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Parallel Importation as a Policy Option to Reduce Price of Patented Health Technologies

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Abstract

The COVID-19 pandemic has burdened most of the health systems around the world. Governments, especially in resource-constrained low- and middle-income countries, are finding it hard to meet the health needs of their nationals. Patent exclusive rights further add to the cost of healthcare by allowing supra-competitive prices of protected technologies. Parallel importation of patented health technologies is a legitimate policy option to obtain patented health technologies at a reduced price. This paper examines the legality and practical significance of parallel trade of patented medicines as a price-reducing policy option and evaluates some of the practical hurdles in the actual use of this important public health flexibility. This study supports the adoption of international exhaustion of patent rights as a mandatory rule for the international trading system.

Keywords: COVID-19, global public health, international exhaustion, parallel importation

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Introduction

Parallel trade or parallel importation in the pharmaceutical industry refers to the practice of legally importing a legitimately manufactured drug, without the authorization of the pharmaceutical patent holder.[1] The legal doctrine of exhaustion provides legality to the practice of parallel importation. As noted by Keith Maskus, 'Once rights are exhausted, it becomes legal for anyone to sell the goods he has purchased within the region of application. Because such transactions occur outside the distribution system of the original intellectual property (IP) rights owner, they are called grey market activities (in the United States) or parallel imports (in the

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[1] Ganslandt, M. and Maskus, K.E., 2004. Parallel imports and the pricing of pharmaceutical products: evidence from the European Union. *Journal of health economics*, 23(5),1035.

EU and most of the world'.[2] Under this doctrine, the right holders right to control or restrict further distribution exhausts upon the first sale. National exhaustion preserves right holders right to prevent importation from other jurisdictions. International exhaustion allows parallel importation from other jurisdictions. The current COVID-19 pandemic burdens most of the health systems globally and highlights the importance of parallel importation of patented medicines as a policy option to improve access and affordability of needed medicines. Parallel trade of pharmaceutical drugs and other health-related technologies deserves increasing attention among researchers and policymakers as a legitimate price-reducing option that aims at achieving a better balance between competing policy interests. Part II of this paper evaluates the legality and practical significance of the parallel trade of patented medicines as a price-reducing option. Part III discusses some of the notable practical hurdles in the actual use of this important public health flexibility.

Parallel Trade of Patented Medicines as a Price Reducing Option

International exhaustion is an important exception to patent rights as the patent owner's rights are considered to be 'exhausted after the first unrestricted global sale by the patent owner'.[3] This exception allows countries to use parallel trade or parallel importation as an access-to-drugs strategy. Parallel imports make it possible to harness the benefits of international price discrimination as IP owners set different prices in different jurisdictions keeping in view the purchasing power of a given market.[4] By using this flexibility, countries may 'purchase drugs from a cheaper source outside the country, import them into the domestic market and place them in direct competition with the patent holder at a much lower price'.[5] This safeguard allows for 'comparison shopping by a third party where a patent holder sells their goods in different markets at different prices'.[6] The flexibility of parallel importation provides access to relatively cheaper patented drugs because it enables import of the patented products to high price jurisdictions so as to make their availability at lower cost possible in the importing jurisdiction.[7] The use of parallel importation seems to be a safer option because the Member States are not

[2] Maskus, K.E., 2010. The curious economics of parallel import. *The WIPO Journal: Analysis of Intellectual Property Issues,* 2(1),123.
[3] Ho, C., 2011. *Access to medicine in the global economy: international agreements on patents and related rights.* Oxford University Press, 7.
[4] Linnosmaa, I., Karhunen, T. and Vohlonen, I., 2003. Parallel Importation of Pharmaceuticals in Finland. *Pharmaceutical Development and Regulation*, 1(1), 68.
[5] Kurpad, M.R., 2014. The Crack in the Wall: Parallel Importation as a Flexibility within the Indian Patent System to Ensure Access to Medicine. *Indian J. Intell. Prop*. L., 7, 32.
[6] Owoeye, O., 2015. Access to medicines and parallel trade in patented pharmaceuticals. *European Intellectual Property Review*, 37(6), 360.
[7] Kurpad, M.R., 2014. The Crack in the Wall: Parallel Importation as a Flexibility within the Indian Patent System to Ensure Access to Medicine. *Indian J. Intell. Prop. L*., 7, 32.

