual property issues.

Keywords: Health, Innovation, IPR, Legal Provisions, Medicines

INTRODUCTION

The healthcare sector signifies intellectual property rights are often used to protect innovations and investments made in the development of new drugs, medical devices, and other health technologies. Patents, in particular, are commonly used to protect these innovations by giving inventors exclusive rights to produce and market their products for a certain period. While intellectual property rights can incentivize the development of new health technologies, they can also create barriers to access for those who cannot afford the high prices associated with patented drugs and medical devices. This is particularly true for developing countries, where the cost of patented drugs and medical technologies can be prohibitive, making it difficult for people to access essential healthcare services. To address these challenges, governments and international organizations have implemented various policies and initiatives aimed at balancing the interests of innovators and patients. For example, some countries have implemented compulsory licensing laws that allow for the use of patented technologies without the consent of the patent holder, usually in cases where the technology is deemed essential for public health. Another approach to increasing access to healthcare technologies is through technology transfer programs, where patented technologies are licensed to developing countries or non-profit organizations to produce generic versions of drugs and medical devices at lower prices. Intellectual property rights play a critical role in the development of new health technologies, but they can also create barriers to access for those who need them the most. Governments and international organizations must continue to explore innovative approaches to balance the interests of innovators and patients to ensure that essential health technologies are accessible to all.

PROBLEM FORMULATION

This paper inspect that how the legal regime concerning intellectual property touches the accessibility of medicines for public and recognize ways of supporting breakthrough inventions and counter.

RESEARCH METHODOLOGY

The research used a variety of scientific methodologies to gather generalised data from monographs and scientific publications with a focus on medicine and law. In particular, under a methodical approach, issues with the pharmaceutical industry and methods of creating both generic and brand-name medications were examined. Comparative legal analysis was helpful for understanding the TRIPS Agreement's flexible procedures and global market regulations for pharmaceuticals.

DISCUSSION AND RESULTS

Based on the study, it was discovered that industrialized nations with a robust pharmaceutical sector,

particularly importing nations, are interested in maximizing the protection of intellectual property rights. For developing nations, the TRIPS Agreement's flexible processes may be helpful.

Patents and Health Technologies

Patents can have a significant impact on the development and availability of health technologies. Patents are legal protections that give inventors the exclusive right to use, make, and sell their invention for a specified period. In the case of health technologies, such as drugs or medical devices, patents can provide the necessary incentive for companies to invest in research and development to create new treatments. It can encourage innovation by providing inventors with an opportunity to recoup their investments and earn profits from their discoveries. This can lead to the development of new and better health technologies that can save lives and improve quality of life. However, patents can also be a barrier to access for those who cannot afford to pay the high prices that often accompany patented health technologies. In the case of pharmaceuticals, for example, patents can prevent generic versions of drugs from being developed and sold at lower prices. This can make it difficult for people in low- and middle-income countries to access life-saving treatments. Some argue that this creates a moral dilemma, where the right to access to essential health technologies is pitted against the right of inventors to benefit from their discoveries. To balance the interests of inventors and patients, some countries have implemented laws and regulations that allow for compulsory licensing of patented health technologies. Compulsory licensing allows a government to grant a license to a third party to manufacture and sell a patented technology without the consent of the patent owner, usually in cases where the technology is deemed essential for public health. Patents can have both positive and negative effects on the development and availability of health technologies. While patents can provide incentives for innovation, they can also create barriers to access for those who cannot afford the high prices of patented technologies. Governments and international organizations must continue to explore ways to balance the interests of inventors and patients to ensure that essential health technologies are available to all who need them.

