Parallel Importation and the Exhaustion of Rights Principle under the “TRIPS Agreement” and the “Doha Declaration”

Introduction and the Concept of Parallel Importation:
Parallel importation\(^1\) is the concept used for the importation and resale of genuine products from a distributor who legally obtained it from a manufacturer at a low price instead of buying directly from the manufacturer.\(^2\) These products are placed on the market in a country with the approval of the intellectual property rights (IPRs) owner and they are imported to another country without the authorization of the IPRs owner.\(^3\) The gains that the importer reaps from cheaper prices are actually losses in benefits of innovation to the IPR owner.\(^4\) One of the implications of parallel import is to challenge the powers of the IPRs owner to engage in price discrimination and differentiation within different countries.\(^5\)

Parallel imports are primarily permitted upon the principle that the IPRs owner once compensated by the first sale or circulation of the products, is not entitled to further control any use or resale of commodities placed on the market. Consequently, the inventors exhaust their rights to stop further resale.\(^6\) Another implication of the authorization of parallel importations is that it enables a developing country to import required medicines at the cheapest price by circumventing authorized distributors.\(^7\)

Parallel importation is built on the principle of exhaustion of intellectual property rights. Basically there are three competing principles of exhaustion of intellectual property rights, which are; the universal or international exhaustion principle, the domestic or territorial exhaustion principle and the regional exhaustion principle. Universal or international exhaustion principle provides that an IPR owner’s rights are exhausted upon the first sale of the goods anywhere in the world. This principle

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\(^1\) In *Weil Ceramics & Glass, Inc. v. Dash*, 878 F.2d 659, 11 USPQ2d 1001 (3d Cir. 1989), the U.S. Court of Appeals for the Third Circuit pointed out that, “the term ‘gray-market’ unfairly implies a nefarious undertaking by the importer, and the term parallel import accurately describes the goods and is, perhaps, a better term because it is devoid of prejudicial suggestion.”


\(^4\) Ibid.


permits resale, exportation and importation of protected products into countries where the intellectual property rights owner has a protected interest.\(^8\)

On the other hand, the domestic or territorial exhaustion principle provides that the holder’s rights remain valid until the first sale of the goods in the country in which he holds a right. Under the domestic or territorial exhaustion principle the intellectual property rights holder can prohibit the exportation or importation of protected products placed on a market by an unauthorized dealer.\(^9\)

The regional exhaustion of rights principle is the third principle and it provides that owner’s rights are not exhausted until the first sale of the product within a defined region or economic zone. Consequently, parallel importation of the goods cannot be opposed upon first sale of the goods within that region.

The above principles have different implications and countries decide which principle best suits their economic policies. For instance, a developing country is more likely to advocate for the international exhaustion principle. This principle permits parallel importation that will enable such a developing country to obtain essential drugs for its citizens at cheaper prices.\(^10\) Further, developed countries are more likely to advocate for the territorial exhaustion and more protection for their IPRs, as this would encourage more research and development projects by the multinational companies who actually develop the drugs.

Most developing countries consider parallel importation not only as an opportunity for economic growth but also a tool for encouraging competition in foreign markets and as a means to prevent anti-competitive behaviour of an exclusive distributor.\(^11\) There are different schools of thought on the concept of parallel importation. While some are of the view that parallel importation restricts competition and the growth of Research and Development (R&D) which results in higher unstable commodity price; others believe that parallel importation enhances competition, improves efficiencies and therefore benefits consumers in importing countries.

\(^10\) ibid.
Additionally, there are different justifications behind the concept of parallel importation. One of these is that a substantial portion of the public in developing countries might not be able to afford the goods which are mostly essential drugs and the exporter tries to find a way to fulfill the demands of the market by exporting drugs which are not counterfeit or fake but are not legally available in that market.

The next part of this paper considers the effects of parallel importation under the “TRIPS Agreement” and “the Doha Declaration”, particularly “Article 6 of TRIPS Agreement” and “Article 5(d) of the Doha Declaration”, which provides for exhaustion of rights. This part examines the flexibility of the provisions of TRIPS to permit its member countries adopt the principle of exhaustion of rights that best suits their economy.

Parallel Importation under the TRIPS Agreement:

Two primary considerations steered the formulation of the “Trade-Related Aspects of Intellectual Property Rights Agreement” (“TRIPS Agreement”). The first is the failed attempt of the United States (US) and other developed countries to increase normative standards for protection through the World Intellectual Property Office (WIPO). Secondly, both the Paris and Berne Conventions left the implementation of intellectual property through judicial and administrative remedies to local decisions. This hampered the effective policing and protection of IPRs within a globalized economy. With globalization there is a need to create higher benchmarks of intellectual property protection and provide for international enforcement, as imposition of intellectual property is traditionally limited to national territories.

