

## ‘Exhausting’ Patent Rights in India: Parallel Imports and TRIPS Compliance

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India’s amendment to her patent regime in 2005<sup>1</sup> to introduce pharmaceutical product patents attracted unprecedented attention, both domestically and globally. While multinational pharmaceutical companies were concerned that the Act withered away their exclusive rights, civil society activists decried the new product patent regime, fearing that it would cause steep hikes in the price of life saving drugs. This politicization of patent law produced some interesting results; most recently, a recent Delhi High Court case that denied an injunction to a multinational patentee on the ground that it sold a more ‘expensive’ drug than the infringing generic manufacturer.<sup>2</sup>

While some provisions in the new patent regime, such as Section 3(d) continue to attract a lot of attention, others have been lost in the legalese. One such provision is Section 107A(b) dealing with parallel imports, which, if read in a strict literal manner could have far reaching implications for the rights of a patentee. This paper aims to highlight this particular provision, which has thus far not attracted the attention it deserves. It explores the ambiguities inherent in this section and discusses the gaps in the Indian law pertaining to exhaustion and parallel imports. Lastly, it goes on to suggest statutory amendments in order to remove ambiguities inherent in the section and expand the scope of exhaustion envisaged therein, whilst at the same time remaining TRIPS compliant.

The paper is divided into four sections: The first section explains the concept of exhaustion/parallel importation in relation to patents. Section two examines the ambiguities inherent in Section 107A(b). It also explores the gaps in the law relating to exhaustion in India and assesses the TRIPS compatibility of the current provision. The third section recommends a creative way of interpreting the current statutory provision so as to remove the ambiguities, and balance out the rights of patentees and parallel importers in an optimal manner without violating the TRIPS Agreement. The final section recommends statutory amendments to Section 107A(b).

**Keywords:** Parallel imports, TRIPS, exclusive rights exhaustion, patented portents, national, regional and interregional exhaustion

### Patents, Parallel Imports and Exhaustion: A Primer

A patent is a bundle of exclusive rights granted to an inventor whose invention satisfies certain pre-requisites such as novelty, non-obviousness and

utility.<sup>3</sup> Such exclusive rights include the right to make, use, sell and import the patented goods into such country.<sup>4</sup>

The doctrine of exhaustion imposes certain limits on the patentees’ exclusive rights. According to this doctrine, ‘a patented item’s initial authorized sale terminates all patent rights to that item.’<sup>5</sup> In other words, she cannot control the resale or re-distribution of the particular good that had already been sold once.<sup>6</sup> Were it not for such ‘exhaustion’ of rights, a purchaser of a patented article might be prevented from selling the said article or even ‘using’ it, since such ‘sale’ or ‘use’ implicates the exclusive rights of the patentee.<sup>7</sup>

Illustratively, a buyer of a patented washing machine is free to do what she wishes with the machine: this includes the freedom to use the said machine, re-sell it, etc., without fear of being sued for

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patent infringement. The rationale underlying the theory of 'exhaustion' and the doctrine of first sale is that the patentee has already been rewarded through the first sale and should not be allowed to profit repeatedly on the same good by controlling its use, resale or distribution.<sup>8</sup> However, the doctrine of exhaustion is circumscribed by the following factors:

- (i) 'Exhaustion' kicks in only if the 'first sale' is made by or with the authorization of the patentee.
- (ii) 'Exhaustion' in relation to a particular patented article does not impact any of the exclusive rights of the patentee with respect to her other patented articles. In other words, a buyer of a patented article does not acquire any rights (such as the right to manufacture or use) over such other patented articles.<sup>9</sup>

Legitimate 'parallel imports' are but a natural corollary of the doctrine of exhaustion and imply the following:

- (i) An export of a patented good from country X (such as Bangladesh)
- (ii) Import of such patented good into country Y (such as India).

A parallel importer essentially engages in price arbitrage and exploits the price difference between the exporting country (Bangladesh) and the importing country (India). Several countries therefore encourage such imports to ensure lower priced patented goods for their consumers.

