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# Patent law and practice parallel imports and its effect on access to medicine

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**Abstract**
The present research paper seeks to discuss the problem of parallel importation and its effects on access to medicine in its legal aspects, to trace the conflict between rights of a patent holder and parallel importation as a defense for the protection of human rights of patients. This paper also aims to recommend the measures that may be adopted by nations and international forums and agencies so as to control and manage the patenting of essential medicines and other health related inventions and its fallouts on access to health and to overcome the defects and inadequacies in the present laws and the legal regime for the protection of patent right s and parallel importation and access to medicine and heal.

Parallel import means importing patented or trademarked products from a country where it is already marketed. The theory of exhaustion of intellectual property rights states that, with the first launch into the market of the product the exclusive right of the patent holder to import the product is exhausted. In a state or group of states when the principle of exhaustion is applied authorization for parallel importation is given within its territory to its subjects otherwise its only available to the person registered with the patent with its territory.

Parallel imports generally takes place where there is differential pricing of the same product, these are often also referred to as grey market products. The agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) clearly states that the practice of parallel importation cannot be challenged under the World Trade Organization (WTO) dispute settlement system and so is effectively a matter of national discretion.

Parallel imports can reduce the price of essential medicines and pharmaceuticals by introducing competition. However, they can also affect the negotiation of tiered pricing regimes with pharmaceutical companies. If a private pharmaceutical company agrees to sell a product at a lower price in poor countries, it will need some assurance that the cheaper product will not be imported back into its rich country markets, undercutting its profits.

**Keywords:** Parallel import, exhaustion, TRIPs, Patent

## 1. Introduction
Parallel imports are one of the most dynamic of international trade. On the one hand, they strictly follow the laws of the market; yet on the other hand, the laws of the market are not the only ones that apply to this kind of activity. While industrial producers are pressing for general barriers in order to maintain price differences of goods among various countries, consumers find such differences puzzling in a world that is increasingly heading towards universal trade and the removal of trade barriers. Easy resolution of the problem is not in sight. The term "parallel importation" refers to goods produced and sold legally, and subsequently exported. In that sense, there is nothing "grey" about them, as the English Patents Court in the Delta methrin decision correctly pointed out. Grey and mysterious may only be the distribution channels by which these goods find their way to the importing country. In the importing country, such goods may create havoc particularly for entrepreneurs who sell the same goods, obtained via different distribution channels and perhaps more expensively. In order to exclude such unwelcome competition, intellectual property rights have sometimes been of help. If products sold or imported by third parties fall within the scope of patents, trademarks or copyrights valid in this particular country, such sale or importation by third parties is generally deemed infringing. Owners of products covered by intellectual property rights have the exclusive right to put such products on the market.

On the other hand, there is little doubt that once the owner of an intellectual property right has put such goods on the market either himself or with his consent, there is little he can do about further acts of commercial exploitation, such as re-sale, etc., on the domestic market. Even if a car is covered by a number of patents, once the car maker has put that car on the market, there is a consensus that he cannot prevent that car from being re-sold, leased-out, etc. The reason for this has been answer differently in different jurisdictions.

**Research Methodology**

The research methodology adopted in the present research paper to understand and analyze parallel importation and its effects on access to medicine is doctrinal in nature and the sources employed for the same shall necessarily be secondary. For the present study, the researcher shall rely upon journals, articles, books, web resources and newspaper articles. An exploratory, explanatory, and analytical approach shall be employed for analyzing the extent and gravity of the problem and critical approach shall be used as far as it analyses the provisions under various national and international. A recommendatory approach shall be employed for suggesting the formulation of socio legal measures and suggest changes in present legal regime for balancing the interests of the patent holders and the public at large in the context of parallel importation and access to medicine.

**The doctrine of exhaustion**

**Meaning**

This doctrine forms one of the limits of intellectual property rights. After a product covered by an Intellectual Property (IP) right, has been sold by the IP right holder or by others with the consent of the right holder, the said right is said to be exhausted. It can no longer be exercised by the IP right holder. This limitation is also referred to as "first sale doctrine". For example, if an inventor obtains a patent on a new kind of mobile phone, the inventor (or anyone else to whom he sells his patent) can legally prohibit other companies from making and selling this kind of mobile phone, but cannot prohibit customers, who have already bought this mobile phone from the patent owner, from reselling suchmobile phone to third parties.

