

## INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO ESSENTIAL MEDICINES: A GLOBAL PERSPECTIVE

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### ABSTRACT

Intellectual property (IP) has distinct bureaucracy; within the case of get entry to to drugs, we're speaking about patents. Patents are a public coverage tool aimed at stimulating innovation. via offering a monopoly through a patent which offers inventors an monetary advantage governments are seeking for to provide an incentive for R&D. on the equal time, the public advantages from technological advancement.

For the reason that creation of trade-related aspects of intellectual belongings Rights (journeys) in 1995, there has been large problem that poor get admission to to critical drug treatments in growing nations would be exacerbated due to the fact strengthening intellectual assets rights (IPR) leads to monopoly of pharmaceutical markets and behind schedule entry of lower-fee popular drugs. however, no matter tremendous research and disputes concerning this difficulty, there are few empirical studies on the subject. on this look at, we investigated the effect of IPR on access to medicines and catastrophic expenditure for medicines, the use of records from global fitness Surveys 2002-2003. The index of patent rights advanced by Ginarte and Park (1997) became used to measure the IPR protection level of each country. Estimates were adjusted for man or woman and united states of america characteristics. inside the consequences of multilevel logistic regression analyses, higher degree of IPR extensively accelerated the likelihood of nonaccess to prescribed drug treatments even after controlling for

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character socioeconomic status and national characteristics related to access to drugs. This take a look at's finding at the bad effect of IPR on get entry to to medicines requires the implementation of extra active policy on the supra-country wide degree to improve get right of entry to in low- and center-income international locations<sup>4</sup>.

**KEY WORDS:** Rips; access To medicines; Catastrophic Expenditure; INTELLECTUAL property right, etc

## INTRODUCTION

A patent, which is a form of intellectual property right (IPR), is a criminal, unique proper granted for the discovery of a new product, technique, organism, layout, and plant. It permits the right holder to exclude others from making, using, or selling the blanketed invention for a duration of twenty years. Patents constitute the maximum not unusual method for governments to inspire studies and improvement (R&D) a good way to find pharmaceutical treatments and healing procedures for sicknesses and other illnesses.

IPR safety and enforcement have developed from an area commonly of national problem to a place of international change coverage. the world trade agency (WTO) settlement on trade-associated factors of intellectual property Rights (trips) established minimum standards for IPR protection and enforcement.

The U.S. government considers the safety and enforcement of worldwide IPR standards, which includes the ones for patents, to be an important goal of U.S. trade coverage for economic, health and protection, and countrywide security reasons. As such, the united states has pursued sturdy IPR regimes via multilateral, nearby, and bilateral loose change settlement (FTA) negotiations and unilateral change policy gear, particularly the special 301 process and the Generalized device of choices (GSP).

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<sup>4</sup>Carvalho NP. The TRIPS Regime of Patent Rights. Norwell, Mass: Kluwer Law International; 2002.

IPR provisions in alternate regulations are among the range of social, monetary, and political elements that could affect public fitness, together with the capability of nations to deliver fitness offerings to their populations. Patents, thru their feasible impact on innovation and drug fees, may additionally affect get admission to to existing drug treatments and the improvement of latest medicines. in line with the sector health organisation (WHO), approximately one-0.33 of the sector's population, broadly speaking the ones living in poorer elements of Africa and Asia, lacks ordinary get right of entry to to critical drug treatments .

### **1.1 WHO, INTELLECTUAL PROPERTY AND ACCESS TO DRUG TREATMENTS**

The earliest articulation of WHO's mandate to work at the interface among access to medical merchandise, R&D in rare and tropical illnesses, and exchange may be traced returned to 1996, in a global health meeting (WHA) decision on the Revised Drug strategy which requested the WHO Director-trendy (DG) to guide Member States in their efforts to enhance get entry to to critical tablets; to encourage the advertising of R&D of drugs for uncommon and tropical sicknesses; and to report on the impact of WTO regarding countrywide drug and crucial medicines policies and make guidelines for collaboration among WTO and WHO as suitable. This mandate has been continually bolstered via subsequent meeting resolutions. it has been extended over the years to consist of upon request, presenting technical and policy guide to Member States, on formulating coherent alternate and health polices and the implementation of journeys flexibilities in collaboration with different relevant global corporations<sup>5</sup>.

