COMMITTEE: World Health Organization (WHO)

TOPIC: Addressing the future of intellectual property rights protection in the pharmaceutical industry to ensure increased equitable access to medication.

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POSITION: Deputy President

Table of contents:

Personal Introduction

Dear Delegates, my name is George Paraskevas, I am 16 years old, and I will be your vice-president during this year's LFHMUN in the Health committee. Alongside Dimitri Kalaitzis, I will be moderating this year's debates and wish you a very pleasant and transformative experience. We are looking forward to meeting you, future delegates, and are enthusiastic about the new ideas and arguments you will bring to the table. I hope you don't find this study guide too boring and manage to read it till the end (even though it can be hard at times) for it will provide you with all the information needed on this topic.

Whatever your motivations for participating in this year's MUN may be, I guarantee you that you will not regret signing up. It constitutes an opportunity to discuss very relevant problems that plague the world in this very moment. This not only sharpens your communication and argumentative skills but also teaches you what it means to be a leader and a problem solver. Besides, you will get to meet new people from different countries (who knows, some of them might become lifelong friends), socialize and have a fun time. If all this intimidates, if it seems too much too handle, let me reassure you, I had the same thoughts and was proven wrong.

During your stay in Athens, our talks will encompass three subjects: Computer-Brain Interfaces, providing healthcare in war-torn countries and, finally, property rights in the pharmaceutical industry.

General Introduction

Around the globe, the development of drugs (to be consumed for medical reasons) and medication is taken over by key industry: the Pharmaceutical one (Pharma for short). Yet, these treatments, which, at times, can mean the difference between life or death, are not easily available to everyone. In Low Income Countries (LIC), a significant number of people die yearly to curable illnesses. At times, high cost is partially attributed to Intellectual Property Rights (or IPR), which are meant to incentivize pharma companies to innovate by giving them exclusive rights over their discoveries for a certain period of time.

The main reason behind this system is for companies to invest in Research and Development (R & D), helping them profit and invent new drugs. On the other hand, it is hard to balance the need for cheap treatments with IP protection.

Recently, this model of IP protection is being criticized more and more. The fact that strict IP laws significantly increase prices and reduce competition are the drawbacks most talked about. They were highlighted by the advent of COVID-19; when it comes to responding to major global crises, there are many gaps to be filled. For the aforementioned reasons, a global consensus is emerging on the need for reforms.

One of the biggest concerns with the current system is the extended market exclusivity granted to pharmaceutical companies, which slows down the introduction of generic

and biosimilar medicines. Generic drugs are much more affordable than brand-name versions and are essential for improving access to treatment. However, strategies like patent extensions, evergreening (minor modifications to existing drugs that result in new patents), and data exclusivity provisions often restrict competition. This is particularly problematic for patients with chronic illnesses such as cancer, diabetes, and HIV/AIDS, where prolonged IP protections can make medications prohibitively expensive.

Enterprises believe that strong IP protections must be kept in order for them to continue pouring money in research. Bringing a new medicine to market requires years of research and billions of dollars in investment. Without strong protections, companies may be reluctant to invest in the development of drugs for diseases that primarily affect lower-income populations, mostly in Africa and Asia. Therefore, any change to the already existing laws must find a way to keep products affordable without limiting progress.

The future of intellectual property rights protection in the pharmaceutical industry needs to be reconsidered to ensure that essential medicines remain both innovative and accessible.

Key Words

Low Income Countries (LIC): Countries whose inhabitants' revenue is low in comparison to the rest of the world.

WTO: World Trade Organization, it regulates global trade.

Pharmaceutical Industry: The sector of companies that is in charge of producing treatments.

IP rights: Intellectual Property rights, a series of laws that forbid the competitors of a company to use discoveries it has made.

Medicines Patent Pool (MPP): A public health organization that negotiates with pharmaceutical companies to license essential medicines, making them more affordable and accessible in low- and middle-income countries. It focuses on treatments for diseases like HIV, hepatitis, and cancer.

