

2023 Global Economic Forum
Intellectual Property and Distribution of Medicines
Background Briefing Paper

Patents, Property, and Distribution

The world as we know it today would not exist without patents. They are an extremely important legal right that has played a crucial role in developing the world for the last 200 years. A patent is a document designed to protect **intellectual property**. It is awarded to an inventor, either an individual or a company who creates a new product and applies for one. If granted, they become the only entity who is allowed to make, use, or sell their invention for a limited period of time. This grants a unique competitive advantage that allows a producer to make a reasonable profit off of their creation.

Patents exist for industrial tools, electronics, art, computer programs, military hardware, and so much more. Patents also exist for medicine and drugs, or more specifically molecular components in drugs and medicines. Not everything can be patented, in fact there is criteria as to what is considered for patent review. Patents are not allowed to be too abstract. It has to be tangible and actually be useful. Additionally they can not be given to natural discoveries, they have to be purified, modified or incorporated as part of a larger invention in order to receive consideration. Lastly patents must be defined and spelt out. An applicant has to prove they have an understanding of how their invention works.¹

In medicine, patents tend to be applied to specific synthetic molecules or delivery techniques that are unique but critical components to the success of that drug. These elements allow a medicine to be brought to market. This also allows some medicines such as insulin to be repeatedly patented, as new and unique improvements are made to it that call for repainting.

Medicines are either patented or generic. When generic is used, think open source. Anybody can produce or sell the medication however they wish but **generic medicines** only exist in the absence of a

¹ "Patents." World Intellectual Property Organization. Accessed February 27, 2023.
<https://www.wipo.int/patents/en/>.

patent. Manufacturers of these medicines have two ways they can bring their product to market. They can either file for a patent or challenge the validity of an existing patent in an effort to remove it.²

The concept of a patent exists universally but across countries there can be a number of key differences. The first is to what can be granted a patent as some countries operate under different criteria. Secondly, the patent length tends to differ from country to country or economic bloc to economic bloc (depending on the uniformity of that bloc). Finally a patent is only valid for that country meaning if Pfizer has a patent for the United States, it can only exclusively produce, use or manufacture in that country. It theoretically could in another country if a patent doesn't already exist but not exclusively and some countries prohibit international companies from applying for patents. Regardless of the country to country regulations, patents remain perhaps the single most important tool a private individual or company can wield to control production and distribution.

Distribution

Medicinal distribution functions within the pharmaceutical supply chain which like every supply chain includes everything from making the item, to shipping it across the country or globally, to someone finding a buyer. The process slightly differs for medicine since there is an entire regulatory process that is subjected to and if selling internationally, multiple regulatory processes.

Issues can occur at any stage of the supply chain flow but when patents are introduced into the mix it increases the chance of error. Problems with production affect the entire market for that drug. Additionally the patent holder becomes the sole buyer that can be negotiated with in a particular market. These are important factors for consideration when shipping drugs nationally or internationally, especially when creating distribution plans in times of emergency.

One of the most expensive parts of the supply chain are **import tariffs** which only apply to drugs being shipped internationally. However, regardless of the location a drug is being shipped to, providers still have to negotiate a fair price which is hard to do with monopolies. Lowering or getting rid of tariffs can help make medicines more affordable, but they are only one major

² Berger, Jan, and Jeffrey Dunn. "How Drug Life-Cycle Management Patent Strategies May Impact Formulary Management." AJMC. MJH Life Sciences, January 20, 2017. <https://www.ajmc.com/view/a636-article>.

contributor to already high costs that affect distribution.³ Costs can be impacted by price ceilings but only in the countries where pharmaceutical companies operate.

Distribution is successful when a medicine is available, accessible, and affordable. Available in the sense that a locality has and is able to successfully maintain a stock of medication, accessible in the sense that anybody who needs it can easily get to it and affordable in the sense that once a patient arrives they can pay for it without significant financial burden. It is between the pharmaceutical company and the purchasing state to make successful distribution happen.

