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Review Article

Global Health in Transit: The Unused Potential of Parallel Imports During COVID-19

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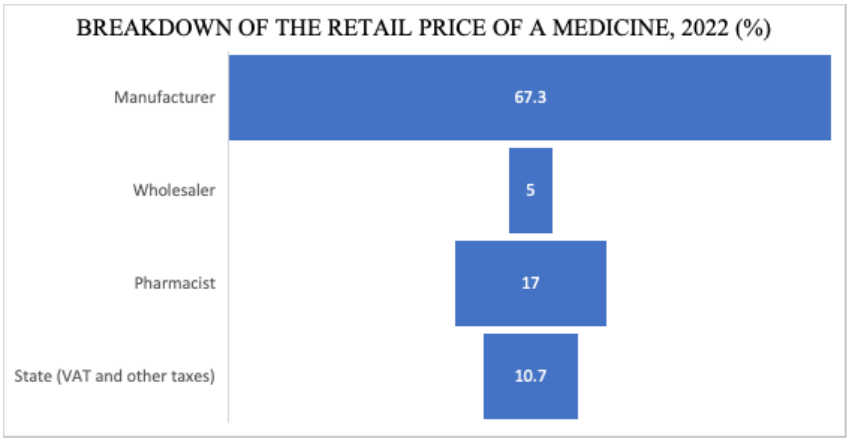
Abstract: Parallel importation is a practice of importing patented or trademarked products from a foreign market without the authorization of the intellectual property (IP) holder has long been a contested tool in the global trade and health governance landscape. During public health emergencies, such as the COVID-19 pandemic, the potential of parallel imports to facilitate affordable and timely access to essential medicines and medical technologies came under renewed scrutiny. This paper explores whether parallel importation serves as a legal loophole exploited during crises or a legitimate, life-saving mechanism consistent with international trade law. It examines the current legal framework under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the role of national exhaustion doctrines, and the operational challenges posed by regulatory, logistical, and political constraints. The paper further assesses the need for international guidelines, improved regional cooperation, and transparency mechanisms to prevent abuse while safeguarding public health priorities. Ultimately, the paper argues that when regulated appropriately, parallel importation is not a legal loophole, but a necessary and lawful policy instrument for mitigating inequities in global health access during emergencies.

Keywords: Accessibility, Affordability, Medicines, Parallel imports, Public health emergencies

INTRODUCTION

Patent Rights vs. Access to Medicines: An Overview

Global health governance has always struggled with the tension between the protection and enforcement of intellectual property rights on the one hand and the equitable access to medicines on the other. While patents stimulate biomedical advancement by pioneering and executing new technologies, patents confer an exclusive right of market access to the company, which results in exorbitant prices of the drug. This tension becomes extremely pronounced in public health emergencies, when timely access and affordability to life-saving medicines and vaccines is a necessity on a global scale.[i] Once more, the COVID-19 pandemic has revitalized discussions on the consequences of IP monopolies. In a world where collaboration is instantaneous, the ability to access new technologies and their accompanying equitable distribution is starkly lacking.[ii] Already the world's poor and middle-income countries are suffering, and the most prosperous countries are more than willing to help. In this type of situation, other countries with looser restrictions should be examined as possible sources of access, which is the notion of parallel imports.[iii]



Source: EFPIA member associations

What Are Parallel Imports?

Importation, in this case, involves the export of a patent protected item, and is done without the permission of the rights owner, but with the approval of the rights owner in the exporting country.

This principle of law cuts across the idea of territorial exclusivity of a patent. Within the context of international exhaustion, a patent holder's rights are said to be exhausted as soon as a particular patented item is legally sold in any country of the world, and re-exemption elsewhere is permitted. In comparison, national exhaustion does not allow such imports and access is restricted to what is produced or legally authorized in that country.[iv]

The issue of parallel imports is more complex, primarily because of the principle of exhaustion of rights to a patent, especially the exhaustion doctrine, which, in a way, sets the boundaries of what a patent holder can do after the first sale of a patented product.
In the case of parallel imports, there are three models which are most noteworthy:

1. National Exhaustion: Patent rights are exhausted only in the country of sale; parallel imports are prohibited.
2. Regional Exhaustion: Rights are exhausted within a regional bloc (e.g., the EU).
3. International Exhaustion: Once a product is sold anywhere in the world, the patent holder cannot block its import elsewhere.

The TRIPS Agreement, with regard to Article 6, permits each WTO member to select its own regime on exhaustion. Some nations, such as India, have implemented international exhaustion to permit parallel imports as a measure to protect Public Health.

Significance During a Global Health Crisis

Public health emergencies during the past few years have highlighted the problem of equitable access to vital medical services and commodities.[v] During the HIV/AIDS pandemic in the early 2000s, a few countries defied the pricing strategies of multi-national pharmaceutical companies and used parallel importation to access HIV and AIDS generic medicines at subsidized prices. The COVID-19 pandemic also saw a sudden surge in the discourse on parallel imports as a methodology for gaining access to overpriced and scarce medicines.[vi]

Regardless of this theory, there are a few nations that are willing to use parallel imports for accessing the COVID-19 vaccines and treatment, suggesting political and legal realignment alongside a fundamental restructuring of the access mechanisms. The absence of legal regulation in real-world situations indicates the necessity of a deep, strategic examination of national and global policies.[vii]

Literature Review

1. Frederick M. Abbott – "Parallel Importation: Economic and Social Welfare Dimensions" (Journal of International Economic Law)[viii]

- Abbott explores how parallel importation (PI) fits within the TRIPS Agreement's exhaustion framework and explains how it can help provide access to important medicines during times of emergency.
- In the article, Abbott describes PI as a reasonable instrument to address the price discrepancies generated from pharmaceutical companies' differential pricing practice.
- Abbott explains how national exhaustion regime helps states free up resources in public health emergencies, and how national exhaustion regimes support PI as a pro-competitive mechanism.

- He emphasizes, however, that alone, PI will not resolve the affordability issue if not accompanied by price-regulating and transparent public procurement systems.
- The article helps shape the discussion towards understanding how PI can be a reasonable, welfare-enhancing practice and not a 'loophole'.