HIV, hepatitis, and AIDS: Treatable diseases, they can all be deadly if medical aid isn't provided. They are especially present in Low Income Countries.

Data exclusivity: When companies are allowed to not disclose important discoveries they have made to limit competition.

Extended market exclusivity: It is a policy that grants pharmaceutical companies additional time beyond a drug's standard patent period to sell it without generic competition. It is often given as a reward for conducting paediatric studies or developing treatments for rare diseases.

COVID-19: The virus behind the global pandemic that appeared in 2019.**Patent**: A legal document that allows a party to have some power over their invention.

General Overview:

What are IP rights?

Intellectual property rights, in the Pharma Industry, help companies profit of the drugs they have produced by granting them ownership over the discoveries they've made.

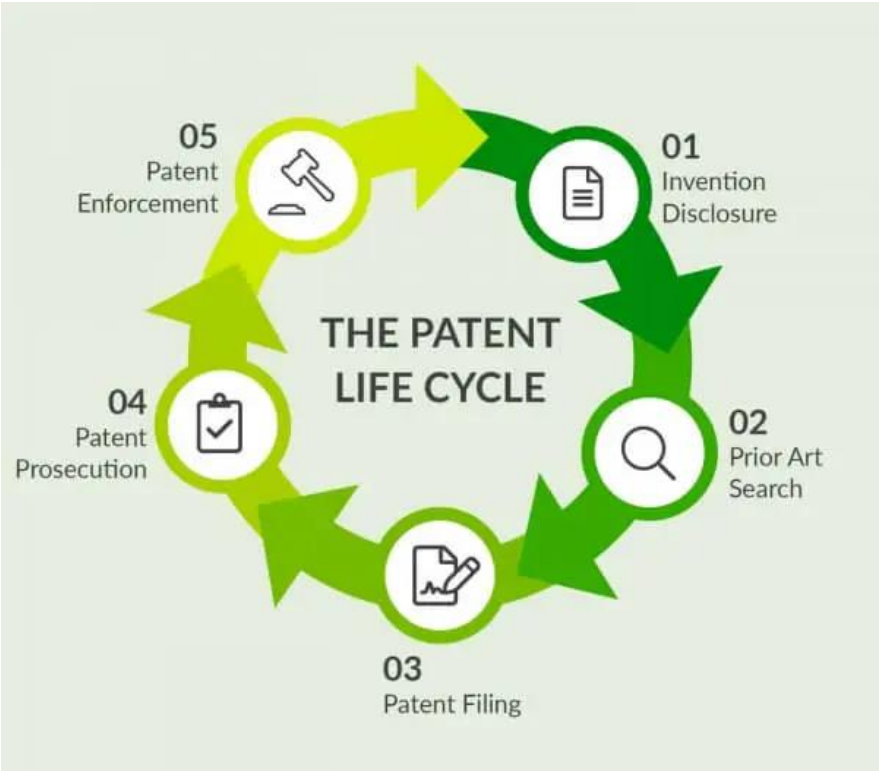
In jurisprudence, there are four main categories of IP rights:

- **Trademarks:**
  They protect a company's identifying traits such as logos and brand names. This is to say that no drugs can be produced under the name of a different corporation than the one making them. Trademarks are not exclusive to pharma firms, almost every major business uses them. They are important because they protect the trust consumers have in a company by ensuring that customers know who has made the drugs they use. As a side note, trademarks will not be the object of the debates for they are a non-negotiable in international laws, modifying them would allow for fraud and a multitude of other problems.

- **Trade secrets:**
  Trade secrets are pieces of information that a company deems so valuable that it is not willing to disclose from fear that they might help competitors. These can be manufacturing processes, formulas and other proprietary information that have been discovered and implemented by the firms that are keeping them secret. Legally, non-disclosure agreements are the main way to maintain trade secrets by forbidding the organization's employees from disclosing sensitive data they have come to know.