**Forms of exhaustion**

Presently, there are three forms of exhaustion that exist worldwide- national, regional and international:

- The national exhaustion principle states that the intellectual property owner's right is exhausted on the first authorized sale in the specified national territory.
- The *regional exhaustion* principle refers to exhaustion of rights of the IP owner in specific region, for instance the European Union and its member states.
- The international exhaustion refers to exhaustion of rights of the IP owner on the product across all the geographies, irrespective of the territory of the first authorized sale [1].

A majority of developing countries across the globe have adopted the principle of international exhaustion, which they believe shall enable them to pursue products, mainly medicines and drugs, from other markets at competitive prices eliminating the enforcement hindrances of the IP owner locally [2].

**Parallel importation**

**Meaning**

Parallel importation refers to the import of goods (referred to as parallel imports) outside the distribution channels contractually negotiated by the IP right holder/owner. In simpler terms, it refers to the importation of a product from another country without the permission of the patent holder of that product, after legally purchasing it from a person from other country who is authorized under law to produce and sell or distribute the product in that country. Because the IP owner has no contractual connection with a parallel importer, the imported goods are sometimes referred to as "grey market goods". However, it is to be noted that these goods are neither counterfeit goods nor pirated merchandise. Parallel imports, infact, are original goods produced genuinely under protection of a trademark, patent, or copyright, placed into circulation in one market, and then imported into a second market without the authorization of the local owner of the intellectual property right. This owner is typically a licensed local dealer. Thus Parallel imports are identical to legitimate products except that they may be packaged differently and may not carry the original manufacturer's warranty [3].

**Relation with Exhaustion Principle**

The phenomenon of parallel imports is a natural consequence of doctrine of exhaustion. Parallel Importation has different implications depending on whether the country of importation applies the concept of national, regional or international exhaustion. The concept of national exhaustion does not allow the IP owner to control the commercial exploitation of goods put on the domestic market by the IP owner. However, the IP owner (or his authorized licensee) could still oppose the importation of original goods marketed abroad based on the right of importation. In the case of regional exhaustion, the first sale of the IP protected product by the IP owner or with his consent exhausts any IP rights over these given products not only domestically, but within the whole region, and parallel imports within the region can no longer be opposed based on the IP right. Where a country applies the concept of international exhaustion, the IP rights are exhausted once the product has been sold by the IP owner or with his consent, in any part of the world.

**Effect of Parallel Importation**

Parallel Importation is a means of increasing competition in the market. IP owners of products covered by intellectual property rights have the exclusive right to put such products on the market. On the other hand, there is little doubt that once the owner of an intellectual property right has put such goods on the market either himself or they have been put in the market with his consent, there is little he can do about further acts of commercial exploitation, such as re-sale, etc., on the domestic market. For instance, if a car is covered by a number of patents, once the car maker has put that car on the market, there is a consensus that he cannot prevent that car from being re-sold, leased-out, etc.Thus, the import of a product sold by a patent holder or his authorized person in another country will not amount to patent infringement

because once sold the rights of the patent holder over the product will be exhausted.

This exemption will not extend to products purchased from a person in a country where patent protection for the product does not exist because the rights of the patent holder over the product will not be exhausted by the sale. For example, '*X'* holds a patent over a pen in India, USA and Europe. '*X'* authorizes '*Y*' to produce and sell the patented pens in USA. '*Z'* buys the patented pen from '*Y'* and imports them into India. Such importation by '*Z'* will be exempt from liability of patent infringement. In this example, the exemption will not apply if '*X'* does not hold a patent for the pen in USA, because no authorization is required for producing and selling pen in USA and a sale in USA will exhaust *X's* patent rights in India. Therefore Parallel importation in such situation will be considered as patent infringement.