2. Carlos M. Correa – "Integrating Public Health Concerns into Patent Legislation in Developing Countries" (*The Journal of World Intellectual Property*)[ix]

- Correa argues that parallel imports are a critical safety valve for developing countries, especially, in the context of expensive pharmaceutical products and the inability to produce the medicines domestically.
- The article locates PI in relation to other aspects of TRIPS flexibilities and argues that it should be standard practice during public health emergencies.
- Correa states that unqualified patent protection combined with no PI (if allowed) can increase mortality and morbidity in poorer countries.
- He shows the gaps in the ability to prohibit PI and the need for specific legal positive grants of PI in the national laws.
- The article's argument in favor of PI is that it is a life-saving measure that is rooted in equity and public health concerns.

3. Frederick M. Abbott and Jerome H. Reichman – "The Doha Round's Public Health Legacy: Strategies for Pharmaceutical Access" (*Journal of International Economic Law*)[x]

- The authors review the effects of the Doha Declaration on legitimizing TRIPS flexibilities (including parallel imports) during a declared emergency.
- They indicate that PI serves as a conduit to obtain essential medicines and other health products from a wide range of global suppliers in a timely manner during a public health emergency.
- The article cites a number of instances where PI (including in other countries) was granted in combination with compulsory licensing.
- Abbott and Reichman identifies PI as the key to ensuring that the spirit of the Doha Declaration is achieved, which is avowedly public health over the protection of the commercial patent interest.
- They warn, nevertheless, that political pressure and trade retaliation continue to limit its overall application

4. Ellen 't Hoen – "Public Health, Intellectual Property and Access to Medicines" (*Health and Human Rights Journal*)[xi]

- 't Hoen examines parallel imports as part of the Access to Medicines movement, describing them as a necessary legal pathway when monopolistic pricing restricts drug availability.
- The article shows how countries such as South Africa, Kenya, and Brazil leveraged PI to address HIV/AIDS treatment shortages.
- 't Hoen explores the legal mechanisms made available to other countries and argues that abuse of emergency conditions for legal monopoly undermines the right to health
- 't Hoen demonstrates that drug manufacturers' legal monopolies on PIs have resulted in preventable deaths
- 't Hoen concludes that in a time of pandemic, when supply chain disruptions are inevitable, PIs contribute to decreased mortality

5. Amir Attaran – "How Do Patents Affect Access to Essential Medicines in Developing Countries?" (*Health Affairs*)[xii]

- Amir Attaran – "How Do Patents Affect Access to Essential Medicines in Developing Countries?" (Health Affairs)
- Attaran assesses whether or not patents, and correspondingly, restrictions on PI, severely or meaningfully limit access to medicines in emergencies.
- He arrives at the conclusion that for a considerable number of essential medicines, patent access barriers are resounding, and therefore, PI would be an invaluable additional measure.
- The article posits that PI is of utmost importance in the case of biologics and products made for pandemics, in which the difficulty of production is of high order, and therefore, production is needed to be supplemented.
- Attaran also sheds light on how PI assists in countering segmentation of the market, as low-income geographies are priced in a dysregulated fashion.
- His critique stresses that PI, while it does not tackle the fundamental issues of affordability, can alleviate shortages for a time in crises.

6. Margaret Kyle – "Strategic Responses to Parallel Imports" (*RAND Journal of Economics*)[xiii]

- Kyle's empirical study considers how pharmaceutical firms alter pricing in response to PI.
- In crises, PI pressure causes firms to reduce domestic pricing to control the market.
- Kyle shows that PI leads to more intra-brand competition that allows governments to

negotiate more favourable procurement agreements.
- While public health crises are not the main focus of the article, the findings of the article suggest that PI is able to act as a lifesaving service by mitigating the impact of high drug prices.
- The study also contends that concerns of PI counteracting innovation are PI innovations fears.

7. Jerome H. Reichman – "Compromising Access to Medicines: The WTO, Patents, and Compulsory Licensing" (*Journal of Law, Medicine & Ethics*)[xiv]

- Reichman highlights the complementary relationship between PI and compulsory licensing during emergencies.
- His assertion is that compulsory licences may take weeks to months to implement, which means PI is an immediate stopgap measure.
- The article addresses the TRIPS-plus provisions in bilateral trade agreements which are likely to restrict PI.
- Reichman views PI as a valid and essential means of protecting public health in times of crisis such as a pandemic.
- PI is framed as a legal right as per TRIPS, but also a moral imperative in the face of a Pandemic.

Legal Framework: The Supremacy of Domestic Law

TRIPS, which is administered by the WTO, provides minimum standards for IP protection and enforcement, however, it does have flexibilities, and exceptions, including Article 6, which, as a result of the legal vacuum regarding exhaustion of rights, permits each country to resolve the matter of parallel imports on a purely national basis.[xv] This means that countries are free to choose a policy of national, regional or international exhaustion and none of these options would be in breach of the obligations stemming from TRIPS.[xvi]

India is an example of the country that had incorporated international exhaustion into its legal framework. Under Authorized User Provisions of the Patents Act of 1970 Section 107A(b), the Authorized User does not require the Patentee's consent to import any of the Patentee's products which are sold and marketed in other jurisdictions by the Patentee or by an Authorized Licensee.[xvii] This, of course, permits Indian importers to purchase and market cheaper versions of patented drugs and distribute them for sale in India.[xviii]

Practical Usage and Protection Issues

Nonetheless, the permissibility of such acts under Indian law does not seem to correlate with the practical application of such acts. Issues such as regulatory costs, political influence by multinational pharma companies, and misplaced priorities are all contributing factors. For example, India has not utilized its parallel import provisions, which permit the importation of vaccines manufactured abroad, although the country has been long facing a deficit of vaccines during the early rollout of the vaccination program.[xix]

In addition, there is a lack of specific, protective measures or guidelines. Customs officials, agents, and officers in charge of public health, and the Intellectual Property system all are devoid of directed initiatives for assessing the legal status of parallel imports, which results in inconsistent practices and legal ambiguity. Indian courts generally lack the appetite for clear cut decisions which only adds to the situation.[xx]

Global Exhaustion: A Pathway to Access or a Threat to Innovation?

