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How Can Lower-Income Countries Access COVID-19 Medicines Without Destroying the Patent System? The National Exhaustion Solution

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Many scholars argued that improving access to medicine requires major amendments to the patent system, which is structured according to the Agreement on Trade-Related Aspects of Intellectual Property Rights. This article argues that the argument is not necessarily true. Amending Article 6 of the TRIPS Agreement to adopt a national exhaustion rule for pharmaceutical patents would be sufficient to achieve a considerable improvement in access to medicine while simultaneously strengthening patent protection. This proposal encourages the pharmaceutical industry to adopt a price discrimination policy whereby Pharma would lower medicine prices in the lower-income countries. Accordingly, global access to new medicines such as COVID-19 medicines could be increased as these countries have the majority of poor people. At the same time, Pharma can continue to sell the same medicine in higher-income countries at higher prices, generating sufficient profits to incentivize research and development.

Keywords: Access to Medicine, Pharmaceutical Patents, TRIPS Agreement, Exhaustion, Pharma, Parallel Trade, Price Discrimination, Arbitrage, Generic Medicine, Patented Medicine, EU Exhaustion Policy

Human history has witnessed many pandemics, epidemics, and other deadly infectious diseases. Plague, for instance, claimed approximately 50 million lives in its first wave between 1348 and 1350, a number that constituted almost a quarter of the world's population at that time.[1] Another example is HIV/AIDS, which has killed 36.3 million people since 1981.[2] The pharmaceutical industry (Pharma) was able to develop a medicine a few years later. However, the medicine does not cure the patients. Instead, the patient must keep taking it for his or her entire life to stay alive, which is obviously very costly especially for the poor.[3]

The most recent global health crisis is the COVID-19 pandemic that emerged in China and spread across the world, causing the death of more than five million people within less than one year.[4]While Pharma is waitingforfinal approvals before distributing new medicines that cure COVID-19, the price of the medicine is very expensive. For instance, *Molnupiravir* medicine, which is developed by Merck and waiting for approval by the American food and drug administration costs $700 per course.[5]Lower income countries, especially the 46 countries determined by the United Nations as the least-developed countries,[6] can never pay such amount of money for one course.

It is evident that Pharma is pivotal in fighting disease by investing in research and development (R&D) to invent new medicines capable of saving human lives.[7] However, the poor, especially in the least-developed countries, struggle to access medicine due to its expensive price.[8] Patenting is commonly accused of considerably increasing the price of medicine. Accordingly, it has been argued that the patent system established by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) conflicts with international human rights law as it impedes access to medicine.[9] The United Nations Sub-Commission on the Promotion and Protection of Human Rights adopted a resolution in 2000 declaring that: *"[T]here are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other.*"[10] Following the outbreak of the COVID-19 pandemic, there was a call to suspend patent rights related to COVID-19.[11]

However, patent protection is necessary to incentivize the innovation of new medicine. Many

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scholars have argued that a lack of patent protection for medicine shall result in a significant decline in R&D investments by Pharma.[12] Lack of patent protection for medicine shall result in a significant decline in R&D investments by Pharma, which means fewer new medicines. It could be argued that compulsory licensing is sufficient to improve access to medicine. However, powerful countries exert pressure on lower income countries to stop using compulsory licensing, so it fails to improve access to medicine. Moreover, excessive use of compulsory licensing could negatively affect the profits of Pharma, leading to less investment in R&D and fewer new inventions.

Therefore, the issue in this article is how to improve access to medicines, especially access to the new COVID-19 medicines in lower-income countries where most of the low-income people live without destroying the global patent system. This article argues adopting a global rule of national exhaustion for pharmaceutical patents would contribute to the improvement of access to COVID-19 medicines, while strengthening patent protection at the same time.