It bears noting that third parties, who may or may not be related to the intellectual property owner, are the ones that essentially effectuate 'parallel imports'. As to whether or not the import of such goods into India (importing country) can be stopped by the patentee by recourse to an Indian court will depend on the laws of India. Illustratively, since the laws of India provide for 'international exhaustion', such imports into India are legal. Contrast this with the US and EU, which do not provide for international exhaustion: any import of patented goods from Bangladesh to the US or any of the EU countries can therefore be prevented by the patentee, even if the patentee herself had placed the goods in the Bangladeshi market. Discussed are various kinds of 'exhaustion'. It is important to bear in mind that the scope of 'exhaustion' would depend upon the kind of intellectual property right (IPR) in question i.e. the rules relating to 'exhaustion' in relation to patents are

quite distinct from those in relation to copyrights and trademarks.<sup>10</sup>

Although the paper is restricted to the norms of exhaustion that apply in the context of patents, exhaustion in the context of other IPR, is also referred where ever necessary.

#### **National, Regional and International Exhaustion**

Consider the following hypothetical built around a recent case in India,<sup>2</sup> albeit with appropriate modifications to illustrate the point better. Roche, a Swiss multinational corporation owns a patent over an anticancer drug, Tarceva in India. It sues Cipla for introducing a generic version of this drug and requests Delhi High Court for an interim injunction against Cipla. The Court decides in favour of Cipla on the grounds of 'public interest' i.e. Cipla was selling a cheaper and more affordable version of Tarceva. Upto this point, the hypothetical mirrors the actual case itself that is currently pending before the Delhi High Court.

Let us now assume that Cipla is injuncted (at the final stage) by the Delhi High Court and cannot sell generic versions of Tarceva in India. Let us also assume that Roche has patents covering this drug in Bangladesh and Pakistan. However, there is a price differential, with the highest price being charged in India and the lowest in Bangladesh. The following questions arise:

- (i) Can Cipla import the drugs from Bangladesh to India and avail of the price differential?
- (ii) Can Cipla buy the drug from Roche in Bangladesh and resell within Bangladesh (particularly to areas that are not serviced by Roche or its distributors)?
- (iii) Can Cipla import the drugs from Bangladesh to Pakistan and avail of the price differential?

The answers to the above questions depend upon the kinds of 'exhaustion' and 'parallel import' laws prevailing in India, Bangladesh and Pakistan. Let us assume for the purpose of hypothetical that Bangladesh and Pakistan follow domestic exhaustion, while India follows international exhaustion. Let us also assume that Pakistan and Bangladesh are part of a regional bloc and they follow 'regional exhaustion' as well.

#### **International Exhaustion**

In the hypothetical, Indian patent law follows international exhaustion i.e. once Roche sells Tarceva capsules in Bangladesh, either through itself or an

authorized representative ('first sale'), its rights stand 'exhausted' *vis-a-vis* that product. Cipla is free to bring these very same capsules into India and sell at a higher price.

While countries such as India, Taiwan, Japan, New Zealand and Australia recognize the principle of international exhaustion,<sup>11</sup> a number of other countries, such as, the US, EU, Brazil and China do not.<sup>12</sup>

***National Exhaustion: Bangladesh***

In the hypothetical, Cipla can buy Tarceva capsules from Roche in Bangladesh and then resell them or re-distribute them anywhere in Bangladesh. Naturally, it will do so only if it can engage in price arbitrage i.e. sell at higher prices in remote areas not serviced by Roche. Here again, since Roche has already sold the drug once (first sale), it cannot control the further sale or distribution within Bangladesh. It is to be noted under principles of 'domestic exhaustion', the purchase of the patented article and its subsequent resale or its re-distribution is to be confined within the territorial limits of Bangladesh.

***Regional Exhaustion: Pakistan and Bangladesh***

Some countries permit parallel import of goods within a specific regional bloc, so long as the first sale is legitimately made by the patentee or her authorized representative within one of the countries in such a bloc. The European Union (EU) is a good case in point and patented goods that have been subjected to a first sale anywhere in the community (e.g. France) can be imported and sold in any other EU country (e.g. UK) without the permission of the patentee,<sup>13</sup> provided of course, the first sale is made by or with the authorization of the patentee. In a similar way, since Bangladesh and Pakistan are members of a regional bloc in our hypothetical, a sale in Bangladesh would exhaust the patentee's rights in the entire bloc. And the goods can cross over to Pakistan without permission of the patentee.