One of the central policy debates focuses on the adoption of a global exhaustion regime, which would permit parallel imported medicine patents without restriction. Supporters of the policy argue that in low- and middle-income countries, it would allow the cross arbitrage of essential drugs and democratize drug access.[xxi]

In contrast to that, what is termed as Big Pharma, the pharmaceutical industry as a whole, is against international exhaustion because it claims the practice eliminates price discrimination and dampens the motivation for innovation. They contend that the necessity to sell at global prices would force countries to disinvest in R&D, especially on neglected, underfunded diseases.[xxii]

Countering Big Pharma's arguments are access-to-medicine advocates, who focus on the public funding, as in the case of the COVID-19 vaccines, that is used in drug development, the excessive profits earned on patented drugs, and the urgent need to save lives.[xxiii] The issue remains controversial, but it became particularly visible in the case of the COVID-19 pandemic, which witnessed a flurry of waivers, patent pooling, open licensing, and calls for global collaboration.

WTO Stance and Implementation of TRIPS Article 6

The position of the WTO, as described in the Doha Declaration on the TRIPS Agreement and Public Health from 2001, understands that TRIPS should not block members from safeguarding public health and increasing the availability of medicine.[xxiv] Article 6 of TRIPS, in particular, relates to exhaustion regimes. However, in reality, the freedom that countries have in exercising this particular article is controlled by, and hence subject to, geopolitical dynamics, trade agreements, and administrative constraints.

Bilateral and regional free trade agreements often contain "TRIPS-plus" clauses that restricts the capacity of states to apply international exhaustion. This undermines the usefulness of TRIPS flexibilities and increases complexity to LMICs.

The Legal Framework of Parallel Imports

The practice of internationally trading for and purchasing medicines and other health-related goods that have not been approved for sale and distributed in a country for use without the permission of the (IP) owner is dubbed parallel importation. This practice is a vital concern to the improvement of public health.[xxv] The practice that is most often associated with this is the doctrine of the exhaustion of rights which determines a boundary to how much control an Owner of an Intellectual Property concerning goods sold is in position to control.[xxvi] This chapter discusses the legal aspects of parallel imports focusing on the doctrine of exhaustion, its application in the TRIPS Agreement, and its approach in the other regions of the world such as the European Union, the United States, and India.

TRIPS Agreement and Article 6

Intellectual property rights are under the Trade Related Aspects of Intellectual Property Rights (TRIPS) document, which is managed by the World Trade Organization (WTO). Each member of the World Trade Organization (WTO) is free to practice the exhaustion of intellectual property rights as they deem fit.[xxvii] In June 6 of the TRIPS Agreement, Article 6 states as follows, "Nothing in the Agreement shall be used to the address the issue of exhaustion of intellectual property rights."[xxviii] It permitting members of the World Trade Organization (WTO) to define their own systems of exhaustion which can be used in their countries relating to cross border selling.[xxix]

Geographical Exhaustion of Rights

Relating to the European Union member states, they have adopted a regional exhaustion of rights policy. One of the important things to be noted in the **European Union (EU)** is the cross border trade, which is the free circulation of services and goods in the block. As a result, once a single part is loaded to a cite, selling the rest is a lot easier, since anyone from a member state can purchase additional parts.[xxx]

United States: The U.S. follows a national exhaustion doctrine which suppression the resale of patented products outside the national boundary of the US. This means that even if a product has been sold outside the U.S. the IP holder has the right to control the product's import to U.S. This means that even if a product has been sold outside the U.S. the IP holder has the right to control the product's import to the U.S.[xxxi]

India: India has adopted an international exhaustion regime which permits the parallel import of patented products after they are sold to any country in the world. Section 107A(b) of the Indian Patents Act, 1970, states that a patented product can be imported without the consent of the patent holder as long as the product is legally manufactured and sold in a foreign country.[xxxii]

WTO Rulings and International Case Law

Exhaustion of rights has been an issue in various jurisdiction around the world:

Impression Products, Inc. v. Lexmark International, Inc.[xxxiii]: In this US Supreme Court case, the court held that the selling of a patented product, regardless of any restrictions which the seller attempts to impose on the buyer, does sell the product, and, therefore, the patent holder surrenders all rights to the product. This case also supported the theory of national exhaustion in the U.S.

Novartis v. Union of India[xxxiv]: This crucial case for the UK Supreme Court deals with the denial of granting a patent to the beta crystalline form of imatinib mesylate as Glivec. The Court maintained the rejection focusing on the demand for improved therapeutic efficacy regarding Section 3(d) of the Indian Patents Act. The case didn't directly deal with parallel imports. However, it reinforced India's intent to balance public health with patent laws.

If a country adopts an international exhaustion regime, it can offer medicines at lower prices using parallel imports. The legal frameworks concerning parallel imports in developing jurisdictions greatly affect the public. Under this approach, the monopolistic pricing of multinational patent holding companies can be relieved. The legal frameworks concerning parallel imports are movement as per the policies of a nation, international treaties, and the principle of exhaustion. These frameworks are imperative for a country's fulfilment of obligations toward international public health. Public health obligations still need to be considered when drafting policies on IP and trade.

Parallel Importation During a Public Health Crisis

Using parallel importation in the context of public health emergencies especially widespread pandemics has become a critical practice due to the ability to bypass the rights of the holder of the IP. This chapter looks at the import of parallel 'improved works' in these contexts by assessing history, responses to COVID-19, and real-time challenges of implementation in the context of these emergencies.