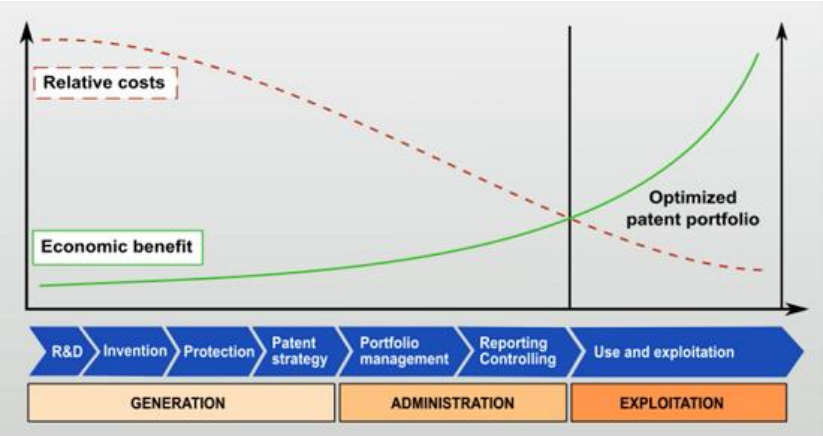
- **Patents:**
  They help the inventor of a drug (most of the times, a private organization) to profit from their discovery by disallowing competitors from producing selling or importing said drug for a given period, usually 20 years from the moment it filed. Patents essentially give one company a monopoly over a product they have discovered. Consequently, it has no competitors and can keep prices very high. They are the most common way of enforcing intellectual property rights; for this reason, patents are going to be crucial for exploring the topic.

  <u>Diagram showing the lifecycle of a patent (how it is obtained):</u>



https://www.inquartik.com/blog/basic-patent-legal-status/

Diagram showing how patent influences company profits:



https://ipbusinessacademy.org/portfolio-analysis-and-the-patent-life-cycle

Consequences:

Positive ones:

Today, the costs of research and development have grown by a huge margin. Pharmaceutical firms find themselves needing to put more time, effort and money into developing new therapies that save millions of lives each year. In these conditions, pharma giants such as Bayer, Johnson &Johnson, and Pfizer don't have sufficient incentive to invest in R & D. This is where IP rights play a crucial role; by giving

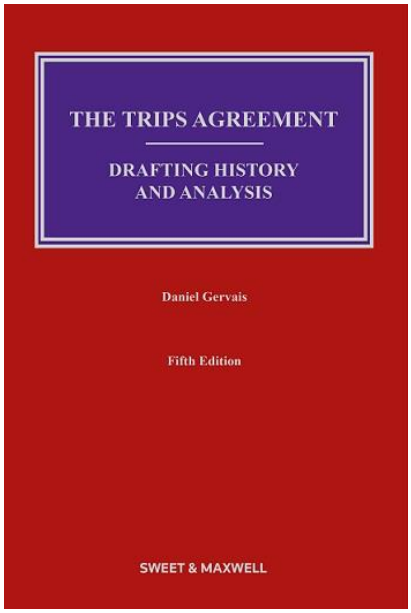
inventors temporary monopolies over the product of their intellectual labour, they drive profits up and give companies a reason to do research.

Negative ones:

IP rights allow corporations to charge very high prices for essential drugs, often making them inaccessible to low-income individuals who need them the most. Quoting Dr. Margaret Chan, former WHO Director-General: *"Intellectual property must be balanced with the right to health. Access to medicines should not be a privilege."* and Dr. Francis Collins, former NIH Director: *"Patents drive innovation, but mechanisms must exist to ensure affordability and global reach."*

Due to various issues associated to IP rights in the Pharma Industries, namely an increase in life-saving drug costs and the undermining of local medicine producers. Some countries have modified their approach and acceptance of the international norm.

In international trade, medical patents fall under the jurisdiction of the Trade Related Aspects of Intellectual Property Rights (TRIPs) agreement. Over the years, TRIP laws have been criticized and opposed by many, the major actors being India and China. We will go over each country's actions in the paragraph down below.



