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Parallel Imports in the Pharmaceutical Sector: Must India be More Liberal?

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A contemporary debate in India's legal and policy circles has centred around the desirability of liberalizing the parallel imports regime in the country. The primary impetus for such a move has been the amendment to Section 107A(b) to the Patents Act in 2005 which allows easier import of products into India which are already under patent protection. This article, focusing specifically on the pharmaceutical sector argues against the all-pervasiveness of such a move in the Indian context. To set the foundation for this argument, the article examines the leading judicial decisions in this regard in the USA and the EU in order to understand the divergent discourses, which exist supporting and opposing freeing of parallel imports. On the basis of these decisions and their applicability to the Indian context, this article proposes a nuanced policy recommendation harmonizing the financial interests of intellectual property owners with those of securing easier availability of key products.

Keywords: Exhaustion of rights, parallel imports, patent, pharmaceuticals

If ever evidence was required regarding the blurring of national boundaries, the deluge of parallel imports flooding domestic markets would be testimony to the same. Typically in parallel importing, a distributor will obtain a product in a low-price country and transport it to an unauthorized distributor in a high-price country, who will then compete directly with the patent holder or the authorized distributor in that country.[1] Though, *prima facie* taking advantage of such a possibility of arbitrage smacks of opportunism, the practice has been sought to be justified on the ground that as long as the good imported is genuine (and not counterfeit) it only leads to greater supply in the market fostering more competition. Hence, the legality of parallel imports is premised on the belief that once certain goods are sold in the market, the owner of the intellectual property right in those goods exhausts his monopoly claim over its production thereby paving the way for competitive products. This issue is particularly acute in the pharmaceutical sector and it is in this context that the paper delves into this central issue of when the rights of intellectual property owners should be considered exhausted and consequently the limits, which must necessarily be placed on, parallel importation. To this end, first an overview of the law relating to parallel imports in the USA and the EU is presented through which the divergent general approaches to this issue in different jurisdictions is sought to be illuminated. Subsequently, specific emphasis has been laid on the pharmaceutical sector in the EU, which has been in the centre of a storm relating to parallel imports. The multiple considerations in the pharmaceutical sector, comprising *inter alia* economic recompense to the intellectual property owner, the need for market integration, a moral obligation to supply cheap drugs, ensuring easy access to drugs to persons in poorer Member States are factors that make the sector appropriate for research. Finally, the article analyses the Indian position of the law on the issue, which has been radically transformed by the Patents (Amendment) Act, 2005 resulting in imports becoming considerably easier. The effect of freeing of such imports on the pharmaceutical sector in India is dwelt upon in an attempt to arrive at a harmonious balance between conflicting and seemingly irreconcilable interests. In the ultimate analysis, the endeavour of this article is to grasp the nuances of the law relating to parallel imports, its consequences on pharmaceutical companies and to ensure that in our quest for liberalism in India, the interests of patentees and innovators are not left unsecured.

Parallel Imports: Divergent Discourses

At the very outset it must be stated that the issue of exhaustion of intellectual property rights is not governed by the TRIPS regime.[2] Hence, determining when the rights of intellectual property owners are exhausted and consequently the extent of

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permissibility of parallel imports into domestic markets, is essentially a question of national governmental policy. The fundamental consideration motivating any such policy must necessarily involve a balancing of competing interests: that of the intellectual property owner and his right to enjoy the benefits of his creation and the need to foster free competition in the market, which is viewed as an absolute good in itself. Since the outlined interests are mutually antagonistic, courts in different jurisdictions have sought to engender reconciliation models which adequately, albeit not optimally, serve both ends. However, whether these endeavours at harmonization are economically efficacious and legally tenable is a matter which requires closer scrutiny.

In the United States till 2001, a rule establishing modified international exhaustion[3] was followed, according to which, subject only to express contractual restrictions entered into by the patentee enforceable against the importer, parallel imports of commodities were allowed. It was consistently recognized that by upholding the monopoly right of the patentee up to the point of first sale, adequate financial incentive would be provided to the patentee to reap the benefits of his creative invention. In the early case of *Curtiss Aeroplane and Motor Corp* v *United Aircraft Engineering Corp*[4], the issue was at what point of time the rights of the intellectual property owner would be exhausted. In the suit for infringement of patent, the Court held that the moment the patentee sells the patented article, the same is freed from the patents contained therein. Hence, when the plaintiff sold the planes to the British Government, the latter as the vendee obtained absolute rights to deal with them in whichever way it desired. Since the defendant's rights accrued from the same and the said rights were without restrictions as to alienability, the plaintiff could not prevent the defendant from importing the aeroplanes to the United States for resale. The logic underlying the decision is that when the patentee, out of his own volition, sells the patented product and chooses not to impose any restrictive conditions on the same, the vendee has an absolute title to the product. Hence, future parallel imports of the product cannot be prohibited by the patentee when it was within his power to prevent the same *ab initio* at the time of first sale, a right which he voluntarily did not exercise. In the paradigm of balancing competing interests also, the Court felt that such a conclusion was justified since the patentee's financial interests were protected in the form of the monopoly he had over it till the first sale which itself would be pursuant to a sovereign decision by him and at the same time, inconvenience to the public by way of limited supply was obviated by not preventing parallel imports after the first sale had been executed.[5]