In 2003, WHO member states agreed thru decision to establish a commission on intellectual assets Rights, Innovation and Public health (CIPIH) which endorsed that "WHO ought to develop a international course of action to cozy stronger and sustainable funding for developing and making accessible merchandise to address

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<sup>5</sup>WHO in the frontlines of the access to medicines battle: The debate on Intellectual property rights and public health", in Intellectual Property in the context of the WTO TRIPS Agreement: Challenges for public health, edited by Bermudez, J.,(FIOCRUZ, ENSP, WHO, PAHO, Rio de Janeiro, 2004), p. 87

sicknesses that disproportionately affect developing nations” and “continue to display from a public health attitude, the effect of intellectual property rights ... on the development of latest products as well as access to drug treatments and different fitness care merchandise in developing countries”. these tips led to the adoption of the global strategy and plan of action on Public fitness, Innovation and intellectual property (GSPOA-PHI) in 2009 and inside the identical yr the WHO-WIPO-WTO trilateral cooperation, that is an interagency collaboration on public health, intellectual belongings and trade was began.

Maximum recent are meeting selections of 2018 on ‘Addressing the global scarcity of, and get right of entry to to, medicines and vaccines’, which requested the DG to “difficult a roadmap file, in consultation with Member States, outlining the programming of WHO’s work on access to drug treatments and vaccines including sports, moves and deliverables for the length 2019 – 2023; and at the ‘international method and plan of action on public fitness, innovation and intellectual assets (GSPOA-PHI): ordinary programme review’, which requested the DG to “implement the tips addressed to the Secretariat in an implementation plan, steady with the worldwide strategy and course of action on public health, innovation and intellectual belongings”. additionally, in 2019 resolution on ‘enhancing the transparency of markets for drug treatments, vaccines, and other fitness products’, requested the DG to “continue assisting existing efforts to decide patent repute of health merchandise and promote publicly available person-pleasant patent popularity records databases for public fitness actors, in step with the GSPOA-PHI and to paintings with different applicable international businesses and stakeholders to enhance international cooperation, avoid duplication of labor, and sell relevant initiatives ”<sup>6</sup>.

## 1.2 ACCESS TO ESSENTIAL MEDICINES

The public health panorama has changed dramatically over the last 30 years. the world has witnessed the emergence of the HIV/AIDS pandemic within the 1980s, in

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<sup>6</sup>Benkimoun P. op.cit p. 187, 188

addition to an growing resistance to treatments against malaria, tuberculosis, and a number of bacteria during the last couple of many years. even as HIV/AIDS is a global pandemic, it disproportionately influences developing nations. further, many other communicable and infectious diseases have the growing global.

Public fitness effects rely on a huge variety of frequently inter-related social, monetary, and political elements, one in all that's get entry to to drug treatments. in line with the U.N. Millennium development goals, get entry to to medicines is defined as "having drugs continuously to be had and cheap at public or non-public health facilities or medication retailers which can be within one hour's stroll from the homes of the population."

In discussing access to drug treatments, many public fitness advocates consciousness on "essential drugs." given that national governments face useful resource constraints in imparting health care, a few argue that governments should rationalize their public fitness coverage choices, which include the supply of drug treatments. according to the WHO, essential drug treatments are people who fulfill the priority health care wishes of the population. they're decided on with due regard to public health relevance, evidence on efficacy and safety, and comparative fee-effectiveness. important drug treatments are intended to be to be had in the context of functioning health structures always in ok quantities, in the proper dosage bureaucracy, with assured fine and ok records, and at a charge the individual and the community can have the funds for. The implementation of the concept of essential drug treatments is meant to be bendy and adaptable to many specific situations; exactly which drugs are regarded as critical remains a national obligation<sup>7</sup>.