Case study: India's actions on the issue

On the world stage, India is notorious for not respecting Intellectual Property Rights and not just in the pharmaceutical Industry. Its government has faced multiple allegations coming from Swiss private companies. As per today, the current government's Commerce and Industry Minister Piyush Goyal has denied them. Saying:

"India is very respectful of intellectual property rights (IPRs). India is very conscious of its responsibilities, and India is a country known to never, ever steal anybody else's technology."

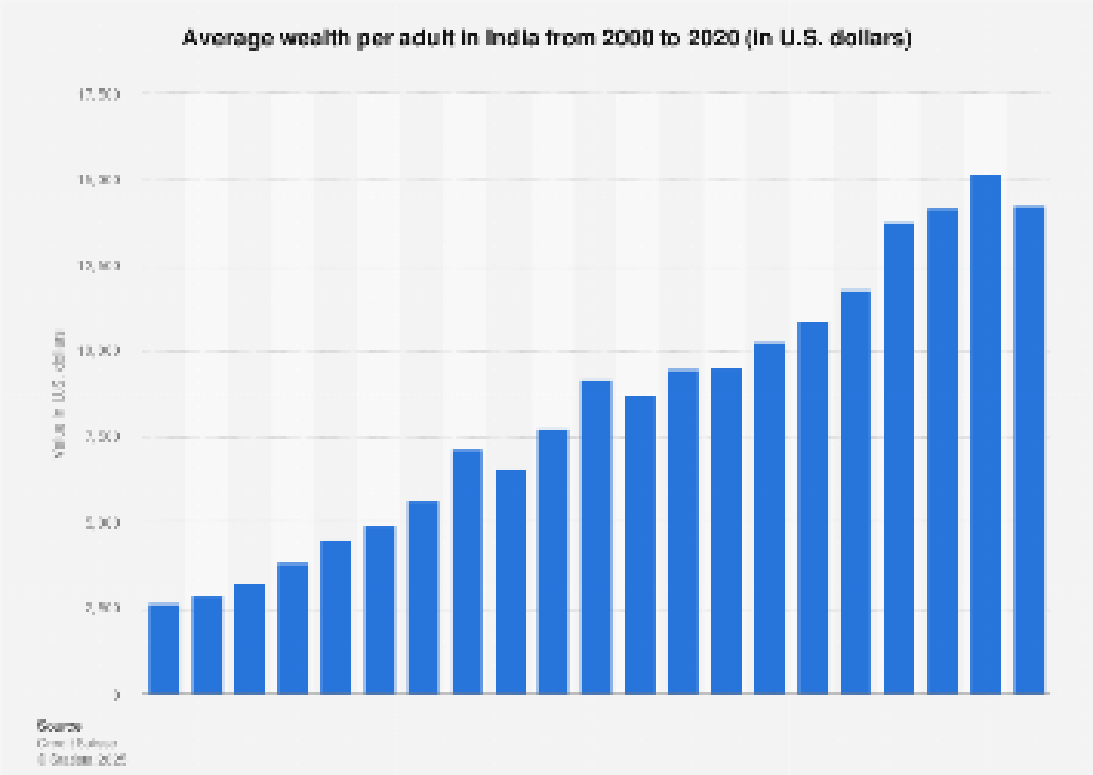
Picture of India's Commerce and Industry Minister Piyush Goyal.

https://newsarenaindia.com/nation/india-s-interest-first-not-deadline-piyush-goyal-on-us-talks/49358

In turn he expressed his concern over evergreening patents. These allow privately owned corporations to extend the validity of their patents by 20 years for already discovered medicines. The extension is justified by minor changes to the original products. This allows the producer to maintain a monopoly over the drug, keeping prices high.

However, in 2005, India amended parts of its legislation to better adhere to TRIPs requirements. We won't delve into the specifics as to not get to technical and to keep the information relevant to the topic.