The fact that exhaustion is triggered by the first sale of the patented product is premised on the belief that the patentee through the sale receives adequate recompense for his creative investments.[6] Thus, it is crucial that the first sale is under the authority or with the consent of the patentee. This particular nuance in the law relating to exhaustion was delved into by the US Supreme Court in the landmark case of *Boesch* v Graff.[7] It was held that parallel imports could be prevented when the imports were pursuant to a prior user law, since the rights of the defendants emanated from the sale made by the German seller who was not acting under the authority of the US patentee. Thus, the rights which were transferred to the defendant could not extend to importing to the USA where the product was independently patented. The rationale of the decision thus lies in the fact that foreign sales of patented products by third parties with no relation to the patentee cannot trigger exhaustion of his rights since such a holding would be financially detrimental to the patentee and insufficient in compensating him for the expenses incurred in creating the product itself.

This modified international exhaustion approach, which had held the field for over a century was surprisingly overturned by the Court of Appeals of the Federal Circuit in the recent case of *Jazz Photo Corp* v *International Trade Commission*[8] which embodies the law on the point in the USA as the Supreme Court denied *certiorari* in the matter.[9] The question was whether by refurbishing cameras patented in the USA and importing them from China, the defendants had infringed on the rights held by the plaintiff by virtue of its patents. The Court held for the plaintiff stating that such parallel importation constituted infringement.[10] What is pertinent to note is that the Court *sua sponte*, raised the issue of territoriality of exhaustion and proceeded to summarily reverse a catena of precedents which had accumulated over the past century. It stated that patent rights of a patentee under US laws couldnot be exhausted by sales of a foreign provenance. For such exhaustion to occur, the first sale must necessarily be in the United States. Any import pursuant to a foreign sale of the product

would thus still be capable of constituting an infringement of US patent laws. The only authority the Court cited in support for its reasoning was *Boesch* v *Graff*.[11] However, as has already been noted, the case is not authority for the proposition that exhaustion must be territorial as opposed to international. On the contrary, it represents a fact specific decision, which states only that for the first sale to exhaust the patentee's rights, the same must be authorized by the patentee himself. This holding plainly does not translate into an inference that all foreign sales are exempt from the doctrine of exhaustion.

Thus, the United States judiciary has performed a sudden and unexpected *volte face* to territorial exhaustion, thereby severely restricting the scope of parallel importation. *In limine* it must be stated that the forum chosen by the Court for effecting this change was far from apposite since the matter of territoriality of exhaustion was not in issue in *Jazz Photo.* Moreover, in the opinion of the author, the reasons given by the Court for the move away from international exhaustion were unsatisfactory. Not only did it ignore several hostile precedents but the ones it relied upon too were contorted to construe inferences, which did not naturally flow out of the decisions. Thus following a policy of territorial exhaustion in principle reflects a retrograde step in the development of intellectual property jurisprudence in the context of world trade.[12] In an increasingly unifying world where norms of protectionism are considered antithetical, this decision championing the cause of territorial exhaustion sticks out like a sore thumb, inhospitable with the global trend of free movement of goods transcending geographical frontiers of nation states.[13]

Across the Atlantic, however, the ECJ has spawned an independent jurisprudence regarding exhaustion of rights and parallel imports seeking to harmonize the interests of integration of the common market and that of the patent holder in receiving a fair return from the patent held by him.[14] In this effort, the Court has arrived at a compromise by which exhaustion of rights is deemed to occur at a community level though patentees may continue to claim protection if they can show that they were under a legal obligation to market the goods in a particular territory.[15] This formulation itself is the result of varying conceptions of exhaustion and policy questions regarding the permissibility of parallel imports. However, it is far from a settled position and thus, any claim that the EU law relating to exhaustion has transcended the moniker of the ephemeral would be premature.