Now that the concepts have been fleshed out, examine the regime pertaining to 'exhaustion' of patent rights in India.

***National Exhaustion: The Indian Legal Regime***

Curiously, the Indian patent regime does not expressly provide for national exhaustion. Contrast this with other IP legislations such as the Trademarks Act, 1999,<sup>14</sup> which appears to recognize such a principle. Section 30(3) of the Act provides in pertinent part that '*[w]here the goods bearing a registered trademark are lawfully acquired by a*

*person, the sale of the goods in the market or otherwise dealing in those goods by that person or by a person claiming under or through him is not infringement of a trade by reason only of- (a) ... or (b) the goods having been put on the market under the registered trademark by the proprietor or with his consent.'*

Although the section does not use the term 'exhaustion', the use of terms such as 'sale of goods in the market' or 'otherwise dealing in those goods' clearly indicates that what is envisaged is 'exhaustion'. Unlike Section 107A(b), Section 30(3) is not limited to 'imports' and can therefore be read to allow both domestic and international exhaustion. A recent decision of the Delhi High Court makes this clear.

In *Xerox Corporation v Puneet Suri*,<sup>15</sup> the plaintiff owned the trademark 'Xerox' and claimed that the defendant's act of importing and selling second hand Xerox machines constituted trademark infringement.

The defendants argued that their acts were covered under Section 30(3), which recognized the principle of international exhaustion.<sup>16</sup> Justice Sanjay Kishen Kaul of the Delhi High Court agreed with the defendants, holding that the 'import of [second hand] Xerox machines that have proper documentation' is permissible under the Trademarks Act, provided that '*there is no change or impairment in the machine.*'<sup>17</sup>

Given this statutory endorsement of exhaustion, both national and international, in the Trademarks Act, might one argue that the absence of a similar clause envisaging 'national exhaustion' in the Patents Act means that Parliament did not intend to provide for such a doctrine?

Since the Patents Act expressly provides for 'international exhaustion', (a point we will elaborate in detail in the ensuing paragraphs) which is a relatively more liberal defense to infringement, it is unlikely that an Indian Court will refuse to endorse a narrower 'national exhaustion' exemption in India. Particularly since the lack of a specific national exhaustion principle appears to be oversight than a deliberate attempt by Parliament to restrict the scope of Section 107(A) (b). More importantly, if a court does insist on a strictly technical reading of the statute to oust national exhaustion, a patentee could sue the buyer of a patented product for violating the exclusive right to 'use'.<sup>18</sup> Surely, such an absurd result was not intended by Parliament.

Therefore, a court is likely to eschew a strictly literal reading in favour of a more purpose driven interpretation to enable subsequent sales or distribution of patented products within India.<sup>19</sup>

***Regional Exhaustion: The Indian Legal Regime***

Although India is a member of associations and trading blocs (such as SAARC and Commonwealth),<sup>20</sup> none of these blocs require 'regional exhaustion' to be built into the respective domestic patent regimes. Consequently, India does not have any such provision in its statute.

***International Exhaustion: The Indian Legal Regime***

As already mentioned earlier, the Indian Patents Act explicitly recognizes the principle of international exhaustion. But first, a bit of history:

The first statutory provision on parallel imports was introduced by the Patents (Amendment) Act, 2002. This section provided that the '*...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.*'

However, the above provision was considered restrictive in scope, as evident from the following hypothetical:

Assume that Roche has a patent over Tarceva in both Bangladesh and India. However, Roche sells the drug (through its licensee, X) at Rs 100 in Bangladesh and Rs 300 in India. Cipla buys the drug from X at Rs 100, imports it to India and thereafter re-sells at Rs 200 per capsule. Since X qualifies as 'a person duly authorized by the patentee', Cipla's import is legal and falls within Section 107A(b). Now let us assume that X discovers that Cipla is engaging in parallel trade and undercutting his market in Bangladesh and therefore stops selling to Cipla. Cipla then approaches a drug store (Y) in Bangladesh that has brought supplies from X. Although Y is not a licensee of Roche, under Bangladeshi law (which we assume recognizes national exhaustion), it is free to resell or redistribute goods bought from Roche/X.