According to the Mirrority Review, "The average (mean) wealth of an adult in India in 2022 was USD 16,500". The relative poverty of the Indian people has raised concerns over the affordability of life-saving products that could save thousands of people with crippling health conditions each year.



https://www.statista.com/statistics/1248500/india-wealth-per-adult/

Graph showing the average wealth of Indians from the year 2000 to 2020.

Case study: China's actions on the issue

On paper, China has a solid judicial foundation when it comes to respecting Intellectual Property. Over the last 20 years, it has undergone a series of amendments as to better accommodate international law as is shown below.

In 2001, China joined the TRIPs agreement and changed its legislation in 1992, 2000 and 2009 to expand pharmaceutical patentability and enforcement rules.

It also created a new government body, the China National Intellectual Property Administration (CNIPA) that enforces patents and trademarks enforcing IP through administrative and judicial channels.

Since the 4th of July 2021, China's drug linkage system lets patent holders or generic applicants request a determination of whether a generic product infringes a valid patent before approval. Further appealing to international standards and laws.

However, there have been a great number of disputes. The main problem being Bolar Exemptions. The law now explicitly allows generic manufacturers to produce patented drugs for regulatory submissions without constituting infringement.

Since China constitutes a large market of approximately 1.4 billion people; large TransNational Corporations (TNC) try to exploit this market for profit, Pharma companies included. The Bolar Exemptions allow local manufacturers to compete with Big Pharma giants (costing them profits) and promotes the development of the local industry.

Graph showing the growth of Chinese pharmaceutical companies in 2019:

https://www.bscapitalmarkets.com/chinese-pharma-industry-too-expensive.html

Concerned Countries and Organizations:

Organizations:

- World Trade Organization (WTO): Ensures rules-based trade; interprets TRIPS and dispute settlement. Seeks balance between IP and access.

- World Health Organization (WHO): Public health guidance, prequalification, and the mRNA Vaccine Technology Transfer Hub; advocates access and capacity building.
- World Intellectual Property Organization (WIPO): Technical assistance on IP systems; supports innovation ecosystems.
- Pharmaceutical & Biotech Industry: Needs predictable IP to justify high R&D risk, particularly for biologics and novel modalities.
- Civil Society & NGOs: Push for affordability, transparency in R&D costs, and robust use of TRIPS flexibilities.
- Regional Bodies (e.g., EU, AU, ASEAN): Harmonize standards, fund manufacturing hubs, negotiate procurement.

Countries:

- United States

Intentions: Preserve strong global IP standards to incentivize high-risk innovation; maintain leadership in biopharma, biotech, and advanced therapeutics.
Interests: Defend patents and data exclusivity; promote voluntary licensing and public–private partnerships; ensure supply chain resilience for critical medicines.
Involvement: Major funder of biomedical research and purchaser (e.g., vaccines). Historically cautious about broad IP waivers but supportive of targeted access strategies (tiered pricing, donations, pooled procurement). Often pursues "TRIPS-plus" standards in trade agreements while acknowledging TRIPS flexibilities in public health emergencies.

- India

Intentions: Expand role as "pharmacy of the developing world" by scaling generics and biosimilars while growing domestic innovation.
Interests: Protect use of TRIPS flexibilities, especially CLs in exceptional circumstances; preserve strict patentability criteria to limit "evergreening"; build vaccine and API capacity.
Involvement: Led calls for pandemic-related IP relaxations; hosts a large generics industry supplying affordable medicines to LMICs; invests in biomanufacturing and R&D ecosystems.

- European Union

Intentions: Balance innovation incentives with patient access; maintain a competitive research base and strong regulatory standards.

Interests: Support robust IP frameworks, including supplementary protection certificates and data exclusivity, while exploring crisis-time flexibilities and joint procurement.

Involvement: Major funder/partner for global health initiatives; engaged in structured dialogues on tech transfer and regional manufacturing (notably Africa and Eastern Neighborhood). Often favors voluntary approaches and regulatory cooperation; internal debates continue over incentives for rare diseases and antimicrobial resistance (AMR).