On one hand, this proposal shall increase the revenues of Pharma since it will be able to adopt price discrimination without fearing arbitrage. This will enable the industry to maximize profits in each country's market by offering medicine at a higher price in higher-income countries and a lower price in lower-income countries. On the other hand, the proposal will improve access to medicine. The poor in lower-income countries will be able to purchase patented medicine at lower prices. Moreover, the transfer of low-priced medicine from lower-income countries to higher-income countries shall be stopped.

This article proceeds by providing a background on the concepts of exhaustion of patent rights and parallel trade. The article then argues that national exhaustion strengthens patent protection and achieves a noticeable improvement in access to medicine in lower-income countries. Finally, it concludes that national exhaustion is the proper form of exhaustion that should be followed in the context of pharmaceutical patents.

The Concepts of Patent Right Exhaustion and Parallel Trade

The doctrine of exhaustion, also known as the doctrine of first sale,[13] defines the territorial rights of a patent holder after the first authorized sale of a patented item.[14] This means that a patent holder exhausts his or her patent right once he or she sells a patented item for the first time.[15] Therefore, the purchaser may resell a specific patented item without infringing upon the patent.[16] In other words, the power of the patent holder to control the distribution of a patented item is limited to the first sale of this specific item.[17] Therefore, the term "exhaustion of patent rights" may be misleading.[18] Patent rights are inexhaustible. Instead, what is actually exhausted is the ability of the patent holder to exercise absolute control over the distribution of a particular sold patented item.[18] The patent holder retains exclusive rights to make, use, or sell other copies of the patented item during the term of the patent.[19]

While the TRIPS Agreement realized an unprecedented achievement in the context of harmonizing patent law globally, it did not obligate member states to adopt a certain form of exhaustion.[20] Article 6 of the TRIPS Agreement shows that the member states failed to compromise and "agreed to disagree" on this issue.[21] The Article provides that:

> "*For the purposes of dispute settlement under this Agreement … nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights*."

Accordingly, each member state is free to choose the rule of exhaustion that most suits its national interests. Moreover, the same country can adopt a different exhaustion rule for various forms of intellectual property rights.[22] Generally, there are three main forms of exhaustion: international exhaustion, national exhaustion, and regional exhaustion.[23]

International exhaustion indicates that when the patent holder authorizes the sale of the patented item in one country, the purchaser shall have the right to export it without the patent holder's consent.[24] Therefore, a wholesaler in any country may import the patented item from the purchaser without the consent of either the patent holder or its licensee in that country. In other words, the patent holder loses control over the distribution of the patented item throughout the world.[14] Consequently, adopting international exhaustion legalizes parallel trade.[22] Most of the countries that have adopted international exhaustion are developing countries such as Egypt, Malaysia, Taiwan, Argentina, and South Africa.[25]

National exhaustion means that when the patent holder authorizes the sale of the patented item in one country, the purchaser shall have the right to resell it

within the borders of that country only. The purchaser cannot export it to another country without the consent of the patent holder.[26] Therefore, while the patent holder loses control over the distribution of the patented item within the domestic market, the distribution of the patented item outside of this single market is still controlled. Accordingly, parallel trade is illegal under national exhaustion.[22] The United States (U.S.) is an example of a country that has adopted a national exhaustion rule for pharmaceutical patents. While the U.S. Supreme Court recently adopted the international exhaustion of patents, the court ruling does not apply to pharmaceutical patents.[27] The Prescription Drug Marketing Act of 1987 provides that:

> *"... no drug ... may be imported into the United States for commercial use if such drug is manufactured outside the United States, unless the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States."*[28]

The third form of exhaustion is regional exhaustion in which a group of countries treats their domestic markets as a single market. Under this form of exhaustion, when a patent holder authorizes the sale of a patented item, the purchaser has the right to resell it within its country or export it to one of the member countries. However, the purchaser may not export it to a country that is not a member.[29] Therefore, while the patent holder loses control over the resale of the patented product in the markets of these countries, it retains control over the resale of the product in other markets. Consequently, parallel trade is partially permitted. It is permitted within the countries belonging to a certain region but prohibited everywhere else.[22]

