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# Social Welfare Impact of Parallel Imports of Pharmaceuticals vis a vis Access to Medicine

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Legitimate parallel imports stem from the doctrine of exhaustion or the "first sale" doctrine in intellectual property law, particularly in cases of international and regional exhaustion. It is the law of the importing country that determines the legitimacy of any particular instance of parallel imports, namely the kind of exhaustion that such country recognises and follows—national, international or regional. Since parallel importation involves taking advantage of price arbitrage by bypassing the official distribution network of the intellectual property holder, it is commonly referred to as the "grey market" and remains a controversial area in law. Under the flexibility provided by Article 6 of the TRIPS Agreement, a country may adopt different approaches to exhaustion for different forms of intellectual property, such as patents and trademarks. This complicates the legal position when the subject matter of parallel imports is protected by multiple intellectual property rights, enabling right holders to use these overlaps to restrict such imports. In the pharmaceutical sector, the additional requirement of marketing and import approvals further makes the import process more complex. In a global context marked by instances of excessive pricing of medicines, the legitimisation of parallel imports through the explicit adoption of international exhaustion has emerged as a potential mechanism to improve access to affordable medicines, particularly in developing and least developed countries. Based on doctrinal and comparative legal research involving the analysis of international agreements, national laws, judicial decisions and existing literature, this paper examines the social welfare impact of parallel imports in terms of their effect on drug prices and domestic pharmaceutical markets. The analysis suggests that while parallel imports can contribute to enhanced price competition and improved access to medicines in certain regulatory and market conditions, their overall welfare impact remains context-specific and empirically under-examined. The paper therefore concludes that parallel imports constitute an important policy tool for addressing access to medicines, but their effectiveness depends on appropriate regulatory frameworks and further systematic research.

**Keywords:** Parallel Imports, Exhaustion of Rights, TRIPS Agreement, Access to Medicines, Pharmaceutical Patents, Social Welfare

Parallel importation of pharmaceuticals is a controversial trade practise having multiple dimensions to it that can be examined through the different lenses of international trade law, competition law and intellectual property (IP) law. It is a complex issue with legal and economic considerations having a bearing on access to medicine worldwide, particularly in developing and least developed countries (LDCs). Having their genesis in the universally recognised doctrine of exhaustion or the 'first sale' doctrine in IP law,[1] 'legitimate' parallel imports of pharmaceuticals are said to be a natural outcome of the same.[2]This doctrine, applicable to all kinds of IP – be it patents, trademarks or copyright, limits the right of IP holders to further control the redistribution of the goods or articles that embody their IP.

This limitation on the exclusive rights of the IP holder coupled with international price discrimination is the reason why parallel imports take place in the first place. Importers look at such a scenario as a lucrative opportunity to take advantage of price arbitrage and provide consumers of the importing country with lower priced yet genuine goods. What makes the entire process so contentious is the fact that parallel imports never take place with the prior consent or authorisation of the IP holder. In fact, their official distribution network is bypassed and this is why the goods so imported (unauthorized yet genuine), are commonly referred to as the 'grey market'.[3]This inherent tension between the rights of the IP holder who are believed to have already profited from the 'first sale' of their IP protected goods on the one hand and public interest (and public heath, in the context of pharmaceuticals) on the other, is one of the key concerns associated with parallel imports of pharmaceuticals.

The fact that parallel imports are not authorised by the IP holder doesn't make them illegal ipso facto. It

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is the law of the importing country that determines the 'legitimacy' of a particular instance of parallel imports.[4]This in turn could vary largely as Article 6 of the Agreement on Trade Related Aspect to Intellectual Property Rights (TRIPS) confers upon the signatory countries the discretion to choose the kind of exhaustion they would like to recognise and enforce in their respective jurisdictions, subject to the 'most favoured nation' and 'national treatment' principles.[5] In fact, paragraph 5(d) of the Doha Declaration on the TRIPS Agreement and Public Health (2001) affirms the autonomy of WTO Members to determine how the principle of exhaustion should operate within their legal systems. It recognises that a Member may adopt an international exhaustion regime pursuant to Article 6 of TRIPS, thereby allowing the import of legitimately marketed, lower-priced medicines from abroad so as to enhance public access to affordable treatment.[6]Surprisingly, while a lot of developed nations follow international patent exhaustion to facilitate access to medicine for their population, many developing and least developed countries (LDCs) that stand to gain more from this flexibility, follow more restrictive policies of national or regional exhaustion.[7]

Another interesting fact to note in this context is that a country, in exercise of the flexibility under Article 6, may follow a different approach towards of exhaustion of rights in case of one kind of IP such as patents from what it does in the case of another kind such as trademarks. This significantly complicates the scenario in the context of the pharmaceutical industry as even though it is highly patent driven in nature, there are certain aspects of pharmaceuticals that are protected by trademarks and copyright. It has been seen that pharmaceutical producers/patentees try to take advantage of this difference in exhaustion policy to block such imports.[7]Apart from this, the additional requirement of marketing and import approvals makes the import process even more cumbersome.[7]