- China

Intentions: Accelerate domestic biopharma innovation and ascend the value chain from generics to novel biologics.
Interests: Strengthen IP enforcement domestically to attract investment while retaining policy space for public health; invest heavily in biomanufacturing and clinical research infrastructure.
Involvement: Reforms patent law and regulatory pathways; rapidly expanding capacity in vaccines, APIs, and advanced therapies; seeks integration into global supply chains and recognition of its standards.

- South Africa

Intentions: Secure timely, affordable access to life-saving medicines and build regional manufacturing.
Interests: Broad interpretation and use of TRIPS flexibilities; support for technology transfer hubs; preference for transparent, equitable licensing models and pooled procurement.
Involvement: Co-sponsored pandemic IP waiver discussions; engages with WHO tech transfer initiatives; advocates diversified, regionalized production to reduce dependency.

Recent Developments:

The debate over intellectual property (IP) in the pharmaceutical industry has grown increasingly prominent in recent years, particularly in the wake of the COVID-19 pandemic. At the center of discussion is the balance between ensuring incentives for innovation and guaranteeing timely access to life-saving medicines. Between 2022 and 2025, the most important developments occurred across the WTO, WIPO, and several key national and regional jurisdictions.

At the WTO, ministers at the Twelfth Ministerial Conference (2022) adopted a limited TRIPS decision that temporarily eased compulsory licensing rules for COVID-19 vaccines. While many developing countries called for an extension to cover diagnostics and therapeutics, negotiations stalled and the Thirteenth Ministerial

Conference in 2024 ended without agreement. This stalemate highlighted persistent divides: states such as India and South Africa emphasized equity and access, while others, including Switzerland and segments of the EU, prioritized the protection of innovation incentives. As a result, countries have increasingly turned toward national compulsory licensing laws and voluntary licensing partnerships as more practical routes.

Meanwhile, the World Intellectual Property Organization made history in May 2024 by adopting the *Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge* (GRATK). This treaty obliges patent applicants to disclose the origin of genetic resources and traditional knowledge when inventions are based on them. For the pharmaceutical sector, the treaty expands the IP debate beyond patents into ethical questions about fairness, transparency, and benefit-sharing.

National and regional reforms further illustrate the changing landscape. In the United States, the Federal Trade Commission has launched challenges against "improper" Orange Book listings, particularly device-only patents used to delay generic competition. In Europe, reforms to the Supplementary Protection Certificate system aim to create a unitary SPC and centralized examination, harmonizing protections across member states. India, for its part, amended its patent rules in 2024 to streamline procedures and reduce administrative burdens, while still maintaining access-oriented mechanisms such as compulsory licensing.

Together, these reforms demonstrate that pharmaceutical IP governance is evolving through a patchwork of multilateral and domestic initiatives. For delegates, the key challenge is to craft proposals that respect the need for innovation while ensuring equitable access in times of crisis, recognizing that effective solutions will likely require cooperation across institutions and regions.

UN involvement:

The United Nations is not the primary lawmaker on intellectual property, but it has become a central political and practical actor in the debate over pharmaceutical IP rights. Its influence is most visible through the World Health Organization (WHO), which has long advocated that access to medicines must be treated as part of the right to health. During the COVID-19 pandemic, WHO promoted mechanisms such as COVAX to distribute vaccines and created the COVID-19 Technology Access Pool (C-TAP) to encourage voluntary sharing of patents, data, and know-how. Building on those experiences, the WHO now leads work on the 2025 Pandemic Agreement, which commits countries to improve equity in access, strengthen supply chains, and support technology transfer during future health crises. Beyond WHO, the wider UN system has also linked intellectual property to human rights and development. The Human Rights Council has repeatedly affirmed that access to medicines is an essential component of the right to health, while the UN Development Programme and UNAIDS assist governments in navigating TRIPS flexibilities such as compulsory

licensing. Perhaps the most concrete contribution has come from the Medicines Patent Pool, a UN-backed initiative that negotiates voluntary licenses with pharmaceutical companies, expanding affordable access in low- and middle-income countries.