In Europe, unlike United States, the issue of exhaustion and parallel imports has been coloured by the need to promote market integration and has hence, ceased to remain a debate purely confined within the parameters of intellectual property law. The principle of exhaustion was first applied by the Court in the case of *Deutsche Grammophon Gesellschaft mbH* v *Metro-SB-Grossmarkte GmbH & Co*[16] which was a matter related to copyright infringement. In this case, the appellant company manufactured certain records under a German copyright and marketed the same in France through an authorized subsidiary. When the respondent, an independent importer, tried to resell the goods in Germany after having purchased the goods in France, the appellant brought a suit claiming that its right had not been exhausted since the records had only been marketed abroad and not in German territory. Applying the concept of community exhaustion, the Court held that as long as the authorized first sale was with the consent of the intellectual property owner, the *situs* of such sale would not be relevant for perpetuation of his exclusive rights. If exhaustion were to be considered national, then it would allow manufacturers to partition the common market, restricting interstate trade which is entirely antithetical to the aims of the EC Treaty. Legally, the Court sought to justify its decision on the basis of a conjoined reading of Articles 30 and 36 of the EC Treaty. According to Article 30[17] broadly all quantitative restrictions on importation are prohibited subject to the caveats contained in Article 36.[18] Article 36 charts an exception by stating that a restriction justified on the grounds on protection of intellectual and industrial property would still be permitted provided it is not tantamount to an arbitrary discrimination between competing products or a disguised trade restriction. [19] Hence, it is clear from a reading of the decision, that the conclusion of the court was not prompted by an analysis of the extent to which intellectual property rights must extend but rather the effect that the granting of such a right will have on the cause of integration of the common market. Another decision on exhaustion related to trademarks also highlights this integrationist approach adopted by the Court. In *Hoffman La Roche* v *Centrafarm*[20] Roche had manufactured valium in Britain. With a view to reselling it in Germany, Centrafarm purchased the pills in Britain, repackaged them and marketed them in Germany with Roche's trademark affixed. The question was whether this

constituted infringement. The Court, despite holding in favour of Roche, stated that the provisions of free movement enshrined in the EC Treaty were overriding and if the effect of usage of the trademark right of the proprietor would result in fracturing markets, the right would necessarily have to be limited.

From an analysis of the aforesaid cases, it becomes clear that the ECJ has been at its wits end attempting to reconcile the divergent interests of free movement of goods within the community and the rights of intellectual property owners in having the exclusive right to exclude others from producing the goods. Though, issues of consent by patentees in putting goods into circulation have been the subject matter for discussion, in the opinion of the author, the overriding consideration of the Court has been to promote the interests of market integration and free movement of goods across frontiers. This aim itself is in consonance with holistic EU policy and is laudable in principle. But in this effort, the Court must not erode the rights and benefits which are the just deserts of the intellectual property owners. As the subsequent analysis of the European pharmaceutical market shows, arriving at a neat balance is far more serious and subtle than such a simplistic summary might suggest and principally subserving intellectual property rights to the aspired end of promotion of a free market would be unwise.

At Home in the Community: The Special Case of Pharmaceuticals

Pharmaceutical products are complex subjects for parallel trade because of the several intellectual property rights which may be attached to them, the governmental regulations which may govern their purchase and resale and the high research and development costs of pharmaceutical production which must be compensated through the ownership of the intellectual property right. Though complexities abound, parallel trade in pharmaceuticals is rampant since the possibility of price arbitrage is high in Europe owing to large scale differences in prices of these products in the member states and the negligible transport costs involved.[21] In this scenario, the need to balance the interests of free competition on the one hand and provide adequate incentives for innovation on the other assumes unprecedented importance. Especially for pharmaceuticals, a sector where research and development costs are tremendously high, the number of patents which actually are registered are negligible to the investment expended and consequently a liberal attitude to parallel trade may lead to disincentivizing path-breaking research, a step that may be socially suicidal.[22]

The first landmark case before the ECJ in this regard, providing an opportunity for the Court to clearly define the extent to which patent protection would be granted was *Centrafarm* v *Sterling Drug (*hereinafter '*Centrafarm')*.[23] The central issue was whether national patent laws could be used to bar parallel imports without falling foul of the principle of free movement of goods. The Court used the principle of community exhaustion of rights and held that once the patentee had consented to the marketing of patented goods anywhere in the common market then irrespective of national patent rights which may exist, the goods could be sold and marketed anywhere in the community. The rationale for the decision is evident insofar as it rests on the twin planks of patentee consent and the need for free movement. Once the patentee has consensually allowed goods to be marketed, he cannot retract this representation and later seek to take recourse to national laws to prevent parallel imports. Allowing him to do so would be akin to partitioning national markets which is anathema to the principle of free movement underlying the entire existence of the EU. The Court however, recognized that derogation from the principle of free movement enshrined in Articles 28 and 29 on the grounds of protection of intellectual property was only allowed insofar as it was justified to safeguard the rights constituting the specific subject matter of that property, the specific subject matter of the property being the prerogative of the owner of the intellectual property to reap the benefits of the first sale of the product.[24] Hence, national laws could only prevent parallel imports where the aforesaid prerogative had to be protected and not as a matter of principle. Since, in the instant case, this exception clause was not satisfied, the rights of the patentee were considered exhausted once goods were marketed with his consent anywhere in the community.[25]