However, under Indian law, Y does not qualify as '*a person who is duly authorized by the patentee to sell or distribute the product*'. Therefore, if Cipla buys from Y, it will not be protected under Section 107A(b) and can be sued for patent infringement by Roche in India. Needless to state, such a legal position thwarts the very idea of international exhaustion and the laudable intent of helping Indian consumers avail

of lower prices, when the patentee has already placed a product in the global market and made profits on the first sale thereon. It is pertinent to note in this connection that according to the 'Statement of Objects and Reasons' appended to the Patents (Amendment) Act, 2002, Section 107A(b) was introduced to 'ensure availability of the 'patented product' in the Indian market at minimum international market price.'

Owing to the restrictive nature of the 'exhaustion' provision as discussed above, Section 107(A)(b) was amended by the Patents (Amendment) Act, 2005<sup>21</sup> to provide that there would be no infringement if there has been an '*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*'.

Therefore, in contrast with the earlier position under the 2002 Act, once the 'first sale' of any product had been authorized by the patentee, a parallel importer could buy that product from any reseller and not necessarily from the one that had the express permission of the patentee to resell or distribute. In other words, such importer did not need to ensure that any of the subsequent sellers from whom she buys the goods (whether second, third or fourth) were expressly or impliedly authorized by the patentee. Of course, this assumes that Bangladeshi patent law recognized 'national exhaustion' and therefore the second or the third seller was 'duly authorized under Bangladeshi law to produce and sell the product'. To this extent, the 2005 amendments implement the principle of international exhaustion in its true spirit.

Another amendment in Section 107A(b), which bears noting is the addition of the word 'produce'. The earlier clause which exempted from infringement the '*...importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product...*' was amended in 2005 to '*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*'. (emphasis by authors). This addition of the word 'produce' appears redundant, since a parallel importer, in the normal course of events, is likely to purchase goods from a person who is authorized to sell or distribute the patentee's goods. It ought not to make a difference to such importer whether this person additionally had the right to produce those goods as well. Conversely, a mere right to produce without the right to sell would be

meaningless in the context of exhaustion. One can envisage a situation where a patentee outsources manufacturing of a patented product to a third party who is authorized only to manufacture the goods for the patentee, but not to sell or distribute the same to others. Therefore, unless such third party has authorization to also 'sell' or 'distribute' goods, she cannot sell to the parallel importer.

It is interesting to note that phrases such as 'parallel imports' and 'exhaustion' have not been used in the Patents Act or in the 'Statements of Objects and Reasons' accompanying the 2002 or 2005 amendments. However, from the various Parliamentary debates<sup>22</sup> preceding the passage of the Patents (Amendment) Act, 2005 as well as from official press releases in relation thereto<sup>23</sup>, it is clear that Section 107A(b) was aimed at permitting parallel imports and endorsing the principle of international exhaustion.

#### **Section 107A(b): Exploring the Ambiguities**

Section 107A(b), in its current form, exempts from infringement an *'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'*.

As stated earlier, this provision plugs a loophole in the earlier provision and implements the principle of international exhaustion in its true spirit. However, it also results in another, probably unintended consequence.

A literal reading of the section suggests that even the 'first sale' need not be authorized by the patentee. Such a reading virtually obliterates the exclusive right to import and runs the risk of contravening TRIPS.

Consider the earlier hypothetical involving Tarceva, an anticancer drug, which is under litigation before the Delhi High Court.<sup>2</sup> Here again, for the purposes of this paper, let us amend the fact situation slightly to assume that CIPLA is injuncted (at the final stage) by the Delhi High Court and cannot sell in India. Cipla now asks its Bangladeshi partner, Beximco Pharmaceuticals Ltd, to manufacture the drug in Bangladesh. It then imports the drug into India.<sup>24</sup> It bears noting that Bangladesh is a least developed country (LDC) and therefore has time till 2016 to implement product patents in pharmaceuticals. Therefore, any manufacture, use, distribution and sale of the drug within Bangladesh does not amount to a patent infringement in Bangladesh.<sup>25</sup>

Under the old regime (prior to 2005), which required any import to be 'duly authorized by the patentee', CIPLA could not legally import Tarceva into India if the seller (in Bangladesh) was not authorized by Roche to sell or distribute Tarceva in Bangladesh. Under the new provision however, one could argue that CIPLA can import Tarceva even without the permission of Roche. It has to only comply with the condition that the exporter of such patented product (eg. Beximco) be 'duly authorized under the law to produce and sell or distribute the product'. 'Duly authorized under the law' is very different from 'duly authorized by the patentee'.