Historical precedents

- *The Pharmaceutical Litigation and Medicines Act of 1997, South Africa*

In 1997, South Africa enacted the Medicines and Related Substances Control Amendment Act[xxxv] , which allowed for the parallel importation of patented medicines and the issuance of compulsory licenses. With regards to the HIV/Aids pandemics, this Act was intended to subsidize the essential treatments of patented medicines. PhRMA and some states fought the Act, spawning litigation.[xxxvi] However, as a result of a

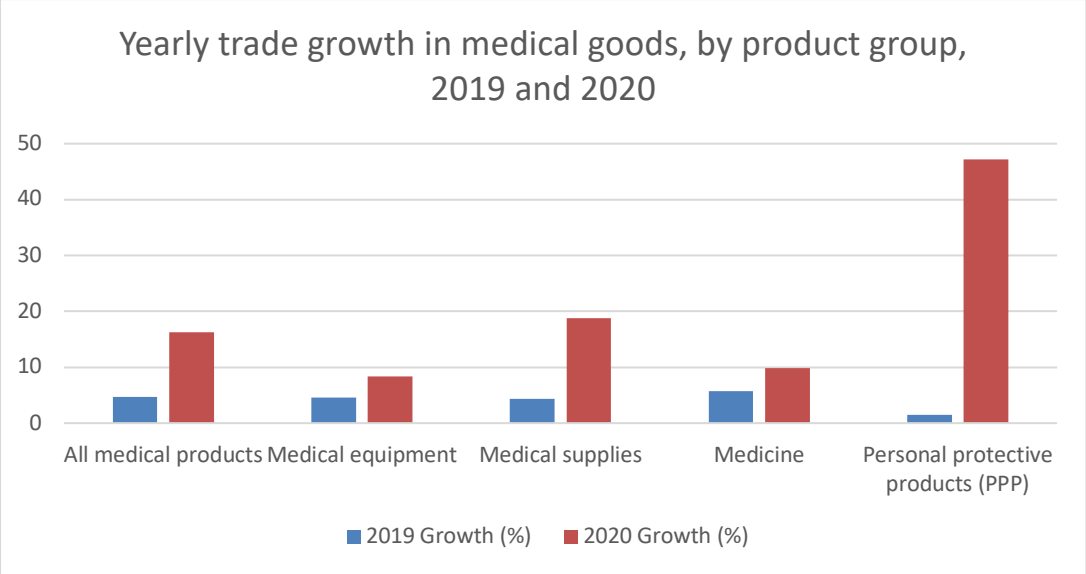
2001 agreement brokered by public advocates, the multinational companies plunked down their allegations, and allowed the law to be enforced without the lawsuit.

- *Kenya, Zimbabwe, and Thailand's Use During the HIV AIDS Epidemic*

In the HIV/AIDS epidemic, some countries took steps to increase access to ARVs by parallel importing and compulsory licensing of ARV drugs. Kenya and Zimbabwe changed laws to allow the importation of ARV generics, therefore, bringing the costs of treatment within reach of the masses.[xxxvii] Quite the same, Thailand's Government Pharmaceutical Organization made cheap generics of efavirenz and other ARVs to make them accessible to its people.[xxxviii]

COVID-19 Responses

The COVID-19 pandemic demonstrated the need of parallel importation as one of the means to the equitable distribution of lifesaving drugs and vaccines.[xxxix] Countries with strong legal provisions on parallel importation used such laws to buy vaccines and therapeutics from other countries by breaking the supply and price monopoly. For example, Within the European Union, countries under a regional exhaustion scheme easily obtained Covid vaccines by importing them from other member countries.[xl] On the other hand, countries with no regional exhaustion policies struggled to get cheaper vaccines, pointing out the gaps in the global health equity.



Source: WTO Secretariat

Top 10 exporters and importers of goods critical to combatting COVID-19

Rank	Economy (descending order of 2020 value)	Value 2019 (US$ million)	Value 2020 (US$ million)	Annual % change 2020	Share of COVID-19 critical goods 2019 (%)	Share of COVID-19 critical goods 2020 (%)
1	China	38195	105457	176.1	12.6	26.7
2	United States	46775	46470	-0.7	15.4	11.8
3	Germany	34208	36863	8.2	11.2	9.3
4	Netherlands	21736	24285	11.7	7.2	6.2
5	Mexico	12137	13163	8.5	4	3.3
6	Japan	12187	12340	1.3	4	3.1
7	Malaysia	7901	12014	52.1	2.6	3
8	Belgium	11260	11931	5.8	3.7	3
9	France	10940	11354	3.8	3.6	2.9
10	Ireland	9439	8892	-5.8	3.1	2.3
	Total share of top 10 exporters				**67.3**	**71.6**

Rank	Economy (descending order of 2020 value)	Value 2019 (US$ million)	Value 2020 (US$ million)	Annual % change 2020	Share of COVID-19 goods 2019 (%)	Share of COVID-19 goods 2020 (%)
1	United States	54744	78327	43.1	18.3	19.6
2	Germany	23681	32479	37.2	7.9	8.1
3	China	21595	24644	14.1	7.2	6.2
4	France	12402	19643	58.4	4.1	4.9
5	Japan	14199	19185	35.1	4.7	4.8
6	United Kingdom	10628	19153	80.2	3.5	4.8
7	Netherlands	16031	18200	13.5	5.3	4.6
8	Canada	8013	11993	49.7	2.7	3
9	Italy	7727	11724	51.7	2.6	2.9
10	Belgium	9438	11003	16.6	3.1	2.8
	Total share of top 10 importers				**59.5**	**61.7**

Source: WTO Secretariat

Obstacles to Consider

- *Legal Concerns*

The imposition of parallel importation of pharmaceuticals during a public health crisis is most often bogged down with regulatory concerns. Differences among various countries' rules, processes, and standards for approval may slow down the importation and the distribution of lifesaving drugs. Additionally, there may be concerns regarding the safety and effectiveness of the imported materials which would demand stringent quality control, quality assurance, and oversight programs.

- *Foreign Relations Problems*

If importation is done without approval of the home country, it tends to cause the countries to be hostile to one another especially if it is patent infringement or there is a compulsory license issued. There may be trade retaliatory actions, and other sanctions, which may cause a delicate balance of foreign relations even during health emergencies, and other international aids will be neglected.

- *Logistical Concerns*

The distribution and movement of other medicines along with the imported drugs to be utilized in the country pose a major problem. Monitoring the movement of these drugs, and other medicines within the country is a challenge. There needs to be a cohesive strategy of support between the country's government and international aids, and private businesses. Supply chain interruptions like those of the COVID pandemic, can disrupt the needed medicines, especially those which are crucial, making parallel importation plans ineffective.[xli]

The use of parallel imports remains crucial in increasing access to vital pharmaceutical products during public health emergencies. Although there are legal, regulatory, diplomatic, and logistical issues to address, the value of ensuring equitable access to life-saving untethered treatments far outweighs such obstacles. Persistent advocacy in defense of strong legal structures, collaboration between nations, and effective management of the global supply chains is crucial in parallel importation advocacy for future emergencies.