Innovation in drugs and healthcare

Innovation in drugs and healthcare is essential for improving patient outcomes and addressing unmet medical needs. The development of new drugs and medical technologies can lead to better treatments, more efficient healthcare delivery, and improved patient outcomes. One of the primary drivers of innovation in drugs and healthcare is research and development (R&D). Pharmaceutical companies invest heavily in R&D to

discover new drugs and medical technologies, often taking several years and billions of dollars to bring a new drug to market. In recent years, there has been a growing emphasis on collaboration and partnerships between different stakeholders, including academia, government, and industry, to facilitate innovation in healthcare. Innovation in drugs and healthcare is not limited to the development of new drugs or medical devices. It also includes the development of new delivery models and technologies that can improve patient outcomes and reduce healthcare costs. For example, the use of telemedicine and remote monitoring technologies has the potential to improve patient access to care and reduce the burden on healthcare systems. Another area of innovation in healthcare is the use of data and analytics. The ability to collect and analyze large volumes of data from multiple sources, including electronic health records, wearables, and social media, has the potential to improve patient outcomes, personalize treatments, and enhance healthcare delivery. It is essential for improving patient outcomes and addressing unmet medical needs. Collaboration between different stakeholders, investment in R&D, and the development of new delivery models and technologies are critical drivers of innovation in healthcare. The continued focus on innovation in healthcare has the potential to transform patient care and improve health outcomes.

Profiling of healthcare sector

The healthcare sector is a vast and diverse industry that includes various stakeholders, such as healthcare providers, pharmaceutical and medical device companies, payers, policymakers, and patients. Here are some key areas of profiling the healthcare sector:

Healthcare providers: This includes hospitals, clinics, nursing homes, and other healthcare facilities that provide medical services to patients. Healthcare providers can be categorized based on the type of care they offer, such as primary care, specialty care, or emergency care.

Pharmaceutical companies: These are companies that develop, manufacture, and market drugs and other pharmaceutical products. Pharmaceutical companies can be categorized based on the type of drugs they develop, such as generic drugs, branded drugs, or biologics.

Medical device companies: These are companies that design, develop, and manufacture medical devices, such as surgical instruments, diagnostic equipment, and prosthetic devices. Medical device companies can be categorized based on the type of device they produce, such as implantable devices, monitoring devices, or therapeutic devices.

Payers: Payers are organizations that provide financial coverage for healthcare services, including health insurance companies, government programs such as Medicare and Medicaid, and self-insured employers.

Policymakers: Policymakers are individuals or organizations that develop and implement policies related to healthcare, such as government agencies, regulatory bodies, and professional associations.

Patients: Patients are individuals who receive healthcare services and are the focus of the healthcare sector. Patients can be categorized based on their health status, such as those with chronic illnesses, those who require long-term care, or those who require emergency care.

The healthcare sector is a complex and diverse industry that includes various stakeholders. Profiling the healthcare sector can help us better understand the roles and responsibilities of different stakeholders and how they contribute to the delivery of healthcare services.

Impact of Disease Burden: Health Profile

The disease burden and health profile of a population can have a significant impact on the healthcare sector, including healthcare delivery, resource allocation, and healthcare costs. Here are some ways in which disease burden and health profile can impact the healthcare sector:

Healthcare delivery: The disease burden and health profile of a population can influence the types of healthcare services needed and the frequency of healthcare visits. For example, populations with high rates of chronic diseases, such as diabetes or heart disease, may require more frequent visits to healthcare providers and specialized care to manage their conditions.

Resource allocation: The disease burden and health profile of a population can also impact the allocation of healthcare resources, such as funding, personnel, and medical supplies. Populations with higher disease burdens may require more resources to manage their conditions, which can strain healthcare systems and lead to resource shortages.

Healthcare costs: The disease burden and health profile of a population can also impact healthcare costs. Populations with higher rates of chronic diseases may require more expensive treatments, medications, and medical procedures, which can drive up healthcare costs.

Public health interventions: Understanding the disease burden and health profile of a population can help policymakers and healthcare providers develop targeted public health

interventions, such as vaccination programs or disease prevention campaigns, to address specific health needs.

Research and development: The disease burden and health profile of a population can also influence research and development priorities in the healthcare sector. Populations with higher disease burdens may receive more attention from researchers and funding agencies, leading to the development of new treatments and interventions.

The disease burden and health profile of a population can have a significant impact on the healthcare sector. Understanding these factors can help policymakers, healthcare providers, and researchers develop targeted interventions, allocate resources effectively, and improve healthcare delivery for all populations.

