The policy balance between encouraging innovation and ensuring the widespread enjoyment of the social benefit of innovation in the field of health will always have to be managed on a tightrope, the tightrope that results from the intersection of economics, health and innovation policy in a fiercely competitive market environment. Staying on the tightrope without losing balance is vital for an economically viable health sector, an innovative health sector that advances the fight against disease and illness and, of course, our most fundamental desire, the enjoyment of good health.”

Francis Gurry, World Intellectual Property Organization Director General

Technological and scientific advancements in the past several decades, driven by innovation in the healthcare sector, have promoted greater access to life-saving medicines and technologies, and legal protections for innovation have ensured compensation for the high costs and risk of medical research. However, rising costs of research and the failure to eradicate preventable deaths from disease have prompted calls for a re-examination of the current system of protections, known as intellectual property rights (IPRs), in order to strike a better balance between public health and the rights of intellectual property (IP) holders. The purposes of patents were to stimulate interest in research and finding solutions to complex problems, and to promote the broader good of the public. The duration of time designated for exclusive use of new technologies was intended to relatively short, allowing the public to reap the technologies’ benefits in perpetuity. However, in the realm of medical and pharmacological patents, the objectives behind IPRs have been warped as drug companies have found that it is financially beneficial to buy the rights to drugs developed by others or to obtain a medication already in existence and monopolistically raise prices, rather than investing in the costly research and development of new medications and technologies. This has two negative consequences: the decline of new medications and technologies entering the market, and the usage of IPRs as a capital investment to the detriment of public access to life-saving medical innovations. Incentives to invest in research and development must be protected, while at the same time expanding access to affordable medicines and technologies, in pursuit of international development targets such as the Sustainable Development Goals (SDGs).

Background:

Article 25 of the Universal Declaration of Human Rights (UDHR) established that “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family” and “the right to security in the event of sickness.” In addition, the UDHR states in Article 27 that “Everyone has the right to the protection of the moral and material interests resulting from any


3 Ibid.
scientific, literary or artistic production of which he is the author.”

In order to best examine the trade-offs involved in IP policy for healthcare and pharmacological patents, as well as assign responsibilities to relevant intergovernmental organizations, the World Intellectual Property Organization (WIPO) has divided the issue into three interrelated and mutually reinforcing areas: public health (ensuring universal access to safe health and medical technologies at affordable prices), intellectual property (promoting innovation and protecting patent holders), and trade (promoting competition and reducing trade barriers). Through a strong tradition of cooperation with both Member States and other bodies within the United Nations, WIPO is capable of coordinating effective action to mobilize IP for public health, as well as economic development.

Agreement on Trade-Related Aspects on Intellectual Property Rights

In 1995, the Agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPS Agreement) under the World Trade Organization (WTO) entered into force, establishing a comprehensive international IP regime on a foundation composed of narrowly-focused treaties and conventions. The agreement defined minimum standards for the protection of IP, to be implemented by State Parties. This included stipulations on what can and cannot be patented, the rights of IP owners, and enforcement measures to take when violations occur. By clarifying and expanding past commitments, the TRIPS Agreement defined the basis of the current conversation about IPR. Subsequently, the 2001 Doha Declaration on the TRIPS Agreement in Public Health started the international dialogue on the role of TRIPS in addressing public health concerns related to IP. Some concerns raised were the effects of IPRs on innovation and healthcare costs, easing restrictions on developing countries, and technology transfer.

The WIPO Development Agenda and Public Health

In order to place development at the center of WIPO’s work, the WIPO Development Agenda, consisting of 45 principles to guide the Organization’s efforts, was created in 2007. The principles are divided into six clusters, each representing a major area of WIPO activities: technical assistance and capacity building; norm-setting, flexibilities, public policy, and public domain; technology transfer, information and communication technologies (ICTs), and access to knowledge; assessment, evaluation, and impact studies; and institutional matters, including mandate and governance. These principles demonstrate the means by which WIPO plans to implement its mandate to ensure the protection of IP and can be applied to cooperation on healthcare and pharmacological patents. Some relevant principles are: promoting cooperation between research

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7 World Trade Organization, “Doha Declaration on the TRIPS Agreement and Public Health,” [https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).
institutions, bridging the digital divide, and increasing partnerships between WIPO and other United Nations entities such as the World Health Organization (WHO).  