It is also to be noted that Parallel Importation is a defense available against infringement with respect to distribution rights only and not with respect to right of reproduction of the patented products. Parallel imports often takes place when there is differential pricing of the same product - either brand-name or generic drugs - in different markets (usually owing to local manufacturing costs or market conditions). Parallel imports can reduce the price of health products and pharmaceuticals by introducing competition. However, they can also affect the negotiation of tiered pricing regimes with pharmaceutical companies. If a private pharmaceutical company agrees to sell a product at a lower price in poor countries, it will need some assurance that the cheaper product will not be imported back into its rich country markets, undercutting its profits (product diversion) [4].

**Legal Provisions With Respect To Parallel Importation Worldwide**

Intellectual Property Rights are recognized on a territorial basis, therefore each nation has established its own policy covering parallel imports. American negotiators in the Uruguay Round tried to incorporate a global standard of national exhaustion into the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 6 of TRIPS states that:

'For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.'

The abovementioned provision implies that the violation or limitation of a TRIPS obligation beyond national treatment (Article 3) and most favored nation (Article 4) may be invoked to challenge the treatment of parallel imports. However, there is legal debate about this interpretation. Overall, it seems that Article Six preserves the territorial Prerogative to regulate parallel trade. This flexibility was important in gaining the acceptance of TRIPS by many developing countries. Debate continues over the question of whether TRIPS should be extended to mandate a uniform global policy. Some analysts advocate a global ban against PI as a natural extension of the rights of intellectual property owners to control international distribution (Barfield and Groombridge, 1998). This position is advanced forcefully by representatives of the research-intensive pharmaceutical firms (Bale, 1998). Others support a comprehensive rule of international exhaustion and would place no restrictions on parallel imports in order to integrate markets (Abbott, 1998). The argument is that restraints against PI constitute non-tariff barriers to trade and are inconsistent with the fundamental principles of the WTO. However, advocates of this view often modify it by recognizing the possible need for restraints in pharmaceuticals.

Japan allows Parallel Importation in patented goods unless the goods are explicitly barred from parallel trade by contract provisions or unless their original sale was subject to foreign price regulation. Australia generally permits parallel imports in trademarked goods but patent owners may block them. Thus, Australian consumers cannot benefit from cheaper drugs available on foreign markets. Developing countries vary widely in their restraints on Parallel Importation of pharmaceuticals. Some nations disallow Parallel Importation because their patent laws provide a strict right of importation to authorized licensees; these laws are common in countries with British or French colonial legacies. Moreover, several developing nations have laws permitting only one national distributor for products imported under trademark, effectively banning parallel imports. A number of developing countries, including Argentina, Thailand, and South Africa, recently have enacted laws permitting parallel imports of pharmaceutical products. In case of India, the Indian Patent Act, provides that-

'For the purposes of this Act, importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights' [5].

The above-mentioned provision, though covers within its ambit parallel importation, the Indian Patent Act, 1970 does not clearly define the type of the exhaustion policy that is followed in India with respect to patented inventions. The Patents Act, 1970 Section 107 A (b): In 2005, the Patents Amendment Act 2005 amended section 107A (b) to bring in full advantage with the principle of parallel importation. Old provision, before amendment, stated – "(b) importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product," New provision, after amendment, states –

"(b) Importation of patented products9 by any person from a person who is authorized under the law10 to produce and sell or distribute the product,"

The new provision removed the earlier restriction of importing the patented products only from a person who is duly authorized by the patentee to sell or distribute, but also include to cover resellers such as wholesalers, pharmacies and retailers. According to new provision, importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product will not be considered as an infringement of patent rights. Section 107A (b) is exemption to infringement of Indian patent, not foreign patent as we cannot regulate infringement in other jurisdiction.

**Concept of access to medicines**

Access to Medicine is a critical component of the right to health. The concept of access to medicines can be broadly understood to mean the physical and economic elements of access, which in simple terms means the availability and affordability of medicines.

Expenditures on medicines can represent up to 66% of total health spending in developing countries and could be a

major cause of household impoverishment, as 50-90% of such expenditures are out-of-pocket expenses. Today, over one-third of the world's population and over one-half of the poorest in Asia and Africa still lack access to essential drugs. According to the WHO such access should cover the therapeutic, physical and financial aspects i.e. cover priority health problems, be available within easy physical reach and be affordable to all [6].

The provision of access to medicines especially to the developing countries depends on four factors:

- Rational selection and use of medicines
- Affordable prices
- Sustainable financing
- Reliable health and supply systems.