Notwithstanding an alleged difference between the two terms, the ambit of the term 'duly authorized under the law' is uncertain. Could this mean that a simple authorization from the Bangladeshi drug controller would qualify Beximco as 'duly authorized' under Bangladeshi law? In this case, would not such imports hit out at the very essence of the exclusive right to import under Section 48? Particularly since the goods are produced by Beximco and not Roche and there has been no 'exhaustion' of Roche's patent right. It bears noting that in our hypothetical, since the first sale in Bangladesh was not authorized by Roche, the possibility of any sort of 'exhaustion' of Roche's rights in Bangladesh does not arise.

But prior to investigating the impact of Section 48 on the above issue, let us resolve a preliminary issue: what is the 'law' that is referred to in section 107A(b)?

#### **Which Law is to Apply?**

Section 107A(b) stresses in pertinent part that any importation of a patented product *'from a person who is duly authorized under the law to produce and sell or distribute the product'* is legal (emphasis by authors).

Does 'law' in the above clause mean the law of the exporting country (Bangladeshi law) or the law of the importing country (Indian law)?

#### **Law of the Importing Country (Indian law)**

If 'law' is read to mean Indian law, one is faced with a logical inconsistency. A parallel import involves an 'exporting' country (e.g. Bangladesh) and an 'importing' country (e.g. India). The 'producer' of the good or the seller/distributor as referenced in Section 107A(b) (e.g. Beximco) is more likely to be based in Bangladesh and the importer (e.g. Cipla) is

more likely to be based in India. Subjecting the legality of 'production' or 'sale' in Bangladesh to 'Indian' law is therefore absurd, particularly when there is no patent in Bangladesh. In other words, were one to interpret 'law' as Indian law, the ridiculous question that one is faced with is this: Under Indian law, can Beximco produce and distribute the drug in Bangladesh? This could not have been the intention of Parliament when it amended the law in 2005 to widen the parallel imports provision.<sup>22,23</sup>

#### **Law of the Exporting Country (Bangladesh)**

The term 'law' therefore has to mean the law of the exporting country i.e. Bangladesh in our hypothetical. And this leads to a question raised earlier: Would a mere drug authorization to sell, distribute and export from the drug authority in Bangladesh suffice to constitute 'due authorization' in so far as Section 107A(b) is concerned? Such a literal interpretation makes the Indian parallel import provision one of the most liberal in the world and is likely to hit at the very essence of the exclusive right to import.

#### **Exclusive Right to Import under Section 48**

By permitting the import of goods manufactured in Bangladesh and other countries (where there are no patents and where the goods are not placed in the market by the patentee<sup>26</sup>), the very essence of a patent is eviscerated. In other words, a third party who cannot manufacture or sell a patented good in India has only to relocate to Bangladesh, manufacture the said good, and import it to India. In effect, this comes very close to rendering the patent grant redundant.

One may contend that the above argument misses an important distinction that the Indian patent regime draws between the exclusive rights to manufacture, sell and distribute versus the exclusive right to import.<sup>27</sup> Section 107A(b) is a defence only in so far as the exclusive right to 'import' is concerned. In other words, the other exclusive rights guaranteed under Section 48, such as the right to sell and distribute are not covered by the Section 107A(b) exemption. If therefore, after importing, the good is distributed or sold in India, this could be prevented by the patentee. Such an interpretation gains credence when one compares the Patents Act with the Trademarks Act, which endorses the right to 'sell' by the parallel importer, once the rights have been exhausted internationally.<sup>28</sup>

However, it is unlikely that a judge would favour such a strict literal reading of the section. Particularly

when the absence of the word 'sale' appears more an oversight than a deliberate attempt to curtail of the scope of the international exhaustion principle envisaged under Section 107A(b). Therefore, a court is likely to interpret the provision purposively to build in such a right to further resell as well, once the patented product has been imported.<sup>8</sup> Consequently, the exclusive rights guaranteed to a patentee under Section 48 are drastically impacted.