For the reasons discussed above, advocates of access to medicine propose the harmonisation of exhaustion policies and by extension, the parallel import laws of various nations.[8]In fact, there is considerable divergence among scholars, legal and economic, on this point.[8]However, the authors believe that in a world where there have been multiple instances of pharmaceutical companies being fined for 'excessive pricing', legitimisation of parallel imports by countries through the explicit adoption of international exhaustion can be a potential solution to the burning issue of lack of access to affordable medicines worldwide, particularly in the case of developing and least developed countries (LDCs). This paper primarily aims to explore the impact of parallel imports on drug prices and domestic pharmaceutical markets of the importing countries, inter alia, in order to assess the potency of such imports as a viable solution to the challenge of access to affordable medicines.

The paper, following this segment, is structured as follows: Part 2 explains the phenomena of the exhaustion of intellectual property rights and parallel trade or imports before it goes on to discuss the legal position regarding the same in multiple jurisdictions. Part 3, that constitutes the main and the largest segment of this paper, attempts to gauge the social welfare impact of parallel imports. It sets the stage by discussing the burning issue of access to affordable medication and the impact that the TRIPS Agreement has had on it particularly in the context of developing countries. This is followed by a discussion on how parallel imports influence the prices of other (patented as well as generic) drugs that are available in the domestic market of the importing country and the impact that they have on the research and development (R&D) activity ofpharmaceutical patentees. Factors that determine the viability and eventual success of any particular case of parallel imports of pharmaceuticals, a case study from South Africa and few landmark case laws from the EU and the US have also been discussed. Part 4, the final and concluding segment, reiterates the main findings of the research as well as the authors' remarks and suggestions on the way forward.

## Parallel Imports of Pharmaceuticals – A Comprehensive Primer

### Concept of Parallel Imports vis a vis Doctrine of Exhaustion

Parallel imports or parallel trade of goods can be defined as the resale of goods between countries in the absence of any authorisation by the owner of the intellectual property (IP) that such goods may embody.[9] It is described as a response to the phenomenon of international price discrimination, whereby different prices are charged for the same, identical product in different countries' markets.[9] A parallel importer, taking advantage of the difference in prices chargedin the exporting country

and the importing country, engages in price arbitrage[2]and sells the goods so imported at a price lower than what they were otherwise available for in the importing country. In fact, it is possible that the importer in this process may secure for people access to a good that wasn't otherwise available locally in the importing country in the first place. In the context of patented pharmaceuticals, this translates to making available to patients an otherwise unavailable drug, thereby promoting access to medicine.

As mentioned earlier, lack of authorisation by the IP holder doesn't make parallel importation an inherently illegal trade practise. It is the law of the importing country, namely the system of exhaustion that the law of the importing country follows, which determines the legality of a particular instance of parallel imports.[4]The doctrine of exhaustion states that the sale of any IP protected product or article after their first lawful release (i.e. the first time such product was put in the market for sale either by or with the authorization of the IP holder) 'exhausts' or terminates the right of the IP holder to control or prevent the further redistribution of that product.[7]This doctrine which developed around the nineteenth century serves to balance the rights of the IP holder against the rights of those who lawfully purchased such products from the market and wish to resell them at any point post such purchase.[7]It is at the buyer's discretion what they wish to do with the product afterward: they can use it themselves or choose to pass it on to someone else or even destroy it for that matter.[10]

Had it not been for this doctrine, many consumers, retailers and second hand dealers would have had to suffer massive, unjustifiable inconvenience as they would have had to approach the IP holder and take their permission every time they intended to resell or put the product in recirculation in any other manner to prevent any potential action for infringement. In fact, this doctrine is based on the premise that IP holders who have profited from the sale of their IP protected products once already should not be permitted to benefit from the same transaction indefinitely. The US Supreme Court in 1941 endorsed this view by stating that once a patentee has obtained remuneration for an article embodying their invention, the patent law does not justify imposing further restrictions on its use or resale.[11] The underlying rationale here is that a seller of property cannot impose unreasonable restraints on the buyer's ability to alienate such property.[12]

It is pertinent to note that the doctrine of exhaustion may not always operate in favour of the buyer or consumer necessarily. This is so because the (geographical) scope or extent of exhaustion recognised by each jurisdiction can differ and with that, differs the extent of the constraints imposed on the IP holder with respect to the product in question. As is known generally, there are three systems of exhaustion - national, international and regional.[1]Let's take the help of a hypothetical to understand the three kinds and their impact on parallel imports. X, an individual, purchases a drug called 'CureY' in Germany from an authorized dealer ofABC Pharma Ltd, a German company that owns the patent for this drug.