The next important case dealing with the twin issues of exhaustion and parallel trade was *Merck & Co Inc* v *Stephar BV*.[26] This case involved the question as to whether pharmaceutical products, if marketed in a country where patent protection for the same does not exist, would lead to exhaustion of the rights of the intellectual property owner. The Court held that the principle of free movement of goods effectively preventing partitioning of national markets could only

be derogated from when derogation was necessary to protect the subject matter of the property right. Reiterating *Centrafarm*, the Court said that the specific subject matter refers to according the inventor the exclusive right to first place his invention on the market.[27] The rationale for recognizing this right is to ensure a reward to the inventor for his creation thereby incentivizing analogous future inventions. Hence, if the patentee consensually markets his invention in any country within the community, the inference to be drawn is either that he has received the reward for his invention or he unilaterally waives his right to the same. This is because of the fact that the decision to place a good for marketing in the community and the conditions under which it is to be marketed is a sovereign decision of the patentee. Once this decision is made, the patentee must also be willingly deemed to have accepted the consequences of the action. At such time, he cannot take recourse to national law to prevent import of goods from another state where he himself has lawfully marketed them. Hence this decision according to the author, much like the previous one, was based on the issue of consent of the patentee in marketing products in member states other than where patent protection exists. The fact that in the previous case a genuine parallel patent existed and in this case marketing of the drug was in a country where patent protection was not available, did not constitute a material difference in the opinion of the Court, since in both cases it was a conscious independent decision made by the patentee. Such being the nature of the decision, in both cases the rationale for the patent, i.e. to confer a reward on the patentee through first sale was held to have been satisfied. Any deferment of exhaustion would lead to skewing of national markets and adversely affect access to drugs of consumers in different markets. Consequently once goods are marketed anywhere within the community with the consent of the patentee, his rights are exhausted and parallel imports are permitted notwithstanding the prejudice this may cause to the patentee.

The final case to be adverted to which presents the law on the issue of parallel trade in pharmaceuticals in Europe is *Merck and Co Inc* v *Primecrown Ltd*.[28] The issues delved into by the Court in this case were whether an exception to the principle of community exhaustion could be charted when drugs were manufactured in countries where they were unpatentable, consequently preventing parallel imports and in the specific circumstance where patentees were under a legal or an ethical obligation to put certain products on the market, whether its patent protection could act as a shield repelling parallel trade. The Court held that a patent holder who willingly placed his products on the market in a country with full knowledge that no patent protection was available therein, exhausted his rights to control the subsequent circulation of those products in the common market. The country where the drug was marketed was an irrelevant consideration since the cornerstone for determining when rights would be exhausted was consent of the patentee in marketing the product. However, where the patentee was under a genuine legal obligation to market goods in a particular country, such consent would not be presumed and his patent protection would continue. In all other cases, consensual marketing presupposed that the rationale of deriving a benefit from the patent had been satisfied and hence freeing the circulation of goods henceforth would not be anathema to the underlying basis for providing intellectual property protection. However, in the opinion of the author, a conclusion suggesting that consent of the patentee itself presented a sufficient indicator that the benefits of the patent had been optimally derived would be illogical. First, when the product is marketed in a state wherein it is unpatentable, then the primary creative reward of the inventor, that of monopoly exploitation is not satisfied. Secondly, in the absence of price harmonization of drugs between countries and mandatory pricing controls of drugs in certain countries, the consent given by the patentee to marketing may not be truly volitional.[29] Again, a practical consequence of considering rights to be exhausted once goods are marketed in countries where no patent protection exists would be economically inefficient and socially inoptimal decision made by pharmaceutical companies, choosing not to supply drugs to such countries despite the sale being profitable resulting in consumers being deprived of the drugs. Such a result would lead to an equal problem of partitioning of markets hitherto unforeseen by the ECJ. Thus, as has been suggested[30] the rule of unqualified community exhaustion should be limited to cases where genuine parallel patent rights exist in different member states. Such a determination would ensure that supply of essential drugs to countries where no patent protection for the same exists would not be diminished and pharmaceutical companies too would receive adequate incentive to continue research and development efforts.[31]

Hence, from the aforesaid decisions it can be inferred that in its endeavour to balance the interests

of market integration and rewarding the creative efforts of inventors through providing adequate returns through patent protection, the courts have leaned towards the former. While ensuring free movement of goods is a lofty goal in abstraction, its achievement at the cost of the profits of pharmaceutical companies is myopic and economically inefficient. This is because research and development costs in the pharmaceutical sector are exceedingly high and due to the high risks involved 90% of R & D spending is financed by the industry itself.[32] Further, the number of patents registered as a proportion of the costs incurred are extremely low. Hence, it is imperative in the interests of research that companies have enough profits to plough back into the creative process.[33] Though, the ECJ decisions may be prompted by the need for market integration which has no relevance in India, the jurisprudence evolved by the Court severely erode the financial capacity of pharmaceutical companies and pose a credible threat to the process of research and development anywhere in the world. Hence, a case-by-case adjudication to ensure that interests of cutting edge research are harmonized better with the need to integrate the common market would be in order, rather than a wide-ranging principle to be applied across the board.