Global Cooperation

Strong international cooperation lays at the forefront of any successful distribution plan. The assured globalization of pharmaceutical companies is largely the result of international cooperation that has made it easier for drugs and medicine to flow from origin to destination. In many instances, this is due to an easing of restrictions that allows medicine to travel from location to location. The ease of regulations has less to do with the cooperation of states and companies, and more so with states and other states. When countries partner with each other to collaborate on scientific efforts (or maintain positive diplomatic ties) it becomes easier for information to flow in a universal and timely manner. This efficient transfer of information allows governments to set regulations quickly and with more information. The result of this practice means more and more countries have similar knowledge of how certain medications function and thus similar regulatory policies, allowing distribution to occur without getting caught up in lengthy bureaucratic procedures.

The benefit of patented medicine as it relates to global cooperation is that by only having one manufacturer, state health departments only have to look at one medication. The ironic disadvantage is that it places more power at the foot of the producer. This development is not inherently good or bad but if an issue occurs on the providers front in terms of production or shipping, the rest of the world feels the brunt of it. This is one of the reasons drug shortages are commonplace worldwide, especially in countries that lack infrastructure to efficiently ship or store medication. The second reason for global drug shortages is more economic.

³ Bauer, Matthias, and Philipp Lamprecht. "How Tariffs Impact Access to Medicines." Geneva Network, October 12, 2021. <https://geneva-network.com/research/how-tariffs-impact-access-to-medicines/>.

By having only one provider of a certain drug, all the price setting power lies at the feet of that developer. States then have to negotiate with that provider and that provider only. As a result, it becomes more difficult to negotiate fair prices. Part of the pricing problem can be attributed to the power that monopolies have to set costs at whatever they please. Businesses have an incentive to maximize profit and because monopolies offer no other alternative, they are free to set the cost at their leisure. However, **Research and Development** is extremely expensive. The average cost of R&D for a new medication is almost \$2 Billion USD. Therefore, companies also have a need to make their money back in full or else there is no company to provide a drug.⁴ In some instances, if a provider is too harsh on a price, governments can always look at a similar drug being produced under a patent in another country. However this can be a very timely process and one still needs to account for the production time, and quality that this provider might be operating under, not to mention the distance from the point of production to the destination.

The R & D issue provides further complexity to international distribution efforts. Because R & D is expensive, and many medicines are being produced under patents, companies usually steer clear from developing a lot of drugs at once, especially when uncertainty exists as to how much they will make off of sales.⁵ Medicines are becoming more advanced and complex, but the development of these sophisticated drugs often means drugs for diseases that are common in specific global regions are not being produced or are not being developed fast enough to keep up with changes in **pathology**.

The Role of Patents Across the Globe.

Patents help to protect intellectual property but they also strongly influence the availability of medicine through increased costs, and a lack of R & D. Drug shortages are very common and largely due to single party manufacturing. By providing a patent, a government essentially provides a monopoly to a producing firm which provides an advantage in negotiations. Availability, accessibility, and affordability are all heavily impacted by a state's ability to successfully negotiate for a fair quantity at a fair price. When only one company controls the production of a specific medicine or medicine technology, it

⁴ "Research and Development in the Pharmaceutical Industry." Congressional Budget Office, April 2021.
<https://www.cbo.gov/publication/57126#:~:text=Only%20about%2012%20percent%20of,than%20%242%20billion%20per%20drug.>

⁵ Blit, Joël. "Are Patents Really Necessary?" Centre for International Governance Innovation, April 25, 2017.
<https://www.cigionline.org/articles/are-patents-really-necessary/#:~:text=Patent%20rights%20can%20promote%20innovation,the%20art%20can%20reproduce%20it.>

drastically hampers the ability of states to provide a good deal to its citizens and opens up the potential for a myriad of supply chain issues and delays that may follow.

This plays a big role in trade agreements as well. In the case of the **Trans Pacific Partnership (TPP)**, many of the developing countries involved in negotiations found themselves at great risk when the United States Trade Representative pushed for a provision that would expand the classification of what medicines could receive monopoly protection. This protocol would not only make it more difficult for governments to control the cost of reimbursement through public health programs, but impact countries like Peru who have a need for long term supplies of medicine to combat chronic diseases. Peru is already stretched thin when it comes to paying into their public health system. An increase in patent protections would make most medication unaffordable for most Peruvians.⁶

There is an argument to be made about whether or not patents should exist in medicine. On one hand, patents slow down the development process greatly. They prevent other parties from also developing a drug which can lead to shortages in the worst of times. Even when governments step in and suspend the enforcement of patents during times of crisis, once those suspensions are lifted companies return to being at eachothers throats very quickly. Generic drugs do not have these issues. Technology can be shared to help produce variants of a specific medication and rather quickly at little cost to the manufacturer or consumer.