Assuming Germany follows the system of national exhaustion for patents, X can resell the drug to anyone within Germany and ABC Pharma Ltd. won't be able to legally stop X from doing so on the ground of exclusivity. However, if X tries and exports this drug to someone outside of Germany, the patentee company would have the right to stop the same from happening as its right to prevent the resale of CureY stood 'exhausted' or terminated only nationally i.e. within the territory of Germany and not beyond that. The company will naturally also have the right to prevent X from importing its patented drug into Germany as under the national exhaustion regime, ABC Pharma's right to control any cross-border sales of the drug remains undisturbed and intact. Thus, as can be seen from this hypothetical, the system of national exhaustion does not favour parallel imports.

Had Germany followed the system of international exhaustion in this hypothetical, X would have been able to sell CureY to anyone anywhere in the world lawfully asABC Pharma's right to control or prevent the resale of its drug stood exhausted internationally. This would still have been the case had X purchased this drug lawfully from the patentee in any other country other than Germany since the patentee's rights would have stood exhausted in the same manner regardless of the country where the first sale happened.[7]This system of exhaustion permits parallel imports that are considered as lawful in the importing country even if the exporting country follows a different regime of exhaustion i.e. either national or regional.[7] Now, let's suppose that Germany followed the system of regional exhaustion which is a cross between national exhaustion and international exhaustion. In such a scenario, X can lawfully sell the drug to anyone within the member countries forming part of the European Union (EU), a regional bloc that

includes Germany. X can buy the drug in bulk from an authorized dealer of ABC Pharma Ltd., export it to a third person in France (another member of the EU) and the patentee would not be able to stop X from doing so since the exhaustion of rights in this case would be effective within the entire region of the countries that form the EU.

To explain the impact of regional exhaustion on parallel imports in particular, we modify our hypothetical a little. Let's assume that CureY is also available for sale in France, Greece and Spain, apart from Germany. Z, a French national purchases this drug from one of ABC Pharma's dealers in the French market and exports it to X, a German national. X, who imports the drug into Germany, sells it at a price lower than what it is otherwise available for in the market. Such parallel importation of the drug by X would be lawful under a regime of regional exhaustion. However, if the first sale of the drug had happened in a country that was not a member state of the EU, the principle of regional exhaustion would not have been applicable.[7]

**Legal Position on Exhaustion and Parallel Imports of Pharmaceuticals in Various Jurisdictions**

As of this date, several developed countries follow the system of international exhaustion - the most liberal and pro-consumer approach towards exhaustion of intellectual property rights, as opposed to national exhaustion that many developing and least-developed countries (LDCs) have chosen to follow.[7]This certainly poses a challenge for the latter group of countries when it comes to access to pharmaceuticals. In fact, it is these inconsistencies in the rules and regulations governing parallel imports across jurisdictions that make the subject controversial in nature. The prevalence of such imports may be affected by changes in the IP law regimes or trade regulations of the jurisdictions involved.[9]

Under the regime of regional exhaustion, free and unrestricted movement of patented goods, including that of patented pharmaceuticals, is permitted within the territory of the EEA (European Economic Area) which includes the EU member states along with Iceland, Norway and Liechtenstein.[13]Once the patented good is put into the market of any EU Member State with the consent of the patent owner for sale, the distribution rights in respect of such good stand exhausted within the EU.[14]In the U.S. and Canada, the system of choice at present is international patent exhaustion as can be seen from judicial precedents.

A landmark judgement by the U.S. Supreme Court in *Impression Prods., Inc.* v *Lexmark Int'l, Inc*.[15], interpreted the scope of exhaustion under the U.S. patent law to be international exhaustion.[15]

The Supreme Court of Canada, in its 1998 ruling in *Eli Lilly & Co* v *Novopharm Ltd*,[16]held that once a patented article has been sold, the patentee's control over that particular item is exhausted, provided the sale was unconditional and for legitimate consideration. The central inquiry in Canada now concerns whether the first commercial transaction, domestic or foreign, occurred with any restrictions attached to it.Across Asia, several jurisdictions recognise some form of international exhaustion for patents.[7] This tendency is often associated with the economic status of these countries, many of which are still developing or fall within the category of least-developed countries (LDCs). Among the larger Asian economies,India[17] and China[18], both follow the principle of international patent exhaustion. A number of other developing countries including Argentina, Thailand and South Africa, have enacted statutory provisions allowing the import of legitimately marketed pharmaceutical products from abroad.[3] However, the laws of several other nations remain silent on this aspect.[19]