Legal and Ethical Issues in the Pharmaceutical Industry

Eroded Patent Protections

The parallel importation of pharmaceutical products, the pharmaceutical industry claims, violates the territorial rights of the patent owners, thereby overriding these interests. Such developments are likely to discourage the innovative spirit of a country and, as a result, its investment in research and development. some fears parallel imports as the means to lowered prices, which in turn, drives a wedge between recovering the expensive estimates to market the a newly manufactured drug.[xlii]

Disruption of Market Price Model

The Disruption of Market Price Model is an equally concerning factor of a pharmaceutical company. Profitable drug companies lose revenue when parallel

imports into the high-priced market. Such companies are in a delicate situation. They satellite countries with low and middle incomes to which medications are sold at token rates and therefore are inexpensive, while drug manufactured and sold in high-income countries is highly priced.

Ethical Issues

- *Essential Medicines Access*

Access to lifesaving medication should be available to everyone without discriminating against their wealth or location. In this instance, parallel importation serves this purpose as it makes expensive medication affordable as well as accessible. For this reason, it upholds to ethical justice principles.[xliii]

➢ *Ethics Of Patent, Innovation And Public Health*

The issue here is the potential conflict between corporate rights, such as patent rights, and the needs of public health. Patents provide motivation for the creation of new products, but their exclusive rights also enable the patent owner to place the essential medicine beyond the reach of the needy. So, the issue is how to sustain public health and protect the patent since in any health crisis, such balance is needed, especially when the delay in medication is critical[xliv].

Trade Retaliation and Diplomatic Pressures

- *U.S. Special 301 Reports*

U.S. Trade Representative has Special 301 Reports[xlv] to put pressure on other countries to IP laws including those dealing with parallel imports. Such countries can face trade sanctions or other diplomatic pressures which creates tension between a country's right to public health and pressure to abide by international laws IP.[xlvi]

- *Implications for Developing Countries*

The developing countries which wish to use parallel importation to increase access to medicines may conflict with developed countries that work to protect IP rights. These countries may not be able to tackle a health crisis policy and public health favor for policy.

Use of Free Trade Agreements (FTAs) and TRIPS-Plus Provisions

- *TRIPS-Plus Provisions*

FTAs tend to cover TRIPS-Plus provisions that go well beyond the minimum requirements of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (IPRs) or the TRIPS Agreement. Such provisions may impose tougher IP protections on the ability of states to engage in parallel importation. For example, patent term extension and additional data exclusivity provisions can impede the market entry of generic medicines and therefore restrict access to low-cost drugs.

- *Effects on Policies of Public Health*

Including TRIPS-Plus clauses in FTAs may hinder a country's ability to implement public health policies focusing on access to medicines. By IP strengthening, these clauses may make it more plausible for countries to avoid using parallel importation as a drug cost reduction strategy, worsening inequity in health.[xlvii]

Conflicts of Jurisdiction and Enforcement Difficulties

- *Contradictory Domestic Legislations*

Conflicting national laws IP Jurisdictional clashes stem from parallel importation. For instance, a country that admits of international exhaustion of IP rights may, on the one hand, permit the importation of a drug from another country where the same drug is lower priced. The importing country may, on the other hand, have laws that prohibit imports of such, breeding legal and enforcement paradoxes.

- *Difficulties of Enforcement*

The enforcement of IP rights is complicated especially when it is done across national borders. Countries may have different legal standards for patentability, and diverse interpretations of the principles of IP, laws, and enforcement. This may augur a lack of uniformity in the application of IP in the country, thus complicating attempts to control parallel imports.

The concept of parallel importation in the pharmaceutical industry also brings legal and ethical dilemmas. On one hand it increases the availability of critical medicines in low-resource settings. On the other hand, it contravenes the conventional IP protective ethos and sows the seeds of apprehension regarding the ever-growing innovation ditches. Reconciling these conflicting interests entails the balancing act between public health and the right of the patent owner. The answer to ever-evolving public health challenges should promote the collaboration and discourse on the development of policies that provide the balanced distribution of medicines with due respect to IP.

Comparative Case Studies and National Approaches

India: Section 107A(b) and Its Use

In India, Section 107A(b) of the Patents Act allows the patent infringement of imported medicines for the purpose of combating public emergencies, so long as the patent holder has "launched the product in the market." This clause has ensured the availability of low-cost medicines in India even during national health crises.

One of the notable examples has been the use of the cancer drug Gleevec (imatinib mesylate). The Supreme Court of India Reasoned that Novartis's patent application for Gleevec could be rejected because of the rigorous patentability criteria India has set forth under Section 3(d) of the Patents Act. This permitted Indian generic manufacturers to produce and export the drug at a fraction of the cost, thus transforming the treatment landscape for patients in India and other developing nations.[xlviii]

During the HIV/AIDS pandemic, for instance, India's contribution to the supply of antiretroviral (ARV) drugs was monumental. The robust generic pharmaceutical industry India possesses was strengthened by the provisions of Section 107A(b) which facilitated the

production and export of the drugs in order to combat the HIV/AIDS pandemic.[xlix]

Brazil: Flexibility in Sourcing Generic Drugs During Health Crises

In Brazil's case, we see a balanced approach to parallel importation with public health as a primary concern. The country's policies permit the importation of generic medicines in case of overcoming a public health emergency, even if there is no prior marketing authorization in Brazil. This case has proven to be of utmost importance during the COVID-19 pandemic, where the rapid access to vaccines and medicines was facilitated.

Aside from this, the government of Brazil also introduced the 'Farmácia Popular' program which allows the public to access basic medicine for a greatly subsidized price. This is possible because the program covers the cost of generic medicines which is often a barrier to access for the Brazillian people.