Indian Pharma: The Perils of Parallel Importing

At this stage, it would be appropriate to turn to the Indian law relating to parallel importation, which is in a nascent stage of its development. However, even in its brief period of infancy it has been the subject of widespread scrutiny and consequently a landmark amendment has been made that looks to alter the very prism through which parallel importing is viewed. Section 107A(b) of the act, as amended originally in 2002 provided for parallel imports of products patented in India provided the importer is 'duly authorized by the patentee to sell or distribute the product.'[34] This required the foreign exporter to be authorized by the patentee to sell and distribute the product. Hence if analysed, it is evident that the fundamental plinth on which the law is based is consent of the patentee. Much like the law in Europe, once the patentee has consented to his patented product being sold or distributed anywhere in the world, he is deemed to have received an adequate return for his creative endeavours in securing the patent and hence cannot prohibit the products from being imported. Nuanced exceptions such as when there is a legal obligation to market goods in another jurisdiction or in cases of compulsory licensing are absent from Indian law. With the amendment to the act in 2005, however, the law relating to parallel imports changed drastically.[35] From being premised on consent of the patentee, the law was amended to allow parallel imports when the person from whom the imports are acquired is one 'who is duly authorized under the law to produce and sell or distribute the product.'[34] Through, this provision hence, consent has been removed as a factor to be considered before exhaustion of the rights of the patentee is deemed. By thus making parallel imports easier, the government has sought not to balance the interest of the patentees with the countervailing interest of promoting free competition but has evinced a clear policy mandate in favour of the latter. While undoubtedly important products should not suffer from shortage in supplies due to the fact of them being patented, such an amendment to the law takes away the very rationale for patent protection, i.e. providing just rewards for creative innovations made.[36] Hence, this amendment strikes a lethal blow to patentees and potential innovators generally by sacrificing the creative process inherent in a product at the altar of ensuring its easy availability in the market.[37]

For the specific impact of the amendment on the pharmaceutical sector in India is concerned, it is necessary to understand the structure of the industry first.[38] The Indian pharmaceutical sector is a veritable success story in the liberalization era. With 23 firms posting a turnover in excess of $100 million in March 2005, it is universally recognized as a potent, emerging market.[39] Key to the spiraling growth of the sector has been a conscious effort to make the industry more globally competitive by moving to a sector, based less on control and more on governmental monitoring. However, with the amendment facilitating parallel imports, the scope for governmental intervention in a relatively freely functioning market is now rife. Further the financial revenues of pharmaceutical firms will be adversely affected since the effect of the provision is to allow sale of generic products without the consent of the patent-holder. With revenues being affected, the obvious impact will be felt in the sector of incremental innovations, which will now enjoy a weak semblance of patent protection. Thus, Indian pharmaceutical firms being adversely affected, the interest of long term research in the sector in India is

being seriously imperiled.[40] This is because smaller pharmaceutical firms will look to seize the immediately profitable arbitrage opportunities provided by easier parallel imports rather than invest in long term research and development of new drugs for which not only is legal protection being made weak but consequently the possibility of economic benefits too is less certain and more distant. On the other hand, the benefit sought to be derived from the amendment is to secure easier access to drugs. It must however be noted that almost 97% of medicines now available, including 350 life-saving drugs, are off-patent.[41] Hence, even if beneficial, it will ease the availability only of a microscopic proportion of the total drugs available in the market. Hence, despite facilitating access to drugs, the overriding bearing of the amendment will be on the long run wherein research and development capabilities of domestic firms will be curtailed leading to an excessive reliance on imports and generics. Such a move while attempting to create a competitive market may actually prove counter-productive by effectively shackling domestic research. Hence, in the opinion of the author, a more balanced equilibrium position needs to be found. Since securing easy access to drugs is undoubtedly a legitimate aim, the following policy changes may be incorporated:

(i) Parallel imports of drugs, which are life-saving (specified by the appropriate authority) to be permitted by those persons who are duly authorized under the law.
(ii) For all other drugs, consent of the patentee must be acquired before parallel imports are carried out.

The aforesaid compromise, according to the author, will ensure that incentives for companies to continue research and development will remain since rights are not considered exhausted, for a majority of drugs, till the consent of the patentee is taken. If the patentee refuses to consent to the request for parallel imports then the same will not be allowed in the light of the elucidated need to protect the economic interests of patentees and privileging the same over possible supply requirements, without which long term research in pharmaceuticals will be severely crippled. At the same time, supply of life-saving drugs, which is a vital governmental concern, will not be stymied by any product patent and the government can authorize the parallel importation of the same, if the need so arises. This determination of what is a life-saving drug will be done by an expert authority set up by the government comprising persons of proven expertise and free from personal bias who would be appointed pursuant to rules which establish minimum criteria that would have to be fulfilled to qualify for being a member of the authority thereby obviating in theory any possibility of classifications which are askew. Hence, in the final analysis as a result of the compromise, both pharmaceutical companies as well as the common man seeking easy access to cheap drugs will be mutually benefited.