However, the system of exhaustion that a country follows for patents might not be the only barrier to parallel imports and access to medicine. The systems in place for copyright and trademarks are relevant in this context as well. It is well established that innovation forms the backbone of the pharmaceutical industry[20]and patent protection incentivises the same. In fact, had it not been for patents, many novel drugs might not have even come into existence on account of how the industry relies on patents to prevent third parties from easily copying these drugs and also, for recoupment of phenomenally high R & D costs. This leads the authors to contend that although patents form the principal means of protecting pharmaceutical inventions, they are not the sole form of intellectual property involved. Many pharmaceutical products are also safeguarded by copyright or trademarks and these overlapping protections can sometimes be invoked by right-holders to prevent parallel imports. Such restrictions are generally justified on the ground that imported versions, though genuine, may differ marginally in packaging or formulation from the variants sold in the importing market.[7]

**Social Welfare Implications of Parallel Imports in the Context of Developing Countries**

Parallel importation has special relevance for developing economies where access to affordable medicines remains constrained. The limited supply of patented drugs and the high prices of those available often make essential treatments unaffordable for large segments of the population.[19] Addressing this inequity requires a global strategy that balances two interrelated objectives: first, fostering research into diseases prevalent in poorer regions; and second, promoting broad and timely dissemination of both existing and newly developed medicines at prices that reflect local purchasing capacity.[21] Because research and development (R&D) in pharmaceuticals is a lengthy and capital-intensive process, it becomes crucial to adopt mechanisms such as controlled parallel importation that can reconcile the need for innovation incentives with public health imperatives.

However, the impact of parallel imports on drug prices and consequently, access to medicine is complex, layered and not that simple to ascertain. While research has revealed that parallel imports can bring down the prices of patented drugs by up to 11 %[22], the same outcome cannot be guaranteed for all markets and for all times to come. Furthermore, the overall effect of these imports on social welfare is a subject of debate. Nevertheless, these imports can be potentially beneficial for low and middle-income countries such as Bangladesh, Sri Lanka and Pakistan for whom the availability and affordability of essential medicines remain a matter of concern.[23]

**Access to Medicine, Patents, the TRIPS Agreement and Low and Middle-Income Countries (LMICs)**

A central aspect of the human right to health is the assurance of access to essential medicines.[24] The expression "access to essential medicines" has been interpreted in various ways because the term "access" itself carries multiple dimensions. Broadly, it refers to the capacity of individuals to obtain necessary medicines in both physical and economic terms.[25] At the heart of accessibility lies the general idea that an effective health policy seeks to ensure that medicines are continuously available, of acceptable quality and priced within the reach of all who require them, thereby suggesting a strong nexus between lack of access to drugs and poverty.[25] Medicines can be regarded as genuinely accessible only when they are simultaneously affordable and obtainable in practice.[26]

The idea of 'access to medicine' has particular resonance in discussions surrounding pharmaceutical patents. Patents can stimulate innovation by providing incentives for research and development, but they may also limit accessibility when high prices prevent wide distribution of new drugs.[27] TRIPS is by any account a treaty of major importance and the most comprehensive multilateral international instrument on intellectual property rights so far.[27] In the field of patents, the Agreement mandates the protection of inventions, be it products or processes, in all fields of technology.[28]

The underlying rationale behind this stipulation and indeed the entire TRIPS Agreement as a whole, lies in safeguarding the interests of intellectual property holders.[27] As its title indicates, the TRIPS regime treats intellectual property primarily as a mechanism to advance international trade rather than as an ethical acknowledgement of inventive or artistic achievement.[27] Nevertheless, TRIPS accommodates a range of flexibilities allowing developing and least-developed members to frame measures consistent with its provisions while advancing their domestic policy objectives. These may relate to areas such as promoting access to medicines, conserving biological resources or more broadly fostering institutional and economic frameworks that sustain national development.[29]

These policy options stem from Article 1.1 of the TRIPS Agreement which empowers member states to decide how they will implement its provisions within their domestic legal systems, provided that such measures do not contravene the Agreement's objectives or principles.[30] Such flexibilities may work in both directions, allowing states either to temper or to strengthen the extent of protection, so long as their chosen approach remains consistent with the overall framework of TRIPS.[29] In the case of downward-acting flexibilities, the TRIPS framework provides WTO members (whether developed or developing) with a certain degree of discretion to tailor their domestic laws when giving effect to the Agreement. This latitude enables states to interpret and apply its provisions in ways that suit their own legal systems, particularly in policy areas not expressly governed by the minimum standards prescribed under TRIPS.[31]

Allowing parallel imports through an international exhaustion approach represents one of the flexibilities recognised under TRIPS, particularly significant in the sphere of public health.[31] Compulsory licences granted to ensure the supply of medicines to states

lacking sufficient manufacturing capacity and the continued exemption of least-developed countries from obligations to grant pharmaceutical patents and protect test data until 2033, provide further illustrations of such flexibilities.[31] Conversely, so-called TRIPS-plus standards extend protection beyond the Agreement's baseline, including provisions within the patent domain such as prolonging patent terms to offset regulatory delays, data-exclusivity regimes, conditions linked to marketing approvals and mechanisms commonly referred to as 'patent linkage', among others.[31]