The European Union (EU) adopted this form of exhaustion.[30] A patent holder or its licensee in a member state of the EU cannot block the importation of a patented item sold in any other member state. However, the same patent holder or licensee has the power to block the importation of the patented product in a non-EU country. Similarly, the member states of the African Intellectual Property Organization have adopted regional exhaustion.It is noteworthy that this organization does not represent all African countries as its name may suggest. Rather, it represents only 17 French-speaking African countries.[31]

As previously discussed, the doctrine of exhaustion controls the legality of parallel trade.[32] In the context of this article, parallel trade refers to the importation of genuine, patented medicine without the patent holder's permission. Parallel trade occurs when there is a difference in the price of medicine between two countries.[33] The higher the price gap between the two countries, the higher the potential for parallel trade.[34] Arbitrageurs take advantage of the price gap by purchasing medicines from a lower-priced country and reselling them in a higher-priced country.[35] The next two parts demonstrate how prohibiting parallel trade could strengthen patent protection and improve access to medicine.

National Exhaustion Strengthens Patent Protection

National exhaustion increases the value of pharmaceutical patents as it outlaws parallel trade, allowing Pharma to practice price discrimination without fearing arbitrage. National exhaustion promotes the power of Pharma over the distribution of patented medicine, enables Pharma to adapt to price control measures on medicine set by many governments, and enables Pharma to compete with generic medicine manufacturers when a compulsory license is issued or a patent term expires.

Strengthening patent protection is realized not only by determining a long patent term but also by increasing the power of patent holders over patented products during the patent term.[36] The power of patent holders will increase when they are able to control the importation of their patented product. International exhaustion and parallel trade prevent Pharma from legitimately achieving considerable profits.[37] Arbitrageurs take advantage of differences in price and currency fluctuations to transfer low-priced medicine offered by Pharma in lower-income countries to the markets of higher-income countries. This also involves free-riding on the advertising campaigns of patent holders and their licensees.[38]

Pharma prefers to practice price discrimination to adjust a medicine's price to consumers' purchasing power in every single market. Consequently, Pharma can offer the same medicine at a higher price in higher-income countries and a lower price in lower-income countries.[43] In so doing, Pharma will be able to maximize profits by selling each medicine at the highest possible price that each consumer can afford.[39] However, arbitrage deters Pharma from following this pricing strategy.[40] By prohibiting parallel trade, national exhaustion eliminates arbitrage

and enables Pharma to enjoy absolute power over the distribution of their patented medicine across the world and therefore enjoy the benefits of price discrimination.

Moreover, there are circumstances under which Pharma has no choice but to adopt a price discrimination strategy, which is practically possible only if national exhaustion has been adopted. For instance, the vast majority of countries apply price control measures on medicine.[41] Because medicine is an essential product, governments consider controlling its price as a form of consumer protection.[42] Additionally, governments recognize the importance of making medicine available to preserve public health and even political stability.[43] Therefore, medicine prices are usually the result of complicated negotiations between governments and the medicine manufacturers holding the patents.[44]

If Pharma does not show flexibility during negotiations by reducing its price, the negotiating government may issue a compulsory license allowing generic medicine manufacturers to produce the patented medicine. To avoid compulsory licensing, Pharma may consider price discrimination as its only rational choice, which would enable it to offer medicine at a lower price in certain countries, while continuing to offer it at the regular higher price in other countries. However, this only works if a national exhaustion rule is adopted. Otherwise, low-priced medicine shall be exported to the markets of the countries in which price controls do not exist.[45]

To illustrate the negative consequences of parallel trade when price controls exist, imagine that a pharmaceutical corporation invests millions of dollars in inventing a new medicine. The medicine is offered for sale in the U.S. market for $1.00 per pill. However, due to the existence of price control measures in a low-income country, it is offered for sale at $0.50 per pill in this country. Wholesalers buy large amounts of the low-priced medicine in this country for $0.50 per pill and resell it in the U.S. market for $0.95. A rational American consumer will, of course, prefer to purchase the imported medicine at $0.95 per pill rather than the medicine specified for the U.S. market that is commercialized at $1.00 per pill.