However it is the same problems that patents have that also contribute to their benefit. While patents create monopolies they provide companies with the assurance they need to continue development. If all drugs began as generic, companies would be hesitant to produce them. Research and development of a drug is an extremely costly process and multiple competitors greatly diminished returns. Patenting provides assurance to the pharmaceutical manufacturer that they are more likely to make the money they spent on R&D back. Patents are also subject to stricter regulation, and having a single bearer of one makes it easier for regulatory agencies to provide oversight and ensure a drug is safe before it hits the market.

⁶ "Intellectual Property and Access to Medicine." Oxfam. Accessed February 27, 2023. <https://www.oxfamamerica.org/explore/issues/economic-well-being/intellectual-property-and-access-to-medicine/>.

The Charge - Create a Regional Policy Proposal Presentation

The **2023 Global Economic Forum** will simulate the international community's fight against growing global risks. The World Bank is seeking to fund innovative solutions to this crisis, and has called for interested policymakers to submit their proposals. Invited Student Delegates (that's you!) will represent an assigned global region and committee topic related to the issue of *Unemployment and Workforce Development*. Each team will present their strategy for combating this evolving issue to other students in their committee representing other global regions at the very beginning of the Forum's first committee breakout session. After hearing each region's initial presentation, your committee will then collaborate on a collective policy proposal aimed at solving your committee's topic on a global scale, while representing the needs and opportunities of each represented regional group.

During the Closing Plenary at the end of the program day, each committee will present their policy proposals to the Closing Plenary. One member of each region in the committee group will present the committee's newly-created collective policy proposal. A panel of judges representing the World Bank will hear each committee proposal, ask clarifying questions, and ultimately determine a winning committee team, awarding them fictitious funding for their policy proposal.

It is critical that you read the separate [Instructions for Creating a Regional Policy Proposal Presentations](#) for further details and expectations. Teams are encouraged to utilize the provided presentation template (in your school's Google Drive program folder) when creating their Regional Policy Proposal presentations. Each team will have 3 minutes to present and should have no more than 5 slides in their presentation (not including the title slide). Each team should be prepared to answer 3 minutes of questions from their peers about their policy proposals.

This briefing paper should serve as a starting point for understanding the overall challenges of your assigned committee topic, however, you will also need to conduct additional research. Please see the Council's Global Economic Forum resources [webpage](#) for suggested additional resources. The purpose of this Forum is not only for Delegates to gain a holistic understanding of the social, political, and economic implications and consequences of the digital divide, but also for Delegates to also gain experience in the policymaking process as it relates to critical international issues. Best of luck!

Quick Facts

Find at least five quick facts from this briefing paper or in reputable online sources that will be useful in creating your Regional Policy Proposal. Quick facts should be about one sentence long and provide useful information on your assigned committee topic.

1. Pharmaceutical companies usually only develop one drug at a time due to high research and development costs.
- 2.
- 3.
- 4.
- 5.

Questions to Consider

Answer the following questions to the best of your ability based on the information presented in the briefing paper above and any additional research you have already conducted on your own.

1. What is the average cost of research and development for new medicines?
2. What are the benefits and disadvantages of the intersectional relationship between research and development and patents in medicine?

How did the Trans Pacific Partnership (TPP) demonstrate the areas in which intellectual property rights and efficient distribution intersect? What are their consequences?

How can your regional assignment best balance the necessity of intellectual property rights with the need for quick, affordable, and efficient distribution of medicines? Does your region have a need for this balance?

Glossary

Term	Description
Generic Medicine	Any medicine that is not protected by a patent
Import Tariff	The tax one pays to receive a specific good being shipped from another country
Intellectual Property	A work or invention that is the result of someone's creativity
Pathology	The science of the causes, effects and evolutions of diseases
Research and Development (R & D)	Work that goes into innovating, introducing, or improving a new or pre existing good
Trans Pacific Partnership (TPP)	A defunct trade partnership between 12 countries in the Pacific Rim