The Role of Patents

According to the WIPO Patent Frequently Asked Questions, a patent is “an exclusive right granted for an invention. In other words, a patent is an exclusive right to a product or a process that generally provides a new way of doing something, or offers a new technical solution to a problem.” A patent guarantees legal protections for its holder to control the use of their invention, which could be a product or a process (e.g. a new way of testing for disease). Patents are granted by a national or regional patent office, such as the European Patent Office, after a set of requirements are met. These differ between jurisdictions, but generally include the following aspects:

1. The invention is “novel” in some way and different from previous inventions
2. The invention is not obvious, i.e. its creation required advanced knowledge in the field
3. The invention can be applied for business or industrial purposes
4. The invention must meet rules for patentability (certain inventions either fall under a different category of IP or are not able to be protected)
5. The invention must be clearly documented so that it can be studied and reproduced

Patent holders have a monopoly over the production and use of their invention and can license it for manufacturing or use it in another invention until the patent expires. This creates two incentives for innovation, firstly by ensuring the ability of patent holders to profit off their inventions, and secondly by encouraging others to “invent around” the first invention and discover new ways to tackle the same problem.

In contemporary patent systems, inventors are rewarded with legal protections to gain income from their creations. To uphold these protections, most countries have courts to settle disputes related to the use of patented creations. In exchange, patent holders agree to give up exclusive rights to their invention, generally after a period of twenty years. This ensures a balance between rewarding creativity and preventing a monopoly on a good or service.

Healthcare and Pharmacological Technologies

The WHO defines health technologies as “application[s] of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives.” These can either be assistive in nature, such as hearing aids or exercise equipment, or for medical interventions. The second category is referred to as medical

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technologies, which is further broken down into preventive, diagnostic, therapeutic, or rehabilitative.\textsuperscript{11}

Pharmacology is “the science of drugs including their origin, composition, pharmacokinetics, therapeutic use, and toxicology,” so pharmacological patents cover a very important sub-group of medical technologies.\textsuperscript{12} The life cycle of a drug starts with obtaining and testing a wide variety of compounds and determining which of them may have a desirable effect, done \textit{in vitro} and in animal subjects. After that, two rounds of clinical trials are held: one to establish whether the drug is safe to use, and the second to determine whether the drug has a significant impact on the condition it is supposed to treat. This process is extremely costly, especially because only a tiny fraction of potential drugs are eventually approved and sold.\textsuperscript{13}

\textbf{Current Issues:}

\textit{International Framework for Patent Cooperation}

In order to address the three dimensions of IP policy for healthcare (public health, intellectual property, and trade), the WHO, WTO, and WIPO began a formal relationship to combine the organizations’ respective expertise and reduce duplication of efforts. This trilateral cooperation has led to a number of joint reports, conferences, and symposia to coordinate policies and identify emerging needs related to IP and public health.\textsuperscript{14} For example, in 2016, representatives from the three organizations held a series of panels and discussions on how to spur development of treatments for antibiotic-resistant bacteria.\textsuperscript{15} Through this channel of cooperation, WIPO is able to call on the other two bodies to take action on areas relevant to their respective mandates. This is important as WIPO’s mandate lies in two main areas: advancing the international system for IP protection and providing technical assistance and policy advice to Member States.\textsuperscript{16}

The \textit{Patent Cooperation Treaty} (PCT) is a mechanism allowing individuals to simultaneously file patents in all Member States that have agreed to the treaty’s terms, without having to fill out separate applications for each Member State. The International Bureau of WIPO, which administers the PCT, is able to draw on the combined expertise of all national IP offices that are part of the treaty in order to best help inventors protect their ideas. In addition, the PCT has reduced the granting of “worthless patents,” or patents that do not meet the criteria for patentability and

\begin{itemize}
  \item \textsuperscript{12} Merriam-Webster Online, \url{https://www.merriam-webster.com/dictionary/pharmacology}.
  \item \textsuperscript{14} “Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade.”
  \item \textsuperscript{16} “Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade.”
\end{itemize}
create “unjustified monopoly restrictions” on economies. However, the PCT process, even with fee reductions for inventors in developing countries, is costly and can take upwards of several years to complete. The PCT also does not guarantee the ability to sell and distribute IP, and in particular healthcare and pharmacological technologies are often subject to lengthy and expensive approval processes that prohibit the sharing of these technologies. Member States could consider ways to streamline the approval process for healthcare and pharmacological patents, in cooperation with the WHO, to ensure regulatory reciprocity for public health.