The TRIPS Agreement, 1994 was never meant to be an end in itself, it only marked the beginning of a larger, ongoing global endeavour to standardize intellectual property laws.[32]The lobbying for stronger patent protection by developing countries did not end after the November 2001 Declaration of the Fourth WTO Ministerial Conference held at Doha, Qatar, popularly known as the Doha Declaration.[32]The Doha Declaration reiterated the right of member States, particularly the developing ones, to prioritize access to medicine and public health over patent protection.[33]Meanwhile, the developed countries, the US in particular, have always been in favour of a strong IP regime.[32]In fact, the US and the EU have been responsible for establishing many TRIPS plus protections by signing free trade agreements (FTAs) with some of its developing country partners.[34]

Having faced strong resistance at multilateral fora, namely the TRIPS Council and Doha, these developed countries decided to enter into agreements that take advantage of the TRIPS flexibilities and provide for stronger patent protection in comparison with what otherwise could be achieved under the TRIPS framework.[32]These FTAs full of TRIPS plus standards could potentially harm access to medicine.[32]

Larger economic clout and greater bargaining power during negotiations enabled developed countries to push for stronger IP protections that served their vested commercial interests. This often happened at the expense of the developing countries for whom safeguarding their public health was a greater priority.[35]Before the TRIPS Agreement came into force, many developed countries either had no system of patent protection or provided for limited patent protection in the pharmaceutical sector. This was on account of the popular understanding that the pharmaceutical sector met a basic need (i.e. healthcare) and thus required protection from complete commercialisation.[27]

India categorically endorsed this position with its strict patent law that did not follow a system of granting product patents for pharmaceutical inventions.[27] However, the scenario underwent a sea change in 2005 when India amended its patent law to bring it fully in compliance with the TRIPS Agreement and introduced the product patents regime for the first time.[36]It was only after the promulgation of the Patents Ordinance 2000 in 2001 that Pakistan started granting patents for both products and processes and the timespan of protection was increased from 16 to 20 years (as calculated from the date of filing of the application).[37]In fact, shortly after becoming a WTO member in 1996, the Pakistan Government expeditiously initiated a system of interim patent protection for eligible pharmaceutical inventions through a 'mailbox' provision to fulfil its obligations under TRIPS.[37] Under the mailbox provision of Pakistani patent law, pharmaceutical patent applications could be filed between 1995 and 2005 but were only examined after full TRIPS compliance. Applicants could also request Exclusive Marketing Rights (EMRs) during this transition period until a patent was granted.

As of 2017, approximately 2 billion people of the world's population stood deprived of the access to basic medicines.[38]A significantly large number of people, particularly those living in developing countries is yet to substantially gain from healthcare related innovations that are treated as standard elsewhere.[38]The situation worsened even further with the onset of the Covid 19 pandemic which also highlighted the significant inequity in access to medicines as the vaccination programmes in multiple countries remained considerably unsuccessful in reaching out to many vulnerable sections of people including those who were economically disadvantaged.[39] Such people were among those who were disproportionately affected.[39]

Securing access to widely affordable medicines for its populace is a critical challenge for health authorities in not just LMICs but high income countries as well.[25]In many LMICs in particular, a large number of people have restricted access to medicines either on account of their unavailability or because they are priced beyond the reach of patients who have to bear the entire cost of their prescriptions and/or treatment in the absence of health insurance, government reimbursements and exclusive access

schemes.[25]In turn, this forces them to lead lives marked by deprivation, poverty or premature death.

**Impact of Parallel Imports on Prices of Competitor Drugs, Innovation and Access to Medicine**

***Impact on Drug Prices***

Ascertaining the impact of parallel imports in terms of social welfare, is not a simple and direct task. When it comes to official trade statistics, parallel imports are seldom recorded separately as they are considered a form of legitimate competition itself.[3] As a result, analysing their impact on prices and competition in general becomes very complicated.[3] Nevertheless, multiple studies have attempted to gauge such impact and it is pertinent to note that not all of them are empirical in design.[40]

While theoretical studies from this lot have shown that parallel imports have led to increased competition and reductions in the prices of competing drugs in the domestic markets of the importing countries, empirical evidence provides a more multifaceted picture, indicating that the degree of impact may vary from case to case with differences in the strength of competition posed by parallel imports and country-specific and market-specific conditions. Furthermore, it becomes difficult to arrive at definitive, concrete conclusions on account of methodological challenges such as weak instruments and endogeneity.[40]Future research in this direction should be focussed on overcoming these challenges and studying the long-term effects of parallel imports, especially in the context of developing countries for whom access to affordable medicines remains a matter of grave concern.