For low-earnings countries and populations, pharmaceutical drug charges may additionally constitute a great barrier in getting access to important and different drugs. In most elements of the world, health offerings are provided through a mixture of public and personal health offerings. typically, in developing countries (and in a

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<sup>7</sup>Antezana, F. and Seuba, X., Thirty Years of Essential Medicines, The challenge. Ed. Icaria, Milenrama, Barcelona, 2008, p. 42

few instances, developed nations such as the USA), clients undergo much in their health care prices immediately. In evaluation, some nations, such as Thailand, Japan, Turkey, and France, have extra publicly-funded pharmaceutical markets, decreasing the expenses borne via purchasers. but, in situations where the government is investment a larger proportion of fitness care, better-priced pills may additionally upload limits to the government's ability to offer public fitness care.

There's extensive debate on the volume to which patent protection affects get right of entry to to essential medicines. The complexity is fueled with the aid of differing definitions of what is meant via "important medicines" and "access to drug treatments." for example, there regularly are no agreed-upon devices of evaluation for comparing access to important drugs. in view that 1977, the WHO has maintained a version essential medicines list (EML) to help country wide governments to pick out drug treatments to deal with their public health desires and to expand countrywide lists. whilst the WHO EML regularly is used as a foundation for analysis, a few global fitness activists specific difficulty that the EML won't be comprehensive. They argue that the EML may additionally exclude essential drug treatments based totally on price concerns. They contend that patents improve the fee of drugs, and that the EML includes only a few drugs presently under patent. but, the EML notes that cost isn't always a reason to automatically exclude a medicine and factors out that a couple of standards are considered inside the decision system.<sup>8</sup>

### **1.3 QUANTIFYING CRITICAL MEDICINES BENEATH PATENTS**

No matter information limitations, some research have attempted to quantify what number of critical drug treatments are patented. in line with one observe published in 2004, 1.4% of critical drugs had been patented in 2003. The study quantified the frequency with which "critical drug treatments" as described through the WHO's 13th model important drugs listing (EML) are patented in 65 low- and center-income

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<sup>8</sup>Velásquez, G., Boulet P., "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement", WHO/DAP/98.9, Geneva, November 1997, page 34.

international locations and tested the data the usage of statistical regression techniques. Of the 349 products listed in the WHO EML, they have a look at concluded that 17 important drugs will be challenge to patents in 2003. even as the overall patent occurrence price for important drug treatments may be low, they observe noted that patents have been extra frequent for antiretroviral drugs (ARVs) for HIV/AIDS remedy. similarly, HIV/AIDS remedy often utilizes aggregate therapy (use of a couple of pills for a remedy), so that a patent on one medication can restriction get right of entry to to "fully-prevalent based totally therapy."

In step with the have a look at, inventors have been much more likely to are searching for patents for patentable capsules in large, evolved markets than in growing international locations, whose markets won't provide enough economic incentives for inventors to incur the fees of seeking patents. The examine located that patenting changed into extra widespread in big, center-income nations, such as China, South Africa, and Mexico. Pharmaceutical agencies additionally may additionally choose not to are seeking for patents in low-income nations due to social motivations to boom get entry to to pills in those countries or reputational concerns. in addition, pharmaceutical groups won't have had the option to apply for a patent if the developing did now not apprehend patents. The study suggests that perspectives of both fitness care activities and pharmaceutical companies are exaggerated: "Patents cannot cause crucial drug treatments to be inaccessible in 'many' developing nations due to the fact they do no longer exist ninety eight.6 percentage of the time; similarly, patents can not be a 'global' necessity of pharmaceutical commercial enterprise because companies forgo them 69 percentage of the time."<sup>9</sup>

#### **1.4 THE WTO AGREEMENT ON TRADE-ASSOCIATED FACTORS OF INTELLECTUAL BELONGINGS RIGHTS**

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<sup>9</sup>WHO Policy Perspectives on Medicines, "Globalization, TRIPS and access to pharmaceuticals", No. 3, (WHO, Geneva, March 2001), page 5.