obligated to prove the existence of certain medical emergencies for using this flexibility.[8] The use of parallel importation is also a safe option in terms of product quality and technical standards as 'parallel trade is not the same as trade in illicit or counterfeit goods and it does not always involve significant re-packaging of products'.[9]

As regards the legality of parallel importation, exhaustion of rights and parallel trade are interrelated concepts. The TRIPS Agreement, an extensive multilateral treaty that represents an enormous step toward harmonized patent law, left exhaustion of rights to the discretion of its Member States. The footnote to Art. 28(1)(a) of the TRIPS Agreement clearly indicates that the patent holder's right to control import is subject to Art. 6 of the TRIPS. Art. 6 mentions 'exhaustion' but leaves it unregulated: 'nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights'.[10] The use of this flexibility by the Member States is subject to Arts. 3 and 4 of the TRIPS Agreement. These provisions are related to the non-discrimination principle enshrined in the national treatment and most favoured nation treatment provisions. A Member State will be in violation of this general principle if it crafts its patent laws to allow parallel imports only for specific countries while excluding others. By not imposing any specific conditions, the TRIPS Agreement recognizes the right of the Member States to determine the exhaustion regime according to their domestic needs. Doha Declaration further clarifies this interpretation and confirms that '[t]he effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of Intellectual Property Rights is to leave each Member free to establish its own regime for such exhaustion without challenge…'.[11] The practical use of this legal option to obtain patented medicines at reduced prices largely depends on the exhaustion regime available in the country using it.

India took the lead role in enacting TRIPS' public health flexibilities by introducing well-thought-out legislative measures to deal with the problem of access to medicines. As parallel trade is not regulated under TRIPS, it does not restrict the Member States from importing drugs from the cheapest available sources. Since the TRIPS Agreement is silent on the doctrine of exhaustion, the Member States enjoy the considerable flexibility to define the extent and scope of exhaustion. To avail itself of this TRIPS flexibility, India, inserted s 107A in the Patents (Amendment) Act 2002 which stipulates: 'For the purposes of this Act, … importation of

[8] Ibid, 40.
[9] Owoeye, O., 2015. Access to medicines and parallel trade in patented pharmaceuticals. *European Intellectual Property Review*, 37(6), 364.
[10] *TRIPS Agreement*, Art. 6.
[11] *Doha Ministerial Declaration on TRIPS Agreement and Public Health 2001,* Para 5(d).

patented products by any person from a person who is duly authorized by the *patentee* to sell or distribute the product, shall not be considered as an infringement of patent rights (Emphasis added)'.[12]

Specific mention of 'patentee' in this provision narrowed down the scope of application of this provision because importation of patented products from a reseller who has not acquired the express authorization of the patentee to resell or distribute would constitute an infringement of patent rights. In order to expand the scope of this provision by removing the restriction, s 107A(b) was amended by the Patents (Amendment) Act 2005. Now it reads as follows: '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 (Emphasis added)'.[13] Under this provision, an importer can obtain the patented invention from the first sale by the patent owner and import the item into India.[14]

The courts have not interpreted this provision because there is hardly any case law on patent exhaustion in India.[15] It is obvious from the language of this provision that this provision embraces international exhaustion of the rights of a patent owner.[16] It is important to note that the Indian patent laws do not specifically recognize the national exhaustion principle because the express mention of the term 'importation' in the provision narrows down its scope to international exhaustion only. Though the term 'exhaustion' is not used in this provision, the overall meaning of the provision clearly indicates that the doctrine of international exhaustion is envisaged in this section. The amendment expanded the scope of application of the section because now a parallel importer can buy the patented products from even those resellers who are not expressly or impliedly authorized by the patentee to resell or distribute. The amended provision is in line with the objectives and the true spirit of the doctrine of international exhaustion of rights.[17]

[12] *The Patents (Amendment) Act 2005* (India), s 107A.
[13] Ibid.
[14] Ghosh, S. and Calboli, I., 2018. *Exhausting Intellectual Property Rights: A Comparative Law and Policy Analysis*. Cambridge University Press, 109.
[15] Ibid.
[16] Ragavan, S., Flynn, S. and Baker, B., 2014. Justifying India's Patent Position to the United States International Trade Commission and Office of the United States Trade Representative. *Indian J. Intell. Prop. L.*, 7, 18.
[17] Basheer, S. and Kochupillai, M., 2008. 'Exhausting'Patent Rights in India: Parallel Imports and TRIPS Compliance. *Journal of Intellectual Property Rights* 13(5), 489.