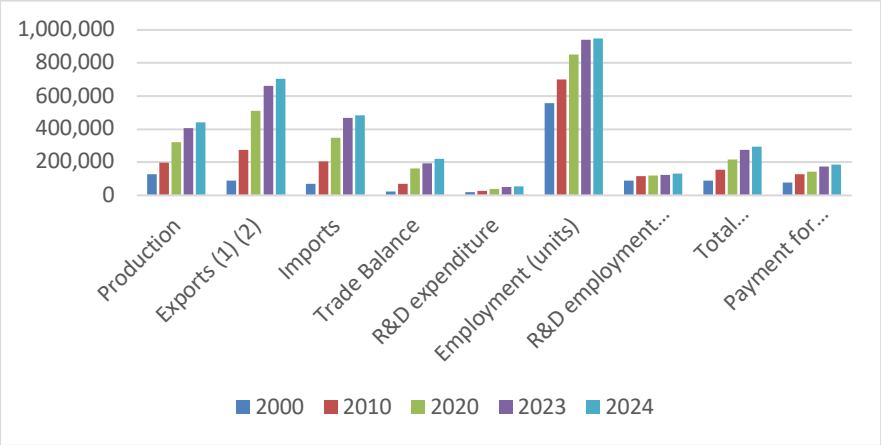
European Union: Comes up with New Framework for Parallel Imports Within the Union

The European Union has provided for the first-time a cross-border framework for parallel importation based on the principle of the internal market for the movement of goods. It permits pharmaceutical wholesalers to export medicines from the lower price member states to the higher price ones, achieving lower prices for higher medicines costs. This development lowers the overall cost of retail healthcare.[l]

EU parallel imports for pharmaceutical products must first have a simplified marketing authorisation. In addition, with the imported product must bear a significant resemblance to the original product. In the framework of level 2, the CJEU has offered rules on the conditions of permissibility of repackaging of parallel imported medicines, protecting the ecological and economic 'substance' of the product and product quality.[li]

The Pharmaceutical Industry: A Key Asset To The European Economy

INDUSTRY (EFPIA total)	2000	2010	2020	2023	2024
Production	1,27,504	1,97,359	3,22,554	4,05,701	4,40,000 €
Exports (1) (2)	90,935	2,76,357	5,09,828	6,61,559	7,05,000 €
Imports	68,841	2,04,824	3,47,124	4,68,032	4,85,000 €
Trade Balance	22,094	71,533	1,62,704	1,93,527	2,20,000 €
R&D expenditure	17,849	27,920	38,736	52,373	55,000 €
Employment (units)	5,56,506	6,99,059	8,50,928	9,40,555	9,50,000 €
R&D employment (units)	88,397	1,16,360	1,21,717	1,23,535	1,30,000 €
Total pharmaceutical market value at ex-factory prices	89,449	1,53,685	2,15,902	2,74,545	2,95,000 €
Payment for pharmaceuticals by statutory health insurance systems (ambulatory care only)	76,909	1,29,706	1,43,762	1,72,689	1,85,000 €

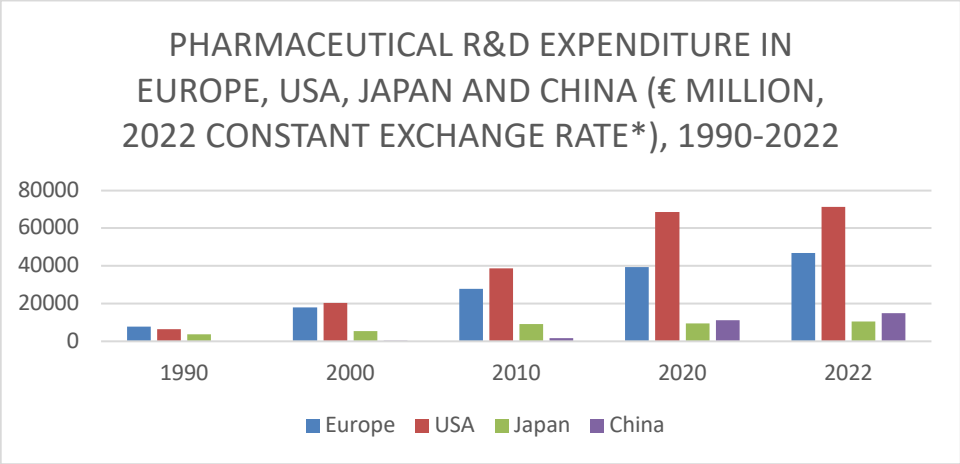


Values in € million unless otherwise stated

(1) Data relate to EU-27, Norway, Switzerland and United Kingdom since 2005 (EU-15 before 2005); Croatia and Serbia included since 2010; Turkey included since 2011

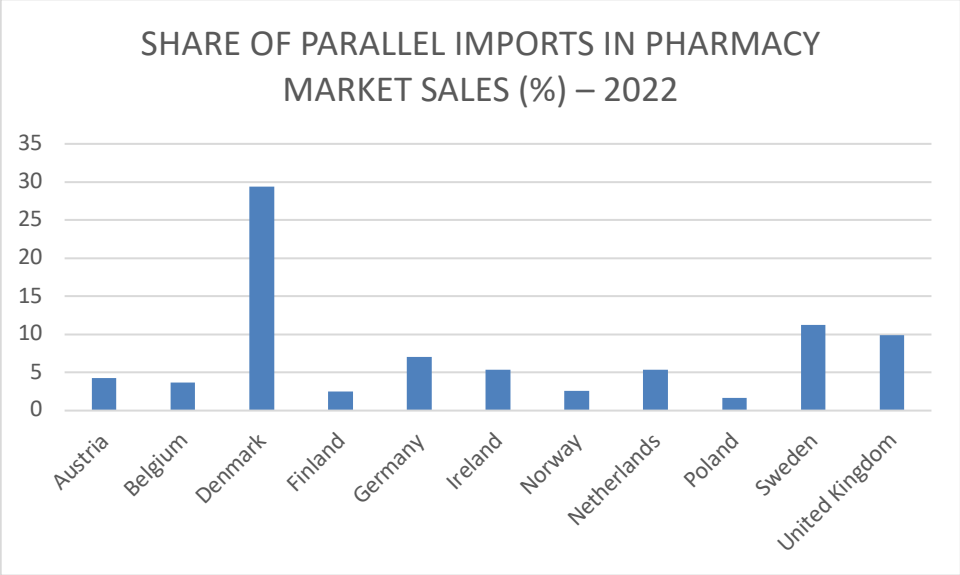
(2) Data relating to total exports and total imports include EU-27 intra-trade (double counting in some cases)
Source: EFPIA member associations (official figures) - (e): EFPIA estimate; Eurostat (EU-27 trade data 2000-2024)

Pharmaceutical R&D Expenditure In Europe, USA, Japan And China (€ Million, 2022 Constant Exchange Rate*), 1990-2022



Source: EFPIA member associations, PhRMA, JPMA, China Statistical Yearbook

Share Of Parallel Imports In Pharmacy Market Sales (%) – 2022



Source: EFPIA member associations (estimate)

Japan and South Korea: Regulation Still Applied, Order by the Government

Japan and South Korea have Controlled more than the economic balance for the parallel importation of medicines Order the importation to cross the border with.