**Problem faced by developing countries with reference to access to medicines**

Patent protection provides for one of the greatest incentives for the research and development of new drugs. However, there is also concern that the TRIPS agreement, which grants extensive patent rights to pharmaceutical companies, will prevent developing countries from producing or buying generic drugs that usually cost much less than the branded drugs. The United Nations Development Programme (UNDP) has questioned the compatibility of the TRIPS agreement with human rights law because of its impact on access to essential drugs in low-income countries [7].

Before TRIPS came into being, most developing countries and some developed countries excluded medicines from being patented even if they fulfilled the criteria of novelty, inventive step and industrial application. Presently, almost all such countries are members of the World Trade Organization (WTO) and in consequence of their compliance with the minimum standards laid down by TRIPS, have allowed for the filing of patents for new pharmaceutical inventions and the grant of product patents or similar exclusive marketing rights on them, where eligible. It must be noted that even under the TRIPS regime, patents are to be granted only on applications received from 1995 onwards for new, patentable pharmaceutical inventions. Thus, prices of existing drugs already on the market, or even those covered by patent applications prior to 1994 anywhere in the world, should not be affected by TRIPS, as these markets could continue to be as contestable as before.

Despite the fact that the poor may still not have affordable access to essential medicines for reasons of low purchasing power and poor infrastructure, fortunately, there are several policy options open to the governments of WTO member countries under TRIPS to diminish the adverse price increases associated with product patents like medicines. Some of these policy options are –compulsory licensing, price control through review mechanisms or cost-reimbursement limitations or through administratively fixed cost-plus prices, government use and parallel importations.

TRIPS provides for the minimum standards for intellectual property law and procedures and remedies that should be available so rights holders can enforce their rights effectively. The default principle concerning patents is that they should be available for any invention, whether product or process, in all fields of technology without discrimination. With respect to pharmaceutical patents, the minimum obligations under TRIPS includes a 20 years term of patent protection from the inventor's filing date [8], patent rights free of discrimination against the origin of invention or production [9], and exclusive marketing rights for the entire patent duration [10]. Transitional periods are granted before TRIPS requirements for patent protection must be met; the deadline for least-developing country members was ultimately extended to 2016.

The rationale behind parallel importing, legally pursuant to TRIPS Article 8.1 and Article 6, is to allow governments and others to "price shop" internationally for pharmaceutical products, based on the underlying principle that the patent holder has been rewarded through the first sale and thus has exhausted his rights.

In practice, governments may realistically be reluctant to exercise TRIPS provisions given some concern about political and economic ramifications, particularly in the area of trade sanctions. The Doha Declaration, issued by the WTO in November 2001, partially aimed to address this concern. It reaffirmed flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines. In Paragraph 4 of the Doha Declaration, governments agreed that:

"The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

The Declaration further states that-

"We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002" [12].

These provisions in the Declaration ensure that governments may take necessary steps (such as including provisions for parallel importation in their laws) to protect public health. One example of the same is South Africa; it recently amended its Medicines Act to allow for parallel imports of medicines, leading to strong pressure from US and Europe based pharmaceutical companies, through diplomatic and legal channels, to amend its policies. However, with domestic and international sensitivities on finding rapid solutions to the AIDS problem in Africa, the USTR announced an agreement with South Africa to respect TRIPS and the pharmaceutical companies were forced to hold their hand on this issue for the time being. Similarly the Thai patent law allows the importation of patented products if the patentee has consented to the manufacture or sale of the product elsewhere. Argentina too has, in its new patent law, specifically permitted international exhaustion. Brazil, however, has opted for national exhaustion of rights i.e. prohibition of parallel imports.

**Impact of parallel importation on the access to medicines**

For developing countries, particularly the least-developed countries and smaller economies, parallel importation can be a significant way of increasing access to medicines, where the prices charged by patent holders for their products are unaffordable. Parallel importation is also likely to act as a relevant tool in combatting situations where the manufacture of the product/medicines locally within the country is not

feasible, because of which compulsory licenses is ineffective.