The amendment gives rise to uncertainty with regards to the ambit of the term 'duly authorized under the law'.[18] The law is completely silent on what does the 'law' mean in this provision because laws of both importing and exporting countries are relevant in the case of parallel importation.[19] Does the law refer to the law of the importing country or the law of the exporting country or it covers laws of both importing and exporting countries? Another uncertainty is with regards to the meaning of 'patented products'.[20] Does the patented product mean patented in the importing country or patented in exporting country or patented in both countries? India, as IP leader of the developing world, needs to fix these uncertainties in its exhaustion regime in order to provide a model legislative framework for the other World Trade Organization (WTO) Member States.

Practical Hurdles in Parallel Trade of Patented Medicines

Though TRIPS Agreement allows the WTO Member States sufficient policy space on exhaustion of rights, parallel importation of patented drugs has always been a highly controversial issue because 'parallel trade can significantly limit manufacturers' profits through the substitution of sales in low price markets for sales in high price markets'.[21] The flexibility of parallel importation, by allowing third parties to enter the market without going through the IP owner's authorized distribution channels, conflicts with the interests of IP owners who constantly seek to maintain exclusivity in marketing and sale of their goods and services.

IP owners may pose commercial impediments to parallel importation. They may use tactics to make parallel trade a hard-to-execute policy option. As noted by Ismo Linnosmaa and others, 'it is possible that manufacturers used different brand-names for the same product in different countries. In this case, the parallel importer has to demonstrate that the proposed import with a different brand-name is identical to the pharmaceutical already licensed on the market'.[22] There may be differences in labelling, packaging, presentation, and instructions for use of pharmaceutical products launched in different jurisdictions. These modifications may appear, for instance, 'in the colour of tablets, in the number of tablets in one package, or in the

[18] Ibid.
[19] Ibid.
[20] Ibid.
[21] Owoeye, O., 2015. Access to medicines and parallel trade in patented pharmaceuticals. *European Intellectual Property Review*, 37(6), 360.
[22] Linnosmaa, I., Karhunen, T. and Vohlonen, I., 2003. Parallel Importation of Pharmaceuticals in Finland. *Pharmaceutical Development and Regulation*, 1(1), 72.

strengths of a pharmaceutical'.[23] Through the adoption of this strategy, IP owners may make it difficult for parallel importers to get import licenses and sales permits in their respective jurisdictions. The WTO Member States need to make regulatory changes, in response to actual or potential use of these tactics, in order to reduce the evidentiary burden on parallel importers.

Parallel importers compete with the registered IP owners and their authorized distributors to sell the products in a given market. This price-reducing competition is beneficial for consumers but it conflicts with profits of IP owners. Brand-name pharmaceutical companies tend to react aggressively if third parties, even by using legitimate means, try to conflict with their profits. In 1998, soon after the adoption of the TRIPS Agreement, a case in the High Court of Pretoria, South Africa, achieved global attention.[24] The constitutional legality of Amending s 15C of the South African Medicines and Related Substances Control Act, which authorized pro-health measures like parallel importation and compulsory licensing, was challenged by the Pharmaceutical Manufacturers Association of South Africa (PMA), a group of 39 pharmaceutical companies including U.S.-based Bristor-Myers Squibb, Eli Lilly and Merck.[25] PMA contended that international exhaustion was prohibited under the TRIPS Agreement.[26] PMA had a weak legal standpoint. South Africa rightly argued that the TRIPS Agreement had not prohibited parallel importation.[27] Though pharmaceutical companies - faced with unprecedented public outcry and widespread condemnation - withdrew the suit before judgment was reached, it highlighted the drug industry's clear stance on the use of parallel importation. More importantly, this case emphasized the potential role of civil society mobilization in combating pressures exerted by originator pharmaceutical companies and powerful countries like the U.S.