IPR aspects in New Drug Discovery

The process of discovering and developing a new drug can be lengthy and expensive, and intellectual property rights (IPR) play a critical role in incentivizing innovation in the pharmaceutical industry. Here are some key IPR aspects related to new drug discovery:

Patents: Patents are one of the primary forms of IPR protection for new drugs. In most countries, a patent is granted to an inventor or assignee who has developed a new and non-obvious drug or compound. A patent gives the holder exclusive rights to manufacture, sell, and distribute the drug for a set period of time, typically 20 years from the date of filing.

Trade Secrets: Pharmaceutical companies may also protect their new drug discoveries by keeping them as trade secrets. This involves keeping the information confidential and taking steps to prevent competitors from discovering or using the information.

Data Exclusivity: In some countries, pharmaceutical companies may also be granted data exclusivity, which is a form of IPR protection that gives the company exclusive rights to the clinical trial data they have generated for a set period of time. This period of data exclusivity typically lasts from five to ten years and prevents other companies from using the data to gain regulatory approval for similar drugs.

Regulatory Exclusivity: Regulatory exclusivity is a form of IPR protection that is granted by regulatory agencies, such as the US Food and Drug Administration (FDA). This exclusivity gives the company exclusive rights to market and sell the drug for a set period of time, typically five years, after the drug has been approved by the regulatory agency. This form of exclusivity is intended to incentivize drug development by providing the company with a period of market

exclusivity to recoup their investment in research and development.

Licensing: Pharmaceutical companies may also license their IPR to other companies in exchange for royalties or other forms of compensation. This allows the company to generate revenue from their IPR while also allowing other companies to develop and market the drug.

Intellectual property rights play a critical role in incentivizing innovation in the pharmaceutical industry, particularly in the area of new drug discovery. Patents, trade secrets, data exclusivity, regulatory exclusivity, and licensing are all forms of IPR protection that pharmaceutical companies may use to protect their new drug discoveries and recoup their investment in research and development.

International Provisions: Pharmaceutical and IPR

There are several international provisions related to pharmaceuticals and intellectual property rights (IPR) that aim to promote innovation and access to affordable medicines. Here are some key international provisions related to pharmaceuticals and IPR: World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS): The TRIPS Agreement sets minimum standards for the protection and enforcement of intellectual property rights, including patents, trademarks, and copyrights. The Agreement includes provisions related to the patentability of pharmaceuticals and the use of compulsory licensing to promote access to medicines. Doha Declaration on the TRIPS Agreement and Public Health: The Doha Declaration, adopted in 2001, affirmed the right of WTO member countries to use the flexibilities provided in the TRIPS Agreement to protect public health and promote access to medicines. This includes the use of compulsory licensing and other measures to ensure access to affordable medicines, particularly in developing countries. World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property: The WHO Global Strategy and Plan of Action, adopted in 2008, aims to promote innovation, improve access to medicines, and protect public health. The Plan includes provisions related to the development of new medicines and technologies, the promotion of research and development, and the use of intellectual property rights to support these goals. Medicines Patent Pool: The Medicines Patent Pool is a United Nations-backed initiative that aims to improve access to affordable medicines for people living with HIV/AIDS, tuberculosis, and hepatitis C. The initiative includes licensing agreements with pharmaceutical companies to promote the development of generic versions of patented medicines. World Intellectual Property Organization

(WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore: The WIPO Intergovernmental Committee aims to develop international legal instruments to protect traditional knowledge, genetic resources, and traditional cultural expressions. This includes traditional medicinal knowledge, which is often used in the development of new pharmaceuticals. There are several international provisions related to pharmaceuticals and intellectual property rights that aim to promote innovation and access to affordable medicines. These include the TRIPS Agreement, the Doha Declaration, the WHO Global Strategy and Plan of Action, the Medicines Patent Pool, and the WIPO Intergovernmental Committee.