There is no international enforcement of IPRs; these rights are protected in different countries by their national legislation within a framework established by international rules. The TRIPS Agreement is one of such international rules, which resulted in a significant modification in international standards relating to intellectual property rights. Based on the TRIPS Agreement, most countries have developed common basic standards of IP protection.

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16 ibid
Notwithstanding, the protection of IPRs accorded by the TRIPS Agreement, the TRIPS Agreement remains a highly debated component of the WTO system. This is due to its extensive implications, especially with regards to developing countries. There were divergent opinions on what the scope and content of the TRIPS Agreement should be amongst global north and south countries and also amongst the global north nations themselves at the Uruguay Round Negotiations.\(^{18}\)

**Different Arguments on Parallel Importation:**

The contention of the developed countries (particularly the United States of America (US)), was that heightened protection standards for intellectual property rights (IPRs), will strengthen the value of IPRs, encourage technological innovation in addition to foreign direct investment (FDI), while facilitating technology transfer to global south countries.\(^{19}\)

On the other hand, many developing countries claim that notwithstanding the attempt in the TRIPS Agreement to create a balance in some provisions, it principally benefits technologically rich or developed countries.\(^{20}\) A lot of reasons brought about these concerns. The primary concern was that in contrast to what was being canvassed by the developed countries, the evidence gathered did not establish that creating enhanced protection for IPRs encouraged increased FDIs or technology transfer in any meaningful form.\(^{21}\)

For instance, a study on the effect of the revised patent law in Thailand\(^{22}\) showed no substantial rise in transfer of technology or FDI, instead there was substantial increase in the expenditure on drugs compared to the overall health care spending. Similarly, in Brazil a report on the effects of the “Industrial Property Code (1996)” concluded that “*the greatest beneficiaries of recent changes in Brazilian legislation and implementation of the World Trade Organization’s TRIPS Agreement have not been Brazilian companies or institutions but rather transnational companies.*”\(^{23}\)


\(^{19}\) Ibid.

\(^{20}\) Ibid.


\(^{22}\) The patent law in Thailand is similar to those required by the TRIPS Agreement.

Despite the dissenting views, it is clear that the TRIPS Agreement allows parallel importation based upon the principle of exhaustion of rights. Furthermore, Article 6 of the TRIPS Agreement stipulates that countries have the discretion to implement their own policies and laws with respect to exhaustion of rights. By this provision, members are free to permit parallel imports. Permitting parallel importation allows anybody in the territory to acquire cheaper products protected under IPRs and may import or export, such products. This provision is vital especially for developing countries, where parallel importation might be an integral part of public health policy.

Article 6 of the TRIPS Agreement provides 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 implication of the flexibility of Article 6 of the TRIPS Agreement is the discretion accorded to Members to decide whether or not to integrate in national legislation the international exhaustion of rights principle. Furthermore, it accords members the freedom to define laws governing IPR exhaustion through the legislature and/or courts. This is conditioned upon them not violating the principles of Articles 3 and 4 of the TRIPS Agreement. Accordingly, Members can regulate the degree to which the principle of exhaustion of rights is operated in their countries without violating any obligation enshrined in the TRIPS Agreement.

Article 28 of the TRIPS Agreement confers upon the patent holder the right to “prevent third parties from making, using, offering for sale, selling or importing” product without the patent holder’s consent. However, it is unjustified to rely upon this provision in order to argue that the agreement mandates national exhaustion

26 See Article 1.1 of the TRIPS Agreement supports the argument regarding the flexibility of exhaustion regimes for member countries; also footnote 13 to Article 51 of TRIPS gives WTO Members the discretion to decide the legality of parallel trade.
28 Ibid.
and prevents parallel trade of patented goods.\textsuperscript{29}

In \textit{Kodak SA v Jumbo-Markt AG}\textsuperscript{30} the Swiss Federal Supreme Court, stated that: “Article 28 of the TRIPS Agreement gives the patent holder the right to prevent third parties from selling and importing patented products”. It argued that, Article 28 merely lays down the IPRs owner’s right to stop the importation of products that infringe without placing a ban on parallel imports. Article 28 of the TRIPS Agreement need not be considered in isolation but \textit{in tandem} with the important footnote 6, which makes Article 28 consequent upon the provision of Article 6 of the TRIPS Agreement. Hence, the exclusion of parallel importation by the IPRs owner is not controlled by Article 28 but is specifically reserved for national laws to regulate within the scope of Article 6 of the Agreement.\textsuperscript{31} Moreover, the intention of the TRIPS Agreement is to create equilibrium between the two interests, which are the need to guarantee freedom of trade and the safeguard of IPRs.\textsuperscript{32}