Conclusion

Parallel imports in the pharmaceutical sector stand at the confluence of the domains economic, social and political. From this murky convergence of distinct interests, it emerges that unlike other sectors, pharma requires a more subtle balance to be drawn between protecting the creative interests of the innovators and the general public good of ensuring steady supply of life-saving drugs. This is because of the high research and development costs that are intrinsic to the survival and perpetuation of the industry and hence any move, which detrimentally affects the financial capabilities of patentees, such as, freeing parallel importation to increase drugs supply, must be scrutinized with great care. The need for reaching an equitable balance is reflected in the general law relating to parallel imports also wherein the divergence of opinion across jurisdictions suggests that the optimal approach to exhaustion of rights cannot be concretized succinctly in principle and must be viewed keeping the varying considerations of each specific case in mind. Hence, as far as the cited decisions relating to pharmaceuticals before the ECJ are concerned, the author believes, that the reasoning is excessively motivated by a general need to integrate the common market by promoting free movement of goods. While laudable in principle, such a stream of decisions cannot be commended when the aspirations are achieved at the cost of owners of intellectual property. If perpetuated, the underlying rationale for granting of patents, which is to ensure a fair return to the innovator, will be defeated. In the light of these international developments, the move to free parallel imports by the lawmakers in India by moving away from a system based on consent of the patentee to that based on legal authority must be criticized for its lack of nuance as has been

highlighted in the article. Hence, the author has proposed an alternative equilibrium, which is felt would facilitate easy access to medicines without prejudicing patentees. Such a formulation, the author believes, would lay to rest the financial concerns of small pharmaceutical companies and also the social concerns of the government since it would not compromise on the availability of life-saving drugs in the market. Thus, in a utilitarian consideration of the promotion of the general public good it is expedient that this reform be effectuated and parallel imports be viewed with a perspective that transcends the straitjacket.

References

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2 Article 6, TRIPS Agreement,'For the purposes of dispute settlement . . . nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.' The TRIPS Agreement explicitly acknowledged this lack of consensus between WTO members on this issue. This should come as little surprise as the debate on parallel trade and the issue of exhaustion incorporates aspects of competition policy and passionate North- South debates. Cottier Thomas, *The WTO system and exhaustion of rights*, Draft manuscript presented at the Conference on the Exhaustion of Intellectual Property Rights and Parallel Importation in World Trade, Geneva, Switzerland, 6-7 November 1998. Barfield Claude E & Groombridge Mark A, Parallel trade in the pharmaceutical industry: Implications for innovation, consumer welfare, and health policy, *Fordham Intellectual Property, Media & Entertainment Law Journal*, 10 (1999) 191.

3 International exhaustion refers to the situation when a patent owner's rights are considered extinguished on the first authorized sale of the patented item, anywhere in the world, thereby legalising subsequent import of the item into the patentee's home country. Mueller Janice M, *An Introduction to Patent Law* (Aspen Publishers, New York), 2003, p. 364.

4 266 F 271 (2d Cir 1920) as cited in Dinwoodie Graeme B *et al*, *International and Comparative Patent Law* (LexisNexis, New Jersey), 2002, p.811. Barrett Margreth, A fond farewell to parallel imports of patented goods: The United States and the Rule of International Exhaustion, *European Intellectual Property Review*, 24 (12) (2002) 571-578 at 573. In this case, the plaintiff company held American and Canadian patents relating to certain kinds of aeroplanes which it licensed to the British government for use during the First World War. After the termination of the war, the British government sold the planes to the defendant who imported them to the United States for resale. The issue was regarding the legality of the same.

5 *Keeler* v *Standard Folding Bed*, 157 US 659 (1895) where the Supreme Court held that the patented product once sold becomes the private property of the purchaser who enjoys an unqualified right in it. Further, it held that the interests of the patent holder was protected since he had absolute monopoly over the product till the first sale and extending the same beyond would constitute a significant public hindrance. *Chaffee* v *Boston Belting Co*, 22 How 217; *Bloomer* v *Millinger*, 68 US (1 Wall) 340 (1863) for the proposition that with payment of consideration on first sale, the monopoly right of the patentee is divested.

6 Barrett Margreth, A Fond farewell to parallel imports of patented goods: The United States and the rule of international exhaustion, *European Intellectual Property Review*, 24 (12) (2002) 572.

7 133 U S 697(1890). In this case, the issue was whether the plaintiff, an American patent holder of lamp burners could prevent the import of the same from Germany by the defendants who had acquired the product from a seller entitled to transact under a German prior user law.

8 264 F 3d 1094 (Fed Cir 2001). In this case, the plaintiffs held patents in relation to a disposable camera which was not designed for reuse after its film was exposed. However, the shells of the camera were reused by certain Chinese refurbishers and the defendants purchased the same, supplied the films and imported these cameras into the US market.

9 For the order denying *certiorari*, 122 S Ct 2644 (2002).

10 Three arguments in which the court held in favour of the defendants was that their act of refurbishment would fall within the parameters of 'repair' which is recognized as an exception to the exhaustion principle. On facts also it held that the plaintiff had not imposed any contractual restrictions on alienability and hence could not claim that the actions of the defendant had been expressly precluded by a contractual stipulation by the plaintiff. Thirdly, it held that the doctrine of exhaustion is not confined solely to apparatus claims but extends to design patent claims and utility patent claims also. 264 F 3d 1094 (Fed Cir 2001).