Traditionally, intellectual belongings rights had been a rely of U.S. national subject, however over time, have developed right into a cornerstone of global trade agreements. at the center of the existing worldwide IPR gadget is the sector change enterprise (WTO) settlement on change-related aspects of intellectual property Rights ("journeys settlement"). the belief of the Uruguay round (1986-1994) of the general settlement on price lists and alternate (GATT) resulted in the introduction of the WTO, an worldwide organization hooked up in 1995 as the successor to the GATT. The Uruguay spherical additionally culminated in numerous WTO agreements on change in items, offerings, funding and other non-tariff obstacles to exchange, one of which was the journeys agreement.

The journeys settlement sets minimum standards of protection and enforcement for patents, copyrights, trademarks and other styles of intellectual property. The agreement is based totally on three center commitments of the WTO: minimal requirements, country wide remedy, and most-favored-country remedy. Adherence to the journeys agreement is a prerequisite for WTO membership, and provisions of the agreement can be enforced through the WTO's Dispute settlement know-how Mechanism (DSM).

Efforts by way of the usa, eu international locations, and the IPR business network inside the past due Nineteen Eighties had been essential in raising IPR as a exchange trouble at the schedule of the Uruguay round of the GATT. They argued that the triumphing international IPR regime, in large part administered through "unenforceable" international treaties, become useless. U.S. industry criticized the lack of consistency within the promoting, safety, and enforcement of IPR across nations. Others contended that IPR protection and enforcement need to now not be regarded as a alternate difficulty. amongst people who held this view, a few may also have agreed that the motion of counterfeit and pirated goods across national borders could be a exchange difficulty, but may additionally have puzzled the inclusion of a much broader-ranging set of IPR problems on the Uruguay spherical schedule.



Most of the debates about the consequences of the TRIPS agreement, one of the maximum controversial is its impact on public health. previous to the TRIPS settlement, growing country governments regulated public health with little involvement of worldwide IPR regimes. that is because growing countries either did not have IPR structures in region or excluded pharmaceutical merchandise from patents. Proponents of the TRIPS settlement, specially developed nations, argued that IPR protection and enforcement make contributions to monetary increase and improvement with the aid of promoting exchange, funding, and era switch. evolved countries additionally asserted that patent protection is essential to public health due to the fact patents provide financial incentives for R&D to find pharmaceutical answers for sicknesses .

In comparison, critics of the TRIPS, which includes many developing nations and civil society organizations, asserted that developed countries, that are the most important producers of Intellectual property, will be the prime beneficiaries of the TRIPS agreement. a few also held the view that the TRIPS settlement might enhance the expenses of IPR-sensitive items, consisting of public health items, constrain the ability of governments to offer health services to their populations, and avoid innovation and monetary development for low-profits international locations. further, many developing international locations desired to discuss IPR issues below the auspices of the arena intellectual belongings organisation (WIPO) as opposed to the WTO. WIPO is a United international locations organisation that administers all international IPR treaties with the exception of TRIPS.<sup>10</sup>

In the end, growing international locations acceded to the TRIPS agreement, after being granted behind schedule compliance periods and after negotiating dreams on other problems within the Uruguay spherical consisting of textiles and garb. additionally they desired the possibility of running underneath a regulations-primarily based buying and selling machine. though, many stakeholders stay essential of the

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<sup>10</sup>Integrating Intellectual Property Rights and Development Policy”, Report of the Commission on Intellectual Property Rights, London, September 2002

journeys agreement. They argue that the IPR regime's architecture is biased in the direction of IP right holders. additionally they contend that, in negotiations, high-profits international locations had more bargaining strength than lower-earnings countries, which can be frequently dependent on evolved nations economically. similarly, some argue that the hobbies of such groups as IP users, clients, small- and medium-sized producers, and public fitness advocates had been not sufficiently represented inside the journeys agreement negotiations .

### **1.5 THE GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY (GSPOA)**

The united states took a ahead stance within the face of the possibility that the sector health meeting might probable adopt this file. After complicated debates, an inter-governmental organization changed into formed in order to analyze and advocate what must be executed with the tips of the CIPIH record, as in 2006 the WHA did now not manage to adopt the file. The inter-governmental group become envisioned as a small institution of round 10 countries represented with the aid of their missions in Geneva, however greater than one hundred countries attended the organization's first assembly held on the quit of 2006. Deliberations and negotiations took two years, from start to approval, within the 2008 WHA on "international approach and course of action on Public health, Innovation and intellectual property".