Such behavior should not be permitted for several reasons. First, Pharma suffers a profit loss due to such practices by wholesalers. Second, access to medicine is not improved in countries in which price control measures exist since the medicine is exported, and Pharma will be reluctant to provide more of the low-priced medicine in its market. Third, the practice contradicts efforts to create incentives to innovate new medicine. Therefore, parallel trade results in a substantial loss for all of the relevant parties when price control measures exist.[46] Parallel trade does not achieve its usual welfare effects in the context of pharmaceuticals due to price control measures being adopted by most countries as a means of protecting consumers' access to medicines.[47]

Frederick Abbott supports parallel trade and the adoption of an international exhaustion rule. However, he also notes that parallel trade should be prohibited, if the prohibition serves "*a social welfare purpose that outweighs*" the effects of restricting trade.[48] The issue is how to determine whether prohibiting parallel trade is the only way to promote social welfare. Abbott suggested that prohibiting parallel trade is not necessary because a pharmaceutical corporation in a situation like the previous example should provide the country in which price controls exist with a sufficient amount that would satisfy only the local market's needs.[49] Abbott assumed that this country's government would prohibit wholesalers from exporting the medicine to keep the low-priced medicine in the domestic market.

However, the exportation of low-priced medicine from developing and least-developed countries is possible due to government corruption.[50] In addition, the amount sufficient to satisfy that country's local market could easily be disputed. Pharma would be required to prove that it provided the country with a sufficient amount of the medicine but the medicine was exported, which could be challenging for Pharma to support their claims with evidence. Additionally, arbitrageurs could easily change the packaging of the medicine, so that tracking its origin becomes almost impossible. While Abbott's argument is sound, practical difficulties may cause many problems and governments may find the opportunity to issue compulsory licenses assuming the patent holder's failure to provide the domestic market with a sufficient amount of the patented medicine. Therefore, prohibiting parallel trade by adopting a national exhaustion rule for pharmaceutical patents is the most convenient solution.

National exhaustion also enables Pharma to compete with generic medicine manufacturers. As previously noted, governments may issue a

compulsory license if negotiations on the price of medicines fail. Article 31 of the TRIPS Agreement determines several cases in which governments can issue compulsory licenses, among of which is cases of emergency.[51] In such circumstances, generic manufacturers offer medicine at a low price, knocking the patent holder out of competition. Under international exhaustion, a patent holder will not be able to offer medicine at a competitive price, fearing parallel trade. However, adopting a national exhaustion rule for pharmaceutical patents will enable Pharma to compete with generic manufacturers in a specific market because it will be able to continue offering the medicine at a higher price elsewhere.

Similarly, national exhaustion enables Pharma to compete with generic medicine manufacturers after the patent term expiration in some countries. Differences in patent terms in different countries require Pharma to adopt price discrimination.[52] While Article 33 of the TRIPS Agreement sets the minimum patent term to 20 years, some countries have engaged in TRIPS-Plus Agreements extending the patent term beyond that period.[53] Price discrimination enables pharmaceutical corporations to set a higher price for patented medicine in such countries. That price cannot be determined in other countries wherein the patent has expired due to generic medicine manufacturer competition, unless a national exhaustion rule is adopted for pharmaceutical patents.