11 133 U S 697(1890).

12 The author is not suggesting that the principle of international exhaustion be made absolute. To protect financial interests of intellectual property owners, an exception to the principle may certainly be made. However, territorial exhaustion as the default norm is being criticised. Barrett Margreth, A fond farewell to parallel imports of patented goods: The United States and the rule of international exhaustion, *European Intellectual Property Review*, 24 (12) (2002) 576.

13 The decision of the Japanese Supreme Court in *BBS Kraftfahrzeugtechnik AG* v *Rashimekkusu Japan Co Ltd and JAP Auto Prods Co Ltd*, Case No. H-6-(Ne)-3272 (Japan 1997), translated in (1998), *International Review of Industrial Property & Copyright*, 29(331).

14 For a detailed analysis of divergent interests of intellectual property owners and promotion of free movement, Thomas Hays, *Parallel Importation under European Union Law* (Sweet and Maxwell, London), 2004, p. 7.

15 *Merck and Co Inc* v *Primecrown Ltd*; *Beecham Group Plc* v *Europharm of Worthing Ltd* [1997] 1 CMLR 83.

16 [1971] CMLR 631.

17 Though in this case, the Court relied on the ideas of arbitrary discrimination and disguised trade restrictions to strike down the argument of national exhaustion, other cases have

adopted a different approach by not only enquiring whether the rule imposing the quantitative restriction on imports actually protects intellectual or industrial property but also the specific subject matter of the right sought to be protected.

18 [1978] 3 CMLR 345.

19 Thomas Hays, *Parallel Importation under European Union Law* (Sweet and Maxwell, London), 2004, p. 62.

20 Pharmaceuticals stand out as a peculiar sector since the sunk research and development costs are exceedingly high and technological innovation is a time-consuming process and usually the result of a collective effort of a group of authors. The proportion of researches which are successful leading to registration of patents to the extent of research undertaken is small, leading to costs of pre-market failure. Even if the research is successful, the priority period between filing of the application and the granting of the patent is seldom used productively since the compliance with regulatory controls is an arduous process. For an exhaustive detailing of the reasons, Thomas Hays, *Parallel Importation under European Union Law* (Sweet and Maxwell, London), 2004, p. 64.

21 [1974] CMLR 1. In this case, Sterling sued Centrafarm for importing into the Netherlands a patented drug, Negram, which was marketed by an equivalent patent in the UK by a subsidiary of Sterling. The price difference of the drug between the different countries was almost 50%. The Court found for Sterling on merits and held that there had been an infringement of patent. However, it held that the patent right had already been exhausted and hence Sterling would be without remedy.

22 [1974] CMLR 1, at para 8. Simon Thorley *et al* eds, *Terrell on the Law of Patents* (Sweet and Maxwell, London) 2000, p. 228, 229.

23 The Court concluded by stating that, 'The question referred should therefore be answered to the effect that the exercise by a patentee of the right which he enjoys under the legislation of a Member State to prohibit the sale, in that State, of a product protected by the patent which has been marketed in another Member State by the patentee or with his consent is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the Common Market.' *Centrafarm* v *Winthrop*, [1974] 2 CMLR 480 wherein an additional argument against exhaustion of rights was raised stating that since the existence of the patent was also a guarantee of quality of the drug, if patent rights were considered exhausted after the first sale anywhere in the community, the quality of drugs could not be guaranteed by the patentee and hence it was in the best interest of the consumer that exhaustion be restricted. The Court refused to extend the exception enshrined in Article 30 which allowed for derogation from free movement in cases where it was necessary to protect the specific subject matter of the property to the need to protect consumers. The specific subject matter of the property was to reap the benefits of the first sale and quality requirements, the need to protect consumers and prevent others from reaping arbitrage opportunities exploiting existing price differences were extraneous considerations.

24 [1981] 3 CMLR 463. In this case, the plaintiff marketed a product which had earlier been sold in Italy, a country where patents at that time were not granted in respect of pharmaceutical products. In Italy, the defendant purchased the product and sold it in the Netherlands. The Court held that rights were exhausted and the plaintiff was not entitled to relief.

25 This rationale was expressly recognized by the ECJ in the case of *Pharmon BV* v *Hoechst AG*, [1985] 3 CMLR 775 where the Court held that when the initial marketing of the good was done not by the patentee himself but by a licensee under a compulsory license, then the rights of the patentee cannot be considered exhausted since he cannot be deemed to have consented in receiving a fair return on his investment through the marketing by the licensee. In this regard see the fallacy of the implied consent theory to exhaustion in Grubb Philip W, *Patents for Chemicals, Pharmaceuticals and Biotechnology*, 4th edn (Oxford University Press, Oxford) 2004, p. 463.

26 [1997] 1 CMLR 83. This case was heard along with *Beecham Group Plc* v *Europharm of Worthing Ltd*. In these cases, Merck held UK patents for a hypertension drug Innovace, a drug, for prostate treatment, Proscar and for glaucoma, Timoptol, while Beecham held a UK patent for an antibiotic drug Augmentin. Those drugs were marketed by both companies in Spain and Portugal at a time when drugs could not be patented in those two countries. They alleged that the defendants, *Primecrown and Europharm* infringed their respective UK patents by importing the drugs into the United Kingdom from Spain and Portugal without lawful authority.