The U.S. government not only supported PMA's actions but also exerted direct trade pressure on South Africa.[28] In February 1998, PhRMA urged the USTR to name South Africa as a 'Priority Foreign Country' claiming that the controversial legislation was in violation of TRIPS.[29] PhRMA contended that South Africa's legislative measures were in conflict with the

[23] Ibid.
[24] Flint, A. and Payne, J., 2013. Intellectual Property Rights and the Potential for Universal Access to Treatment: trips, acta and HIV/aids medicine. *Third World Quarterly*, 34(3), 507.
[25] Ibid.
[26] Abbott, F.M., 2016. Parallel trade in pharmaceuticals: trade therapy for market distortions. In *Research Handbook on Intellectual Property Exhaustion and Parallel Imports*. Edward Elgar Publishing. 146.
[27] Sundaram, J., 2018. *Pharmaceutical Patent Protection and World Trade Law: The Unresolved Problem of Access to Medicines.* Routledge, 176.
[28] Ibid, 175.
[29] Ibid, 177.

U.S.' 'long-standing commitment to improving the terms of protection for all forms of American intellectual property, including pharmaceutical patents'.[30] As a result of PhRMA's efforts, the Clinton Administration USTR Charlene Barshevsky placed South Africa in the USTR Super 301 Watch List in 1998.[31] In 1999, Charlene Barshevsky once again placed South Africa in the Special 301 Watch List claiming that South Africa's controversial legislation 'appears to grant the Health Minister ill-defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights'.[32] Barshevsky announced an out-of-cycle review for South Africa.[33] The USTR reports totally overlooked the fact that the TRIPS Agreement had expressly included public health safeguards like compulsory licensing and parallel importation.

The timing of these actions coincided with the presidential election campaign in the U.S. Presidential candidate Al Gore's support for the PMA, while ignoring the right to health, led to the 'erection of such politically-damaging banners as 'Gore's Greed Kills''.[34] Thousands of people demonstrated in support of South Africa's pro-health legislative measures and condemned the pressure tactics of PhRMA and the U.S. International NGOs like Oxfam and MSF joined hands with the South African civil society organization Treatment Action Campaign (TAC) to turn the case into a high public profile case at a global level.[35] MSF launched a petition against PMA and garnered around 250,000 signatures for the petition.[36] Adverse public opinion and intense media attention exerted formidable pressure on PhrMA and the U.S. In 2000, due to outrage around the world from the AIDS activists, human rights groups, and the general public, the U.S. decided to back away from its original stance and the USTR removed South Africa from its watch list.[37] An executive order issued by President Clinton recognized the severity of AIDS epidemic in Africa and stated that the U.S. government will not press sub-Saharan African countries to revoke any policy that 'promotes

[30] What is the U.S. Role in Combating the Global HIV/AIDS Epidemic?: Hearing Before the Subcommittee on Criminal Justice, During Policy, and Human Resources of the Committee on Government Reform, House of Representatives, One Hundred Sixth Congress, First Session, July 22, 1999.
[31] Sundaram, J., 2018. *Pharmaceutical Patent Protection and World Trade Law: The Unresolved Problem of Access to Medicines.* Routledge, 177.
[32] 1999 Special 301 Report (April 30, 1999), Office of the U.S. Trade Representative.
[33] Ibid.
[34] Yu, P.K., 2008. Access to medicines, BRICS alliances, and collective action. American journal of law & medicine, 34(2-3), 355.
[35] Matthews, D., 2011. *Intellectual property, human rights, and development: the role of NGOs and social movements.* Edward Elgar Publishing. 99
[36] Ibid.
[37] Sundaram, J., 2018. *Pharmaceutical Patent Protection and World Trade Law: The Unresolved Problem of Access to Medicines.* Routledge, 178.

access to HIV/AIDS pharmaceutical or medical technologies for affected populations in that country'.[38]