This -year negotiation may be considered the maximum relevant and critical negotiations that have ever passed off within the 65 years of the lifestyles of the WHO, after the negotiation and the adoption of the conference towards tobacco, (FCTC)forty one. It become in particular interesting because the developed nations inside the WHO have been there with the "ghost" of the Mrs. Dreifuss file, specifically in mild of what it already endorsed, exploring the opportunity of creating an international treaty for pharmaceutical investment and research and development (R&D). before the concept of a binding mechanism happened, the drafting of a non-binding resolution like decision 61.21 on international strategy was a negotiation where every word and comma counted. at some point of the negotiation, growing

international locations pointed out that the report presented via the WHO Secretariat as the idea of the dialogue left out elements associated with Intellectual assets<sup>11</sup>.

These aspects made up the relevant recognition of the hints of the record chaired by way of Mrs. Dreifuss on which the inter-governmental group turned into requested to give steering. It changed into evident that in the context of the negotiations the topic of intellectual assets became the common denominator that crossed all of the topics of the report proposed by way of the WHO Secretariat. as opposed to admitting that each thing of the proposed factors truly contained elements of intellectual belongings, the WHO created a separate item, detail. "utility and control of intellectual assets to make contributions to innovation and sell public health". at the quit there were 8 elements and only one coping with intellectual assets. the global approach managed to approve diverse factors in its motion plan<sup>44</sup>, however there was a impasse regarding detail five, which involved the difficulty of intellectual assets and various factors of the course of action were positioned in brackets. As a result, in 2008 the arena fitness meeting created an professional working group to observe the troubles of coordination and investment of medical R&D that become known as the EWG (professional operating institution on R&D financing and coordination).

The mandate of the EWG turned into to endorse international locations and the WHO, regarding the recommendations of the report via the expert institution chaired by Mrs. Dreifuss. The record, as cited referred specifically to intellectual property and among other things, the possibility of a binding worldwide treaty on R&D. it is essential to be aware that paragraph 2.three. (c) of the GSPOA made reference to a probable global treaty on R&D of latest tablets as a subject on which the EWG have to recommend. consequently, the negotiation and the adoption of an international tool on medical R&D should be a key detail within the implementation of the GSPOA. no matter the insistence of some contributors of the EWG, the organization's file absolutely

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<sup>11</sup>Resolution WHA61.21 "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual property", Geneva, 2006.

disregarded any connection with the opportunity of a binding conference or treaty, the principle purpose why the record became not followed by means of the 2010 WHA<sup>12</sup>.

## CONCLUSION

Due to the fact that 1970, India's Patent Act has allowed Indian manufacturers to legally produce popular variations of drugs patented in different nations. India's expertise in opposite drug engineering and the performance of its pharmaceutical production industry fast installed it as the high supply of typical drugs within the world. 2005 marks a essential and probably dramatic alternate in get admission to drugs in developing countries: countries which do now not but provide patents on drugs, such as India, now need to enforce patent legal guidelines in compliance with the world trade business enterprise (WTO) trade-related factors of intellectual belongings Rights (trips) agreement. The Act has some clean provisions to defend the interests of the home established manufacturers. It has carried out a fairly exceptional balance amongst stringent IP measures, while using a number of the flexibilities that journeys gives. The amended Patents Act has an powerful competition machine for hard frivolous patents, restrained patentability exceptions, intricate provisions concerning compulsory licensing, and parallel importation. The changes to the new Patents Act should permit India to preserve gambling the pioneer position that it performed in the pre-journeys duration, making capsules available at reasonably-priced prices to customers both locally, and around the sector .

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<sup>12</sup>Public Health, Innovation and Intellectual Property Rights", Report of the Commission on Intellectual Property Rights, Innovation and Public Health, ISBN 92 4 356323 8, Geneva, 2006, 204 pages

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