Whenever Governments deem it appropriate, adoption of the principle of international exhaustion of rights can be a useful tool for health policies. For instance, if say the prices of pharmaceutical products are lower in a certain foreign market, the Government may decide to allow importation of such products/medicines into the national market, so as to permit provision of drugs at more affordable prices. Such measures may prove to be very effective in prevent anti-competitive practices on behalf of patent owners who offer their patented products/medicines at unreasonably high prices in the domestic market. In this case, patent owners would compete with other legitimate products. Considering that their exclusive rights would be exhausted, the interests of the patent owner would hardly be damaged.

It is to be noted that Article 6 of TRIPS does not prohibit members from following their national laws on the question of parallel imports or exhaustion of IPRs as long as there is no discrimination amongst IPR owners on grounds of nationality. Given the fact that there are huge price variations in the prices of identical medicines across countries, some see this provision as a major policy option for developing countries to attenuate the ill effects of strong intellectual property protection, apart from eliminating unfair duplication of the rights of IPR holders. Others argue in favour of clearly prohibiting parallel trade in products protected by all IPRs, particularly pharmaceuticals, to protect the incentive to innovate. They attribute price differences to many factors outside the control of pharmaceutical companies and argue that prices do not fall even with parallel imports. However, such a prohibition would require TRIPS to be amended.

Parallel importing introduces more challenges. Administrative capacity issues exist with parallel importation. In many countries, import permits for companies engaged in the parallel importation of drugs are difficult to obtain. Also, parallel importing may act as a disincentive to differential pricing by research-based pharmaceutical companies due to a risk of diversion of low-cost products to lucrative, developed country markets. Furthermore, the consumers in developing countries from which parallel imports originate may experience a rise in prices or may face inadequate availability of the product subjected to parallel exports. However, this is a matter of empirical study and verification. Also, it is not clear, a priori, which countries would be parallel exporters and which parallel importers as this would differ with product and perhaps, over time.

Thus, it can be said that for parallel importation is to be useful to developing countries, their administrative, institutional and managerial capacity must be developed for effective implementation, to prevent the unlawful importation and exportation of products and to ensure quality.

## Conclusion

One of the most controversial and dynamic aspect of international trade is parallel importstion. Parallel imports though falling within the bounds of market regulation and not barred by TRIPS, or any other international agreement, still falls within the ambit of ‘grey market goods’. The term “parallel importation” refers to goods manufactured and sold legally, and subsequently exported and imported within the bounds of international trade. In this rapidly globalizing world with ever increasing emphasis on making trade barriers otiose, parallel importation has become a major challenge for industrial producers advocating general barriers in order to maintain price differentiation.

Parallel imports in patented and branded drugs arise for a variety of factors associated with price differences across markets, price discrimination by manufacturers, vertical price setting within distribution systems, and differential systems of price controls. As may be expected, Parallel importation has complex effects on markets in theory. Prima facie, it appears that parallel imports may be a tool that can help procure medicines and pharmaceutical goods from the desired source without being at the mercy of the patent owner in the destination market, but this may not be a panacea that addresses the issues faced by the developing countries, specifically the countries with raging epidemics. The procurement is not the end-point as it would be a pre-mature stage to assess the to such procured products which would deter parallel traders to re-export the procured goods.

Parallel importation of pharmaceuticals stands at an social economic and political crossroads. From this convergence of distinct interests it emerges that unlike other sectors the pharmaceutical sector needs a more critical balance between protecting the general interests of the innovators and inventors and the general interests of the public for easy and economical access to life saving drugs. This is because of the high research and development cost that is intrinsic to the survival and perpetuity of the industry and hence any move that has a potential to adversely affect the pecuniary resources of the patent holders, eg free parallel importation of drugs must be critically examined. The need for reaching a equitable balance is reflected in the general law relating to parallel imports. The myriad views and across jurisdictions relating to exhaustion of rights, suggests that a concrete view on exhaustion of rights and parallel importation of pharmaceuticals is not practically possible at present and it has to be dealt on a case to case basis. In the light of world-wide developments the move by the Indian regime to free parallel imports by moving away from a system based on patentees consent to one based on legal authority is not optimum and must be criticised for its lack of nuance. Thus in the utilitarian consideration of promotion of general public good, it is imperative that reform be initiated and a more flexible approach be adopted.

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