Once a patent is granted, the patent owner is the only person or entity legally able to create, use, and sell their invention. However, there are a number of circumstances that warrant the limiting of these rights, especially in the face of serious dangers to public health. The tools and procedures that allow the limiting of patent holders’ rights are called flexibilities. The current arrangement of flexibilities, established under the TRIPS Agreement, is another means to promote a better balance between public health and the rights of IP holders through international cooperation. Flexibilities for developing countries, particularly least developed countries (LDCs), under the TRIPS Agreement enabled greater access to HIV/AIDS medications and helped alleviate the epidemic. Some examples of flexibilities are: deferred periods for developing countries and LDCs to implement international agreements, allowing free government and educational use of patented inventions, and regulatory review exceptions (allowing individuals or companies to apply during the life of the patent for the rights to produce generic versions of medicines immediately when the patent expires). Another important flexibility is compulsory licensing, which allows governments to contract the production of an invention without the consent of the patent holder. This was envisioned to be a means for the generic version of a drug to be produced domestically, but has also reduced the cost of medicines in developing countries and LDCs.

Strengthening Technical and Policy Assistance

Member States have discretion over patent requirements, which gives them policy space to affect the balance between IP and public health. Though there are common criteria for patentability, there is no consensus on the interpretation and implementation of these criteria. WIPO can provide technical assistance to Member States on policies and procedures related to the patent process and establish guidelines on how technical assistance should be given. These guidelines could cover what kinds of inventions are patentable, determining what is novel, and how documentation is processed and publicized.

There are a number of other regulatory issues where WIPO can offer technical guidance. Regulation is necessary to ensure that products are safe and effective for consumers, but can also

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delay or prevent access to life-saving healthcare and pharmacological technologies. One such regulatory concern is addressing spurious, falsely-labeled, falsified, or counterfeit (SFFC) medical products. Combating this particular threat requires training across a wide variety of public sectors, including healthcare regulation, law enforcement, and customs.\textsuperscript{21} WIPO can take a number of actions to this end, including by organizing training events and workshops. For example, WIPO conducted a workshop to train customs officials on trade-related aspects of SFFC medical products, including counterfeiting, privacy, and border controls.\textsuperscript{22}

Promoting Research and Development

There is an ongoing debate on the best way to leverage IP toward promoting increased research and development on healthcare and pharmacological technologies. This is particularly the case regarding neglected diseases (diseases that disproportionately affect impoverished people in developing countries that have not been countered with significant public health interventions). This debate has yielded a variety of proposals and policy options for both WIPO and Member States. One method is to empower researchers and innovators in developing countries in order to promote a more market-based approach. WIPO created the Re:Search tool to foster public-private partnerships and linkages between the health sectors of high-income and low-income Member States. However, some experts maintain that more intervention must be done in order to fix perceived failures of market-based approaches to combat neglected diseases. There have been a number of tools put forward to mobilize IP for public health: open-source drug development, tax breaks, patent pools, and priority review, for example. There have also been calls for a global legally-binding treaty on research and development for neglected diseases, and WIPO has much to contribute to this effort. Examining the role of WIPO in advancing research and development for neglected diseases, including through technical aspects of technology transfer and dissemination, policy advice, and designing and implementing flexibilities will help to leverage IP to counter some of the world’s greatest health challenges.\textsuperscript{23}

Future Outlook:

WIPO has a dual responsibility to ensure that healthcare and pharmacological patents preserve the benefits of innovation while also advancing public health. Assisting Member States with formulating effective national IP policy should occur in parallel with action to encourage greater international cooperation for public health, in pursuit of the WIPO Development Agenda. Additionally, WIPO’s actions should be considered in the context of trilateral cooperation with the WHO and WTO and draw upon these two organizations to achieve complimentary aims. Furthermore, there is potential for greater international cooperation on a more integrated system for IPR protection beyond what is outlined in the PCT.

\textsuperscript{23} “Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade,” \url{https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf}.
There are a variety of emerging areas that pose unique policy challenges to Member States and the international community, including increased awareness of traditional medicine. Another challenge, brought about by advancements in medical technology, is the patentability of genetic resources. An effective IP regime must be able to respond to new developments in healthcare research while reconciling public health needs with promoting and protecting innovation.\textsuperscript{24}

\textsuperscript{24}“Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade,” \url{https://www.wto.org/english/res_e/booksp_e/pamtiwhowpowtoweb13_e.pdf}.
Focus Questions:

1. What is the relevance of healthcare patents to the *Charter of the United Nations*?
2. What types of policy assistance and training should WIPO provide?
3. What roles should WIPO, governments, non-governmental organizations, and the private sector play in promoting research and development?
4. How can WIPO utilize new developments in healthcare technologies for public health?
5. Does your Member State participate in the PCT?
Bibliography