Finally, it could be argued that price discrimination is not that important for Pharma since consumers have an inelastic demand for medicine, meaning that medicine consumers are supposed to continue purchasing medicine regardless of price. Therefore, higher prices of medicine will not result in a decline in demand. However, official reports by international and non-governmental organizations have proven that patients in the least-developed countries die due to a lack of access to medicine. These patients and their governments cannot afford the expensive price of medicines. Those who died due to a lack of the medication would have increased the demand for medicine if they could have afforded its price. Therefore, declining medicine prices will increase the demand for medicine. Pharma prefers to divide medicine consumers into two categories: price-sensitive consumers and price-insensitive consumers. Pharma prefers to charge price-sensitive consumers a lower price, which is a strategy that everyone should support, not only because it rewards the medicine's inventors but also improves access to medicine, as shown in the next part.[54]

National Exhaustion Improves Access to Medicine

This part argues that while encouraging Pharma to reduce medicine prices is essential to improving access to medicine, several other issues must also be considered. Pharma must be encouraged to offer medicine for sale as soon as possible to accelerate access to medicine. In addition, access to medicine should be interpreted to mean access to safe medicines. The national exhaustion of pharmaceutical patents will encourage Pharma to offer new, safe medicines at affordable prices as soon as possible. Therefore, parallel trade should be limited to the same exceptional cases that permit compulsory licensing.

As previously noted, access to medicine will be improved if medicine prices become affordable for consumers, especially in the least-developed countries where most of the poorest people live. National exhaustion can achieve this goal since it enables Pharma to adopt price discrimination. It is commonly argued that price discrimination increases consumers' access to any product.[55] Thanks to price discrimination, Pharma can adjust medicine prices in each country according to the purchasing power of the consumers therein. Therefore, Pharma will likely offer medicine at the lowest possible price in the least-developed countries; possibly, a price that is just above the marginal price. As for the developing countries, Pharma will offer medicine at a moderate price that is proportional to the purchasing power of the consumers in these countries. Regarding developed countries, Pharma will charge a higher price for its medicine. While the main incentive of Pharma in offering medicine at different prices in different counties is maximizing profit, this will also improve access to medicine.

Moreover, national exhaustion will encourage Pharma to offer medicine in every market. It has been argued that in the absence of price discrimination, Pharma may choose not to serve the markets in developing and least-developed countries to avoid arbitrage, or they may at least delay introducing medicine in these markets.[56] By contrast, when national exhaustion is adopted and price discrimination is permitted, Pharma will seek to serve all possible markets, increasing global access to medicine. Moreover, national exhaustion will accelerate access to medicine by encouraging Pharma

to provide every market with new medicine as soon as possible. This could save lives as well. As noted before, the EU practices a regional exhaustion rule. It is legal in all EU member states to import medicine from other member states, while it is illegal to import the same medicine from a non-member state. This has resulted in a decrease in medicine prices in the importing countries.[57] However, it has also resulted in the loss of profit for Pharma due to the transfer of low-priced medicine in low-income member states to the markets of higher-income member states.

Consequently, Pharma had to delay the introduction of some medicine in certain countries to avoid arbitrage. For instance, GlaxoSmithKline (GSK) delayed the introduction of its anti-migraine medicine, Sumatriptan (Imigran®), for several years in France because French price control measures required GSK to offer the medicine at a lower price than in other EU countries. GSK noted that offering the medicine at a lower price in France would "*undercut its higher price elsewhere*."[58] If the EU followed the rule of national exhaustion of pharmaceutical patents, the French consumer would not have been deprived of this medicine for so many years, and access to it would have been accelerated.

The GSK incident in France is not an exceptional case. Other pharmaceutical corporations with patents have refrained from introducing their medicines in low-income EU countries to avoid the arbitrage of medicine in these countries into the markets of high-income EU countries.[59] Rich patients in low-income countries were able to purchase these medicines from high-income countries' markets, leaving the poor excluded and unable purchase them.