During the negotiation of the TRIPS agreement the member parties were unable to reach agreement regarding exhaustion. This disagreement is reflected in Article 6 of the TRIPS Agreement. The international exhaustion doctrine is clearly, not within the ambit of the TRIPS Agreement. Therefore, the resolution of exhaustion issues is left to national laws, as there are no international or customary law norms applicable in this area. The various positions of WTO members differ widely, this was also confirmed at the Doha Declaration, where the members reaffirmed that members are permitted to determine their regime on exhaustion.\textsuperscript{33}

\textit{Parallel Trade and the Doha Declaration:}

The legality of parallel trade as postulated in the TRIPS Agreement was reaffirmed at the “Doha Ministerial Conference in November 2001” (“the Doha Declaration”).\textsuperscript{34} The “Doha Declaration on the TRIPS Agreement and Public Health” confirms that the TRIPS Agreement is expected to unriddle and applied to safeguard

\textsuperscript{29} Op.cit 3 p. 5.
\textsuperscript{30} 4C. 24/1999/nd, December 7, 1999.
\textsuperscript{31} Op.cit 5 p. 447.
\textsuperscript{32} Op.cit 3 p. 5.
\textsuperscript{33} Op.cit 2 p. 735.
\textsuperscript{34} Op.cit 3 p. 6.
public health and stimulate access to drugs for everyone.\textsuperscript{35} This was a hallmark achievement in international trade, as it signified a harmonization of a rule-based trading scheme with public health interests.

The Doha Declaration reaffirms that Members can create adequate use of the safeguard requirements of the TRIPS Agreement to defend public health and improve access to drugs for all, a principle, which the “World Health Organisation” (WHO) has openly endorsed recently.\textsuperscript{36} Furthermore, the declaration affirms the ability of WTO members to implement the stipulations of the TRIPS Agreement, which afford for flexibility for this purpose.\textsuperscript{37} According to Paragraph 5(d) of the “Doha Declaration” the flexibility includes the freedom to implement an exhaustion doctrine and the freedom to decide the issue of parallel trade in pharmaceuticals.

Paragraph 5 of the “Doha Declaration on TRIPS and Public Health” provides that:

“According and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

\textit{d. The 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, subject to the MFN and national treatment provision of Article 3 and 4}”

The implication of Paragraph 5(d) of the “Doha Declaration” is that it affords developing countries the sought after clarification on the validation of parallel imports under an international principle of exhaustion as it provision is “… is to leave each member free to establish its own regime for such exhaustion without challenge”.\textsuperscript{38} With these provisions, the Doha Declaration is regarded as a turning point in intellectual property. The safeguard of intellectual property should operate as a social policy tool for the advantage of the entire community, rather than as a means to protect limited business interests.\textsuperscript{39}

In order for countries to benefit from this and further flexibilities permitted by the

\textsuperscript{35} Op.cit 24 p.17.
\textsuperscript{36} Ibid.
\textsuperscript{37} Paragraph 4 of the Doha Declaration on TRIPS Agreement and Public Health.
\textsuperscript{38} Op.cit 24 p.17.
“TRIPS Agreement” and affirmed by the “Doha Declaration”, national laws must adopt the relevant provisions.\textsuperscript{40} If there are no such provisions in the national laws, the government or private parties cannot protect themselves from legal actions founded on laws and regulations that do not incorporate the relevant provisions of the TRIPS Agreement. These flexibilities are not automatically translated into national regimes.\textsuperscript{41}

Although, it is argued that for developing countries an international regime of exhaustion may be more appropriate.\textsuperscript{42} A developing country may nevertheless apply a national exhaustion regime as opposed to a regime of international exhaustion based on its socio-economic needs and relevant development policies. Additionally, a developing country may apply a regime of international exhaustion to only certain categories of IPRs.\textsuperscript{43} Thus, due to the flexibility granted through the “TRIPS Agreement” and affirmed in the “Doha Declaration” the regulation of parallel trade in products varies among developing countries. The exhaustion of rights principles are country specific, that is, it is not a case of one measure fits all. This is one of the rationales behind the flexibility in the TRIPS Agreement, it allows governments in different countries to use parallel importation to meet specific purposes.

\textsuperscript{40} For example legal provisions allowing for parallel imports would be normally necessary in order to benefit from the principles of international exhaustion of rights.
\textsuperscript{41} \textit{Op.cit} 24 p.18.
\textsuperscript{43} \textit{Op.cit} 3 p. 6.