Possible solutions:

Many proposed ideas to solve this challenge. One option is to expand voluntary licensing agreements, where large pharma companies allow generic manufacturers, particularly in LICs, to produce and distribute their medicines at lower prices. The Medicines Patent Pool (MPP) is a successful example of this approach, improving access to treatment for diseases like HIV, AIDS and hepatitis. Additionally, some governments have used compulsory licensing—permitting the production of generics without the patent holder's consent—to lower drug prices during public health emergencies.

Furthermore, the way R & D receive their funds can be rethought, moving away from a system that relies so heavily on high consumer costs. Other models include prize funds, patent buyouts, and increased public investment in pharmaceutical research: all feasible to implement. These approaches could help stimulate innovation while ensuring that medications remain widely accessible and affordable.

International cooperation (which is why you, delegates, are here to discuss) is also key to shaping the future of IP rights. Organizations such as the World Health Organization (WHO), the World Trade Organization (WTO), and the United Nations (UN) play crucial roles in facilitating discussions between governments, pharmaceutical companies, and advocacy groups to develop fairer IP policies. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and its associated flexibilities should continue to be reassessed to ensure they support both innovation and public health.

The future of intellectual property rights protection in the pharmaceutical industry needs to be reconsidered to ensure that essential medicines remain both innovative and accessible.

Bibliography:

- PTI. "Indian Pharma Firms Not Copying Products, India Respect IP Rights, Says Goyal." *The Economic Times*, Economic Times, 10 June 2025,
- https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indian-pharma-firms-not-copying-products-india-respect-ip-rights-says-goyal/articleshow/121757603.cms?from=mdr

- https://www.facebook.com/ActizaPharmaceutical. “Impact of Intellectual Property Rights on Indian Pharma - Actiza Pharmaceutical PVT. LTD.” *Actiza Pharma*, 2 Aug. 2024,
- https://www.actizapharma.com/impact-of-intellectual-property-rights-on-indian-pharma/
- Craft, Rachel. “Pharmaceutical Patent Disputes in China | the Nuances of “Offer to Sell” - Spruson & Ferguson.” *Spruson & Ferguson*, 26 Aug. 2024,
- https://www.spruson.com/pharmaceutical-patent-disputes-in-china-the-nuances-of-offer-to-sell/
- PricewaterhouseCoopers. “Intellectual Property Protection.” *PwC*, 2022, www.pwc.com/il/en/pharmaceuticals/intellectual-property-protection.html.
- https://www.pwc.com/il/en/pharmaceuticals/intellectual-property-protection.htmlhttps://pmc.ncbi.nlm.nih.gov/articles/PMC3217699/

Bhattacharya, Sanjib, and Chandra Nath Saha. “Intellectual Property Rights: An Overview and Implications in Pharmaceutical Indrustry.” *Journal of Advanced Pharmaceutical Technology & Research*, vol. 2, no. 2, 2011, p. 88. *ncbi*. intellectual property & drug discoveryYouTube · Chem Help ASAP29 Jul 2023

Salib, Veronica. “Exploring 5 Types of Intellectual Property Protections in Pharma.” *Pharma Life Sciences*, TechTarget, 2024,

https://www.techtarget.com/pharmalifesciences/feature/Exploring-5-types-of-intellectual-property-protections-in-pharma

- Hoen, Ellen t. “UN “Pact for the Future” Intellectual Property Actions Need Revision to Ensure Innovation and Access to Health Products for All | Medicines

Law & Policy." *Medicineslawandpolicy.org*, 13 Sept. 2024, https://medicineslawandpolicy.org/2024/09/un-pact-for-the-future-intellectual-property-actions-need-revision-to-ensure-innovation-and-access-to-health-products-for-all/

- Boscheck, Ralf. "Intellectual Property Rights and the Evergreening of Pharmaceuticals - Intereconomics." *Intereconomics.eu*, 2015, https://www.intereconomics.eu/contents/year/2015/number/4/article/intellectual-property-rights-and-the-evergreening-of-pharmaceuticals.html