Some studies evaluating the impact of parallel imports of pharmaceuticals in terms of social welfare have concluded that such imports have a beneficial effect on access to medicine on account of the fact that they cause manufacturers of competing drugs in the target market to reduce their own prices. A study conducted in 2014 disclosed that parallel imports led to a downfall in the prices of patented drugs by 11 % in Germany, causing increased consumer surplus.[22] Similar was the outcome of another study published in 2015 that found a 15-17% decrease in the prices of locally sourced, patented drugs in the Swedish pharmaceutical market in response to additional competition from parallel imports.[41]While the empirical literature that exists on this subject is limited, there is evidence to support that competitive pressure from parallel imports has a downward effect on drug prices and thereby benefits consumers in terms of reduced prices.[19]This can be particularly favourable for developing countries that grapple with the challenges of high drug prices and limited access.[19]

Meanwhile, there are also some studies on record whose findings have concluded that competition from parallel imports does not substantially affect drug prices and domestic competition in the importing countries' markets.[42] Often, the real beneficiaries of parallel trade of pharmaceuticals are the distributors as opposed to consumers and health insurers.[42] Interestingly, the same study that revealed that parallel imports led the prices of patented drugs to decrease by 11 % in Germany also revealed that such imports had no significant impact on the prices of generic drugs.[22]

***Impact on Innovation (R&D)***

The impact of parallel imports on innovation in R&D-intensive industries such as pharmaceuticals is hotly contested in IP and antitrust policy debates.[43] The pharmaceutical industry likes to underscore that the losses that pharmaceutical companies would have to suffer on account of parallel imports would naturally bring down their revenues and inevitably lead to reduced investments in R&D, consequently having a negative impact on innovation in this field.[44] This contention has been largely rebutted by advocates of international patent exhaustion and convincingly so.[7]The proponents have rightly argued that the industry has not produced any compelling evidence in support of these purported losses and that they would in turn affected the reinvestment in R&D.[7]

The presumption that consumers worldwide will be better placed if originator pharmaceutical companies earn more is flawed and presents certain challenges. It is based on the premise that as the earnings of these pharmaceutical producers increase, so does their investment in R&D, which eventually leads to the invention ofnew products. However, a study published in 2007 found evidence to the contrary.[45]It noted that the industry spends vast sums of money on the advertisement and promotion of "lifestyle" drugs (for e.g. Viagra) that are highly profitable, as opposed to rechanneling all their profits to R&D activity.[45] The same study revealed that on average, originator companies invest approximately 15 % of their gross income in R&D and even then, a considerable share of that amount is directed towards "lifestyle drugs" and obtaining minor variations in already existing

therapies (the so-called "me too" drugs those pharmaceutical drugs that are quite similar to drugs already in existence in terms of molecular structure, therapeutic use and mechanism of action).[45]

According to a study published in 2019, the extent of heterogeneity in demand for a particular drug (in both the exporting and importing countries) is a crucial factor that determines whether parallel trade incentivizes or discourages innovation and social welfare.[43]When the demand for a drug in the importing country is the same as or similar to the demand for that drug in the exporting country, parallel trade encourages innovation and improves welfare and vice versa in case demands in the two countries in question differ from each other.[43]In case the demand in both countries is similar, pharmaceutical companies will continue to sell considerable quantities of their drugs in both countries' markets in spite of parallel imports occurring simultaneously. The volume of sales remains relatively high across the two markets thereby ensuring that the companies have enough revenue to continue to invest in new R&D activity and innovate. This is significant because any loss of revenue on account of price differences could have led these companies to cut down on the sum that they would have otherwise invested in the development of new drugs. Overall, this study in its conclusion states that the impact of parallel imports of pharmaceuticals on innovation and social welfare generally depends on the degree of homogeneity between the trading countries.[43] In other words, if the countries are relatively similar and have similar environments, parallel imports enhances social welfare in the country importing the medicines and in case the countries are relatively different, such imports have a detrimental impact on welfare.[43]

***Overall Welfare Impact of Parallel Imports: Factors Responsible and State of Research***

A general, broad viewpoint of this subject suggests that the influence of parallel imports on pharmaceutical markets, innovation and by extension, consumer welfare is nuanced and context-based. A vast range of factors associated with the importing country namely the legal and regulatory frameworks governing the pharmaceutical sector (including the IP law regime in operation), systems in place for pricing of essential medicines, public health policies of the government, import regulations, market conditions, consumer demand and awareness, market responses and pricing strategies of the IP holder, currency fluctuations and trade relations with the exporting country, inter alia, are taken into consideration by a parallel importer to determine if they can execute such imports legally and make a profit for themselves at the same time.Some of these factors such as market conditions and currency fluctuations for instance are more volatile and dynamic than the others. The cumulative effect of these factors differs from market to market and this is precisely what makes the uniform measurement of the overall welfare impact of parallel imports a rather difficult task to accomplish.