Indian Legal Provision Concerning Intellectual Property and Health

India has several legal provisions related to intellectual property and health that aim to balance the interests of innovators and public health. Here are some key legal provisions related to intellectual property and health in India: Patents: India's Patents Act, 1970 provides for the grant of patents for new inventions in all fields of technology, including healthcare. However, the Act also includes provisions for compulsory licensing, which allows the government to grant licenses to manufacture and sell patented products without the consent of the patent owner in certain circumstances, such as public health emergencies or when the patented product is not being made available to the public at a reasonable price. Trademarks: India's Trademarks Act, 1999 provides for the registration and protection of trademarks, which are used to identify and distinguish goods and services. This includes pharmaceuticals and medical devices. The Act also includes provisions for the cancellation of trademarks that are deemed deceptive or misleading. Copyrights: India's Copyright Act, 1957 provides for the protection of literary, artistic, and scientific works, including those related to healthcare. This includes protection for research papers, medical textbooks, and other healthcare-related literature. Geographical Indications: India's Geographical Indications of Goods (Registration and Protection) Act, 1999 provides for the registration and protection of geographical indications, which are used to identify goods that originate from a specific geographic region and have specific qualities, characteristics, or reputation. This includes traditional medicines and other healthcare products that are specific to certain regions. Traditional Knowledge: India's Traditional Knowledge Digital Library (TKDL) is a database of traditional medicinal knowledge that aims to prevent the misappropriation of traditional knowledge and protect the intellectual property rights of traditional knowledge holders. India has several legal provisions related to intellectual

property and health that aim to balance the interests of innovators and public health. These provisions include compulsory licensing, trademark protection, copyright protection, geographical indication protection, and traditional knowledge protection.

CONCLUSION

Therefore, in order for the pharmaceutical industry and health care to develop successfully, the following actions must also be taken: - public health improvement must be acknowledged as a primary goal of government policy; - significant state support intended to increase drug availability on the domestic market and strengthen export potential; - reduce patent protection of medicines and encourage the launch of generic copies on the market.

REFERENCES

Artikel

Gupta, A., Goyal, R. K., Joiner, K. A., & Saini, S. (2008). Outsourcing in the healthcare industry: Information technology, intellectual property, and allied aspects. Information Resources Management Journal (IRMJ), 21(1), 1-26.12-17.

Dixit, T., Srivastava, S., Sahu, S., & Selvamurthy, W. (2018). Intellectual property evolution and innovation ecosystem as effective tools in strengthening Indian healthcare sector. Current Science, 1639-1649.

Dwivedi, S., Anand, G., & Yadav, D. (2022). Intellectual property rights in healthcare: an overview. Biotechnology in Healthcare, Volume 1, 259-266.

Williams, H. L. (2016). Intellectual property rights and innovation: Evidence from health care markets. Innovation Policy and the Economy, 16(1), 53-87.

Pashkov, V. M., Golovanova, I. A., & Olefir, A. A. (2016). The impact of the legal regime of intellectual property protection in the pharmaceutical market. Wiadomosci Lekarskie (Warsaw, Poland: 1960), 69(3 pt 2), 582-586.

Srinivas, S. (2008). intellectual Property rights, innovation and Healthcare: Unanswered questions in Theory and Policy. econômica, 10(2).

Skiba, D. J. (1997). Intellectual property issues in the digital health care world. Nursing Administration Quarterly, 21(3), 11-20.

Singh, H. B., Jha, A., & Keswani, C. (Eds.). (2016). Intellectual property issues in biotechnology. CABI.

Amado, R., & Gewertz, N. M. (2004). Intellectual property and the pharmaceutical industry: A moral crossroads between health and property. Journal of business ethics, 55, 295-308.

Deshpande, A. P., Ankola, A. V., Sankeshwari, R., Jalihal, S., Kabra, L., Bhat, D. V., & Choudhury, A. R. (2022). Assessment of knowledge and awareness regarding intellectual property rights among the health-care professionals in Belagavi city: A cross-sectional study. Journal of Education and Health Promotion, 11.

Rao, S. L. (1994). The Indian health care industry: role of intellectual property rights. Intellectual Property Rights, (1), 165.