As Harvey Bale notes, the EU Exhaustion Policy "*is an example of what not to do*" as its underlying policy relates to "*politics and rhetoric*."[60] If European decision-makers believed that parallel trade promoted consumer welfare, they would have adopted international exhaustion instead of regional exhaustion.[66] Therefore, the EU model does not support the adoption of an international exhaustion rule that permits parallel trade.[61]

Moreover, access to medicine should be interpreted as meaning access to *safe* medicine. It is imperative to note that parallel-traded medicine raises serious health and safety concerns.[62] Medicine manufacturers become unable to track the location of medicine when it is parallel-traded. Therefore, recalling defective medicine could become impossible in some cases, as it could have been transferred anywhere in the world.[63] National Economic Research Associates (NERA) reported "*numerous examples of faulty batch-numbering such as different batch numbers on the blister and the box which could become dangerous in the event of arecall*."[64]

In addition, parallel trade increases the risks associated with storing and transporting medicine. It is well-known that certain medicines must be stored carefully at a certain temperature range. Medicine may lose its efficacy or even become harmful if it is stored in a place that is humid or that has a high temperature.[65] That is why it is always advisable to transport medicine under the supervision of the manufacturer. However, this is not possible for parallel-traded medicines. Merchants who lack the necessary knowledge are those who supervise the transportation process. What adds insult to injury is that visual inspection by customs officials is not sufficient to determine if the medicine is defective.[66] Therefore, parallel-traded medicine could actually worsen a patient's health condition.

Additionally, as parallel-traded medicine packages are not provided by the manufacturers holding the patents, the imported medicine packages may even include counterfeit medicine.[67] This risk forced Kenya to outlaw parallel trade in pharmaceuticals.[68] Tracing the origin and history of the parallel-traded medicine could be impossible.[69] Customs officials may fail to distinguish between parallel-traded medicine and counterfeit medicine, especially in developing countries.[62] Counterfeit medicines raise serious health risks. It may cause resistance to genuine medicine, worsen the patient's condition, cause new symptoms, prolong treatment, and sometimes even lead to death.[70]

The labels and leaflets of parallel-traded medicine are usually written in the exporting country's language rather than the importing country's language. Consumers in the importing country who are unable to understand foreign languages may therefore misuse the medicine.[63] Other problems arise if the medicine packaging is changed. NERA reported that some parallel-traded medicines contained an "*inaccurate description of the active ingredient*."[71]

It is noteworthy that policymakers across the world have realized the risks associated with parallel-traded medicine. In the U.S., the Senate Finance Committee Report reported that parallel-traded medicine threatened public health in two ways. First, foreign counterfeit medicines can be falsely described as re-

imported medicine. Second, storage and handling procedures cannot be guaranteed since parallel-traded medicines come from foreign countries.[64]

Similar concerns exist even in developing countries. A letter from a senior drug regulatory agent in Kenya pointed out to her counterpart in South Africa some of the problems associated with parallel-traded medicine from a regulatory standpoint, such as:

> *"(1) the application of double standards for approved packaging and labeling; (2) required cooperation of manufacturers and distributors in determining counterfeit products; (3) patient confusion due to multiple presentations of the same product; (4) the persistent threat of intellectual property infringement challenges; (5) the inability of the Pharmacy and Poisons Board to ascertain that the parallel import was manufactured with GMP [Good Manufacturing Practice] standards; and (6) in the event of quality control problems there was an inability to implement necessary product recall policies."*[72]

Finally, there might be circumstances in which parallel trade should be permitted to improve access to medicine. However, parallel trade should remain an exception to patent rights, and it should only be allowed when compulsory licensing is permissible according to article 31 of the TRIPS Agreement.

Conclusion

This article argued that a national exhaustion rule for pharmaceutical patents promotes access to medicine and patent protection at the same time. It maximizes the profits of Pharma by knocking out arbitrageurs, paving the way for a price discrimination strategy when appropriate. However, it simultaneously promotes access to medicine since Pharma shall be encouraged to offer medicine at a lower price in lower-income countries in which the majority of low-income people reside. It is a win-win proposal for Pharma and low-income consumers of medicines. Adopting this proposal improves access to medicine without destroying the international patent system.

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