This difficulty arises as the markets of different importing countries respond differently to patextallel trade in pharmaceuticals based on the prevailing regional conditions. For instance, in a country where high drug prices are an issue and affordable medicines are in demand by many, parallel imports can facilitate access to the same for consumers provided all other material factors are conducive to these imports. In contrast, a country with a well-established pharmaceutical industry of its own, might try to thwart parallel imports to protect domestic drug manufacturers causing legal and regulatory obstacles for the importers. Also, in a situation where the drugs so imported turn out to be substandard or of inferior quality and the importing country lacks a regulatory framework that is strong enough to prevent such drugs from entering the market, consumers' trust is likely to get undermined.

As mentioned earlier, drawing generalized conclusions about the welfare effects of parallel imports across various regions is not a viable approach. In fact, as per a 2005 study, parallel imports can be shown to either have an amplifying or diminishing effect on welfare based on which of the following aspects the researcher takes into consideration: a) drug price regulations across nations, b) actions taken by IPR owners to dictate the price of their drugs throughout the supply chain to reduce the price differences between countries and minimise the scope of arbitrage, c) the extent of variation in demand across markets; and lastly, d) the need for producers to recoup the costs incurred in global R&D.[46] Thus, it is safe to conclude that the literature on the welfare impact of parallel imports remains conceptually vague and empirically limited. On account of the diverse methodologies and analytical approaches used in the various studies on parallel imports of pharmaceuticals, direct comparisons between any two case studies in question are not just quite challenging but also inappropriate

from the perspective of research. The outcome is a highly scattered and fragmented body of literature on the subject. Additionally, the economic and social impact of parallel trade on the performance of pharmaceutical companies, especially in developing countries, is also an area that is under analysed and has considerable scope for further research and investigation.

**Parallel imports in practise: South Africa's fight against AIDS and a few judicial pronouncements from the US and the EU**

***South Africa, the AIDS Crisis & Parallel Imports to the Rescue***

A noteworthy example of a country's successful use of the provision of parallel imports to provide access to life-saving medicines is that of South Africa. The latter part of 1990s and the early 2000s saw South Africa battle an alarming HIV epidemic that left over 4.5 million people infected with the virus.[47]Antiretroviral(ARV) drugs were being sold in South Africa at prices substantially higher than those in other nations such as Brazil where government intervention led to the introduction of free access to antiretrovirals and reduced the death rate among HIV/AIDS patients by half.[47]To deal with this crisis, the Government of South Africa enacted the Medicines and Related Substances Control Amendment Act in 1997 that permitted the Heath Minister of the country to import through the channel of parallel imports, ARV drugs that were sold legally in the markets of other countries and were excessively priced in South Africa.[3] The aim was that the overwhelming number of people in need of these medicines could afford them.

A lawsuit was brought against the South African government by Bristol-Myers Squibb and GlaxoSmithKline (two pharmaceutical giants that were also the patentees of key ARVSs used to treat HIV/AIDS in South Africa at the relevant time) and several others, to prevent the government from legitimizing the parallel importation of patented medicines by enacting the 1997 Act.[48] Their contention, patently inaccurate as it was, was that the TRIPS Agreement prohibited international exhaustion and by extension, parallel imports.48Legally speaking, this was clearly erroneous as the Agreement is explicitly neutral in the context of exhaustion of intellectual property rights.[48]

The dispute brought attention to the perpetual tussle between patentees' vested interests and the safeguarding of public health that demanded access to essential medicines. While the pharmaceutical companies dropped the case eventually, the aftermath of the case led to the adoption of the Doha Declaration.[7]Kenya, which also had an HIV/AIDS outbreak and struggled to provide affordable treatment to its populace like South Africa did, resorted to parallel imports inter alia to combat the epidemic.[49] Same was the case with Brazil.[50] Interestingly,India was one of the countries Kenya used to import antiretrovirals from.[49]

As far as India, which is hailed as the 'pharmacy of the world' is concerned, it does permit parallel imports of patented pharmaceuticals under its amended patent law.[17] However, there isn't any case study or judicial pronouncement on the subject on record as of yet to the best of the researchers' knowledge. The researchers speculate that this may be the case on account of India's formidable domestic pharmaceutical industry that is the third largest producer of generic medicines by volume and fourteenth largest in terms ofvalue.[51] This substantially reduces the need for India to rely on parallel imports to satisfy its requirement for medicines. Moreover, the provision of mechanisms such as compulsory licensing under the Indian Patents Act, 1970 further reduces the need to resort to parallel imports. Thus, for the aforementioned reasons, there hasn't been any motivation or necessity to utilise the provision of parallel imports for importing pharmaceutical drugs into India.

***Divergent Judicial Approaches of the EU and the US***

Decisions by courts in the EU and the US have a major influence on international norms, setting precedents having a strong persuasive value for courts and fora/authorities in other jurisdictions. Undertaking a comparative analysis of the contrasting approaches of the aforementioned two authoritative jurisdictions serves a dual purpose: not only does it highlight the constant, ever-present tension between the exercise of intellectual property rights and public health but also sheds light on how these judgements shape the global discourse on access to medicine vis a vis intellectual property rights. These rulings have the potential to bring about changes in market dynamics, pricing of medicines and their affordability and accessibility worldwide. Thus, it's crucial to study them in order to fully appreciate the complexities of parallel imports of pharmaceuticals.