Pharmaceutical companies, as strong supporters of the maximalist view of patents, aggressively oppose parallel importation as it compromises their financial interests by removing barriers to arbitrage. Frederick M. Abbott precisely explained how parallel trade hurts the brand-name drug industry:

> When a rule of international exhaustion is applied, the pharmaceutical patent holder does not determine the selling price of the product other than its initial sale. If the pharmaceutical patent holder elects to sell a drug at a low price in one country, the drug may be resold at that price in another country. This resale may deprive the patent holder of a higher price sale in that other country. Arbitrageurs may take advantage of the differences among prices and retain a portion of the differential on resale.[39]

This study supports the adoption of international exhaustion of patents as a mandatory rule for the international trading system. Practically, parallel importation option has remained seriously underused.[40] There are complexities and pressures involved in parallel trade of patented drugs. The U.S. has vigorously negotiated provisions in many of its bilateral free trade agreements to prohibit the parallel importation of patented products.[41] For instance, the U.S.-Morocco free trade agreement prohibits implementation of international exhaustion by specifically requiring that the exclusive rights to prevent importation 'shall not be limited by the sale or distribution of that product outside its territory'.[42] Similarly, The U.S.-Australia Free Trade Agreement precludes a regime of international exhaustion.[43] The proliferation of TRIPS-plus bilateral and plurilateral trade agreements offends the spirit of the Doha Declaration. Any attempt to erode the flexibility provided under Art. 6 of TRIPS, dealing with exhaustion of rights, needs to be condemned, especially in the wake of global health challenges posed by COVID-19.

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[38] Executive Order 13155 of May 10, 2000, 65 Fed. Reg. 30521.
[39] Abbott, F.M., 2016. *Parallel trade in pharmaceuticals: trade therapy for market distortions. In Research Handbook on Intellectual Property Exhaustion and Parallel Imports.* Edward Elgar Publishing, 151-152.
[40] Ibid, 147.
[41] Rajec, S.R.W., 2014. Free Trade in Patented Goods: International Exhaustion for Patents. *Berkeley Technology Law Journal*, 355.
[42] United States-Morocco Free Trade Agreement, Art. 15.9(4), June 15, 2004.
[43] United States-Australia Free Trade Agreement, Art. 17.9(4), January 1, 2005.

This study proposes that the use of TRIPS Agreement's contentious patent flexibilities - like compulsory licensing, parallel importation – should be backed by civil society mobilization. Civil society organizations need to support governments in handling these pressures because the use of patent flexibilities is in line with civil society's shared values and common goals. Sustained and strategic pressure applied by civil society, within the normative framework of human rights and sustainable development, can neutralize the massive pressure exerted by Big Pharma and high-income countries. Civil society organizations should use their potential in a more organized and more systematic way to back governments' use of legitimate public health safeguards provided under the TRIPS Agreement and reaffirmed under the Doha Declaration.

Conclusion

Parallel trade in patented medicines is one of the traditional legal mechanisms to improve consumer welfare by reducing the prices of pharmaceutical drugs. It has the potential to alleviate some of the financial burdens of the COVID-19 pandemic by improving access to cheaper medicines. It is important for the WTO Member States to fully embrace the flexibility provided under Art. 6 of the TRIPS Agreement and adopt legislative measures for the adoption of international exhaustion of patents. More importantly, the WTO Member States need to make practical use of the parallel trade flexibility. In the current global scenario, when most of the health systems are financially constrained because of the substantial burden of the pandemic, relying on the benevolence of multinational pharmaceutical companies is not a very dependable way of addressing the health needs of their nationals.

This study argued that parallel importation of patented medicines remained controversial because of the competing interests of stakeholders. For developing countries, the use of parallel importation flexibility is a bold and highly challenging step in the international arena because of the gross asymmetries in political and economic power. In order to combat these pressures and to utilize this flexibility as a price-reducing option in the wake of COVID-19, this study proposes that the use of this legitimate safeguard should be backed by community mobilization within the framework of human rights and global public health. Civil society mobilization has the potential to combat massive pressures exerted by brand-name pharmaceutical companies and powerful countries like the U.S.