In Japan, government ind United States borders, which includes parallel imports, is re gated by the Pharmaceuticals and Medical Devices Agency (PMDA). The PMDA is responsible for assessing safety and efficacy of foreign drugs, and for parallel imports, all of them must meet Japan's standards. This set of regulations ensure imported medicines are of good quality and safety, and fulfills Japan's requirements for fundamental standards of imported medicines.

In South Korea, the parallel import is regulated by the Ministry of Food and Drug Safety (MFDS) which is the same as Japan. However, the imported medicines must go through proper reviews and assessments before being sold in the market. The MFDS has set standards for the quality, efficacy, and safety of medicines that has to be met by any imported drugs.

Both nations have put in place preventative measures that bar the entry of poor quality and fake medicines. This will protect the welfare of the people, while reaping the benefits of importation.

African Regional Procurement and Medicine Imports

In Africa, regional cooperation has improved the access to medicines through the parallel importation. The African Medicines Agency (AMA) which is part of the African Union aims to streamline the African regulations on medical imports and exports to promote

safe and effective importation of medicines. The East African Community and the Southern African Development Community are Regional Economic Communities that have adopted policies on the parallel importation of medicines within their borders. Such policies facilitate sourcing medicines from countries that have an excess to ensure that the shortfalls in one country can be met by imports from another.[lii]

The case is the same with the SADC which during the COVID 19 pandemic, the other members of the SADC, with the SADC, managed to facilitate the import of critical shortage medicines. The parallel importation of vaccines within the EAC made it possible for the EAC to quickly obtain parallel imported vaccines within the EAC borders for sale.[liii]

Policy and practice of parallel importation do differ from country to country with regard to the approach taken to the legal system as well as in the health system. Countries such as India and Brazil have flexible policies towards the provision of medicines while countries like and Japan and South Korea are strict. Africa provides on of the best examples, within the region, on the benefits of collaboration on the availability of medicines. The other countries provide valuable lessons.[liv] The countries of Africa also show the potential to gain from. As global health challenges transform the niches of health, the lessons came from these countries will serve as valuable points in the complex realities behind parallel importation.

Reforming the Legal Framework for Future Emergencies

The COVID-19 pandemic and other global health emergencies has highlighted crucial gaps in the international legal system governing access to medicines and medical technology. The legal instruments available, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), have some room for flexibility with mechanisms such as compulsory licensing. The mechanisms of parallel imports imports of goods for which the legal permission has been obtained for sale in another country are indeed quite underused.[lv] Given their ability to ease supply bottlenecks, lower prices, and increase access to medicine in times of crisis, parallel imports deserve far more legal and policy attention than they currently receive. This chapter presents a tactical approach for restructuring international law to enhance the use of parallel imports in global emergencies.

Establishing Emergency Global Guidelines on the Use of Parallel Imports by WHO or WTO

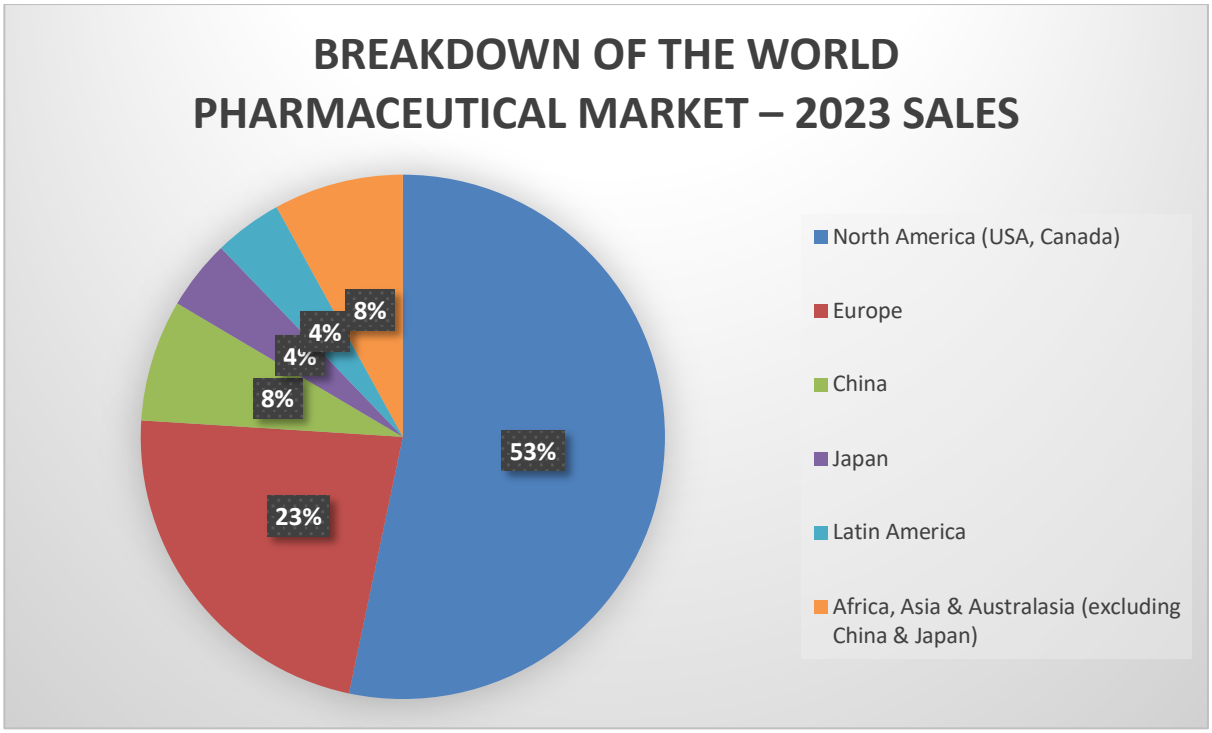
Foremost among the obstacles to the more widespread use of parallel imports during emergencies is the absence of specific minimum standards with the parallel. While Article 6 of the TRIPS Agreement decouples Members from the need to exercise international control on the exhaustion of rights, it leaves many States in a position of legal and practical ambiguity in times of emergencies. It is, therefore, imperative that the WTO, together with WHO, develops and disseminates non-binding universal standards outlining best practices for the use of parallel importation during public health emergencies.