The first time the European Court of Justice (ECJ) had the opportunity to deliver a landmark judgment on this subject was in *Centrafarm* v *Sterling Drug*

*Inc*.[14]The Court held that if the patentee allows for the distribution of their patented good into the market of any EU Member State, that exhausts their distribution rights within the EU.[14]Stating that "a product lawfully (for) sale in the Community must be able to circulate freely within it"[14] , the ECJ laid down the 'free movement' rule for articles or goods first sold within the territory of the EU. This case, in substance, bolstered the principle of the single market in the EU by giving precedence to free trade over safeguarding intellectual property and curtailing IP owners' ability to constrain the circulation of goods within the EU based on their respective national laws.

However, in case the product in question is a patented pharmaceutical manufactured with the intent of getting marketing approval as opposed to commercialisation, exhaustion would not apply.[52] A little over four decades later, in 2016, the ECJ took a pro-exhaustion stance once again in the ruling in *Merck* v *Sigma*[53]as it had done in the *Centrafarm* case.[54]In*Boehringer Ingelheim & others Swingward & others*[55], the ECJ dealt with a dispute that required it to rule on the extent to which importers of branded pharmaceuticals traded across EU borders can change their original packaging. The Court ruled that such repackaging if done to satisfy the marketing requirements of the importing country is permissible provided it does not tarnish the reputation of the relevant trademark in any way.[55]

Speaking of American case laws, a landmark case on patent exhaustion is *Quanta Computer, Inc.* v *LG Electronics, Inc.*[56]The U.S. Supreme Court held that once a patented product is sold with the prior authorisation of the patentee, they no longer have the right to control or place restrictions on the downstream use of that product.[56] This ruling fetters the ability of patent holders to enforce post-sale restrictions which is quite significant for the pharmaceutical sector, where patent holders might try to influence how a patented drug is resold or used after its initial sale in the market.

In 2017, the US Supreme Court, in another landmark decision dealing with international patent exhaustion ruled that once a patented product is placed on the market with the authorisation of the patent owner, the patentee's rights in respect of that item are deemed to be exhausted.[15]The Court clarified that when a patent holder or its licensee undertakes a lawful sale, the patentee cannot thereafter rely on post-sale conditions to control the use or resale of that product.[15]Carrying wide-ranging repercussions for parallel trade, this ruling reiterated that patent holders do not have the right to prevent the importation of goods sold abroad with their authorisation. This case is of significance for the pharmaceutical industry where companies often resort to the strategy of differential pricing based on market segments, among other factors, in order to maximise their revenue.

## Conclusion

This paper has explored and highlighted the complexities surrounding the parallel trade of pharmaceuticals and their contribution to improving access to medicines, particularly in LMICs such as India. The introductory segment emphasized the need to look at parallel imports through the broader lens of social welfare, laying the foundation for an extensive analysis of the legal frameworks governing parallel imports in various jurisdictions including that envisaged by the TRIPS Agreement 1994. The close connect between patent rights, access to affordable medicines, the TRIPS Agreement (including the flexibilities it offers) and the Doha Declaration of 2001, has been discussed at length.

TRIPS being the single most comprehensive and significant international agreement on intellectual property rights in the world, has decisively shaped the patent laws of WTO member countries (be it the high-income countries or the LMICs).As has been the case historically, the developed countries lead the lobby for stronger patent protection while the developing and least developed countries try to balance that with safeguarding access to medicine and by extension, public health. Furthermore, the in-depth analysis of how parallel trade of pharmaceuticals influences pricing of drugs, local market conditions and innovation (R&D) in the domestic market of the importing country, illustrated their potential to create more competitive markets with better price competition and a wider choice of products for the consumers to choose from. A plethora of factors that determine the feasibility of carrying out parallel imports and their likely success in achieving a positive impact on consumer welfare have also been discussed in what the researchers would call a very important segment of this paper.

Despite these findings, as mentioned earlier, the literature on the welfare impact of parallel imports of pharmaceuticals remains conceptually vague and empirically limited. The body of literature on the subject is highly scattered and fragmented. This

research gap underscores the necessity for further studies to understand the extent to which parallel imports can be practically used to address the healthcare needs of the relatively disadvantaged and vulnerable communities in developing and least-developed countries. To be precise, the exact standing of parallel imports in the global discourse on access to medicines is yet to be clearly determined and there is ample room for more research in this direction. In a similar vein, the economic and social impact of parallel trade on the performance of pharmaceutical companies, especially in developing countries, is also an area that is under analysed and has considerable scope for further investigation.

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