27 The issue of different national healthcare policies and price control regimes was expressly recognized in the case of *Commission of the European Communities* v *Bayer AG* (Adalat case), [1996] 5 CMLR 416. The Court recognized the impact of administrative and purchasing policies of states, different levels of reimbursement by social security systems which lead to market distortions that need to be corrected before any community-wide rules can be effectively implemented. Schaeffer Fiona and Kon Stephen, Parallel imports of pharmaceutical products: A new realism, or back to basics, *European Competition Law Review*, 18 (3) (1997) 123-144.

28 Opinion of Advocate General Fennelly delivered on 6 June 1996 as cited in Schaeffer Fiona and Kon Stephen, Parallel imports of pharmaceutical products: A new realism, or back to basics, *European Competition Law Review*, 18 (3) (1997) 137.

29 The effect of the decision in Primecrown as it stands has been recognized in academic writing as a severe detriment in the efforts of the European pharmaceutical industry to maintain profits sufficient to support and expand their R & D base. Keyder Virginia Brown, European Court of Justice: Patents - parallel imports of pharmaceuticals, *European Intellectual Property Review*, 19 (3) (1997) D 88- 89. Schaeffer Fiona and Kon Stephen, Parallel imports of pharmaceutical products: A new realism, or back to basics, *European Competition Law Review*, 18 (3) (1997) 123-144.

30 Vicien Concepcion Fernandez, Why parallel imports of pharmaceutical products should be forbidden, *European Competition Law Review*, 17 (4) (1996) 219-225; Nazerali Julie S, Parallel imports of pharmaceuticals- A prescription for success or a free market overdose, *European Competition Law Review*, 19 (6) (1998) 332-342.

31 Four reasons have been suggested for allowing controls on parallel trade all of which are applicable to the pharmaceutical

sector. These are: First in high-technology industries, particularly, those with a high ratio of sunk joint R&D costs, where parallel trade affects the ability of firms to recoup fixed costs and reducing their ability to innovate; Secondly, in situations where differential pricing will enhance welfare by facilitating entry into new, low-priced markets and thus expanding output for producers; Thirdly, in cases where monopsony power by public authorities creates price distortions and drives price down below average fixed costs and fourthly when parallel imports can freeze out authorized distributors through lower prices, thus undercutting information and value-added service activities. Barfield Claude E & Groombridge Mark A, Parallel trade in the pharmaceutical industry: Implications for innovation, consumer welfare, and health policy, *Fordham Intellectual Property, Media & Entertainment Law Journal*, 10 (1999) 187.

32 Section 107A(b) of the Patents Act as amended in 2002 stated, Certain acts not to be considered as infringement- For the purposes of this Act, - (b) importation of 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.'

33 The amendment was first brought about by the Patents (Amendment) Ordinance, 2004, an ordinance passed pursuant to India having availed of the additional transitional provisions in Article 65.4 of the TRIPS Agreement, which necessarily mandated introduction of product patent for pharmaceuticals and agri-chemicals by 1 January 2005.

34 In this regard it also believed that the provision, since it does not involve an exhaustion of rights issue at all but allows imports into India provided they are authorized under the law of the exporting country, may fall foul of Article 6 of the TRIPS Agreement read with Article 5(d) of the Doha Declaration and Article 28 of TRIPS. Basheer Shamnad, India's tryst with TRIPS: The Patents (Amendment) Act, 2005, *Indian Journal of Law and Technology*, 1 (2005) 30-31.

35 For a criticism of the amendment and its detrimental impact on research and development, Gupta Uttam, Patents (Amendment) Act 2005 - Setback for innovators and R&D, *Business Line*, 23 September 2005.

36 For an elaborate overview of the Indian Pharmaceutical industry and its competence in the new product patent regime, FICCI Report on '*Competitiveness of the Indian Pharmaceutical Industry in the New Product Patent Regime*' (FICCI, New Delhi) March 2005. *Frost and Sullivan*, IndiaChem 2006 White Paper (FICCI, New Delhi) 2006.

37 Cygnus Business Consulting and Research, Top 100 Companies by Turnover, March 2005, www.pharmexcil.com/v1/docs/top100pharmacompany2005march.pdf (23 January 2007).

38 It is believed that as a result of the amendment, MNCs with deep pockets will be benefited whereas India's 5500-odd small sized pharmaceutical companies will face difficulties in continuing their research process. Titus Diljeet, A new patent regime, *Asia Law* (May 2005), http://www.asialaw.com/default.asp?page=14&ISS=14978&SID=502651 (24 January 2007).

39 Titus Diljeet, A new patent regime, *Asia Law* (May 2005), http://www.asialaw.com/ default.asp?page=14&ISS=14978&SID=502651 (24 January 2007).