These standards should articulate conditions that would activate use of parallel imports, such as public health emergencies of international concern (PHEICs) as defined by WHO. Furthermore, they should outline best practices to achieve regulatory equivalence for the controlled imports, identify and resolve issues related to lex conflicts on labeling and safety, and promote equitable compensation practices to curb excessive market distortion. Such a construct would complement the proposed WHO Model Law on Medicines Regulation, enabling countries to adopt a manageable, parallel importation response to a national emergency.[lvi]

Clarifying and Strengthening National Exhaustion Clauses

Legal doctrines dealing with the exhaustion of rights often state that when a product is sold by or with the permission of an intellectual property holder, the holder's rights to that specific product are 'exhausted'. This principle is important for initiating parallel imports. Each country may implement a regime of national, regional, or international exhaustion with varying consequences for parallel trade. Unfortunately, a lack of statutory language or judicial interpretation on exhaustion during periods of turmoil is still a prominent issue across many jurisdictions.

To avoid a lack of preparedness, international exhaustion should be incorporated into national frameworks with national laws on parallel imports allowing access to the IP protected goods sold legally in a foreign market. This form of national legislation comes with a great deal of adaptability when regional stock is unavailable, or when there is a deficit in domestic production. The IP protected goods should be legally sold in foreign markets while primary legislation should substantiate measures against counterfeit imports, which may be impeded by the erosion of quality. This primary regulation should delineate that inspection must originate from jurisdictions with strong regulatory frameworks such as the EMA and the FDA.
Governments must be careful in their wording, such as 'authorized sales' which is ambiguous and gives room for narrow interpretation by a judicial body. International bodies have the capacity to assist national policymakers improve such aspects lexically, by formulating model laws or treaties focused on defining exhaustion with precision and keeping exhaustion clauses strong.[lvii]



Note: Europe includes Belarus, Turkey, Russia and Ukraine; percentages might not add up due to rounding
Source: IQVIA MIDAS (audited sales) Q4 2023 MAT, May 2024; data relate to the 2023 global retail and hospital pharmaceutical market (prescription only) at ex-factory prices.

Increasing Coordination by Region and Joint Procurement

Cooperation at regional levels will offer the most effective means of scaling the advantages of parallel importation while alleviating the constraints of legal and logistical processes faced by individual countries. The African Union, South Asian Association for Regional Cooperation, and Association of Southeast Asian Nations should formulate strategies for pooled procurement and importation of parallel imports without policy restrictions during emergencies.

The establishment of regional consortia for the importation of goods would enable member countries to collaboratively share individual country regulatory evaluations, better negotiate pricing, and achieve efficiencies in distribution and allocation. As an example, a SAARC Medicines Access Platform could fast-track the approval processes of generic pharmaceuticals with competitive pricing for essential medicines so the members can legally import them from each other or third-party sources.

These arrangements are far more effective at alleviating the patent country and corporate political and economic pressures that are more likely to occur with small-state parallel importation. Regional economic communities may negotiate with patent and country exporting dominants to simplify the legal terrain and grant advance permission for parallel importation.

Integration with TRIPS Waiver Mechanisms

The flexibility provided under TRIPS Article 31 and the 2022 TRIPS waiver for COVID-19 vaccines suggests that legal emergency measures can be expanded during global health crises.[lviii] However, the current TRIPS framework does not explicitly link waiver mechanisms with parallel importation rights. Future waivers whether general or product-specific should include explicit provisions enabling automatic parallel importation rights for products covered under the waiver.

This integration would pre-emptively authorize member states to import qualifying goods from any WTO member without separate negotiations or proof of market failure. Such a mechanism would work along with compulsory licensing in cases where a licensee is authorized to manufacture a product, but lacks the supply or distribution to meet domestic demand.

WTO Members might also contemplate a General Council Decision clarifying that, for the duration of the emergency, any product subject to a waiver, compulsory license, or similar measure may be freely parallel imported across WTO territories.[lix]

Transparency and Notification Rules to Avoid Abuse

To maintain the legitimacy of and avoid the abuse of parallel importation, a system of global notification and transparency needs to be instituted. This would mean that in countries invoking parallel importation during emergencies, notification to the WTO and other concerned parties, including the original rights holder, would need to provide:

- the nature and volume of the products,

- the legal justification for the importation,
- the legal and regulatory framework for the improved assurance of the product

Such transparency could be modelled on the notification requirements on the export of medicines that are produced under compulsory licenses, TRIPS Article 31bis.[lx] Making such information available in the public domain enhances both accountability and trust in international supply chains.

CONCLUSION

When it comes to emergency situations, parallel importation instils confidence of economic efficiency while ensuring essential health commodities are available during such situations. Nonetheless, the unrealized potential of such theory breaks down because of disjointed legal frameworks, inadequate policy infrastructure, and lack of cross-border coordination. Global benchmarks should be created by WHO or the WTO to define the borders of national exhaustion rules, the available regional procurement frameworks, the linked TRIPS waiver, and the transparency frameworks to policy. These steps will provide the world with an opportunity to streamline preparedness for the future health emergencies. Instituting these reforms now will ensure that access to lifesaving technologies will not be restrained by legal barriers during the next pandemic or emergency.

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Finally, the system could have a grievance redress mechanism where the holders of the International Protection would be able to respond to the imports that they consider to be contrary to the established parameters, although they would still not be able to stop the imports once the proper notification has been provided. This balances the interest of rights holders and the need to provide access during emergencies.

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