Even assuming that a judge adopts a strict literal interpretation and does not include the right to sell, the exclusive right to import is likely to be significantly impacted. Consider our hypothetical concerning Tarceva; under a strict construction of Section 107A(b), Cipla can only import the drug into India, but cannot sell it to the patients or to medical stores thereafter. Of course, Cipla could circumvent this prohibition on sales and distribution by asking patients or stores to order directly from its Bangladeshi suppliers, in which case, the 'import' from Bangladesh would be directly by the patient or the store.

Although this is a possibility, it is clear that Cipla cannot use this strategy to make as much money as it would have, had it been given a free hand to sell and distribute the drug as well. Therefore, a literal reading of Section 107A(b) to permit Bangladeshi imports may not obliterate the rights of a patentee fully, who can still block subsequent sales and distribution of imported goods. However, it eviscerates the right to 'import' significantly. And to this extent, any such literal reading of Section 107A(b) is likely to render the exclusive right to import under Section 48 almost redundant.

Apart from the above, a reading of Section 107A(b) that permits imports from Bangladesh, when the first sale has not been authorized by the patentee, has serious TRIPS implications, as discussed below:

#### ***TRIPS Compliance?***

TRIPS provides considerable flexibility to member states to determine the scope and extent of 'exhaustion'.

Article 28 of TRIPS mandates that every patentee shall have the exclusive right to make, use, offer for sale, sell, or import the patented product or process in question.

However, footnote (6) to Article 28 adds a small caveat to the exclusive right to import, by clarifying that "*This right [i.e. the right of importation], like all other rights conferred under this Agreement in*

*respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.”*

Article 6 in turn states that *‘nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.’*

The meaning of Article 6 is made clear by Article 5(d) of the Doha Declaration which states that *“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 ...”*

It is therefore, clear that TRIPS permits Member States to limit the exclusive right to import guaranteed by Article 28 to the extent that such limitation relates in some way to the concept of ‘exhaustion’.

It is important to note that in our hypothetical example of CIPLA producing generic versions of Tarceva in Bangladesh and exporting to India, there is no first sale by the patentee (Roche) and consequently, no ‘exhaustion’ of Roche’s rights. This lack of ‘exhaustion’ means that Article 6 (which only confers flexibilities around determining the scope and extent of ‘exhaustion’) cannot apply in the case of the Indian provision.

And since Article 6 does not apply, it is likely that Section 107A(b) will be held to violate the exclusive right to import under Article 28. Further, such a provision virtually eviscerates the right to import. Therefore it might be very difficult to argue that it is a ‘limited exception’ to a patent right falling within the scope of Article 30 of the TRIPS Agreement, which provides that *‘Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.’*

In *Canada—Patent Protection of Pharmaceutical Products*,<sup>29</sup> the only panel decision to have interpreted Article 30 so far, the panel, while interpreting the term ‘limited’ used in Article 30, relied on its close proximity with the word ‘exception’ and noted that: *When a treaty uses the term ‘limited exception’, the word ‘limited’ must be given a meaning separate from the limitation implicit in the word ‘exception’ itself. The term ‘limited exception’ must therefore be read to connote a narrow exception - one which makes only a small diminution of the rights in question.*<sup>30</sup>

As to whether an Indian judge is likely to review and interpret Section 107A (b) in accordance with TRIPS is a moot issue. In the Novartis case,<sup>31</sup> the judge refused to entertain a TRIPS challenge to Section 3(d) of the Patents Act on the ground that it had no jurisdiction. It held that the Swiss government (home government of Novartis) ought to agitate this before the Dispute Settlement Body of the WTO.

In coming to this conclusion, it referred to a British case, *Salomon v Commissioner of Customs*,<sup>32</sup> where Lord Diplock had held that: *‘if the terms of legislation is not clear, and is reasonably capable of more than one meaning,’ the terms of international treaties to which the government is signatory, become relevant.... There is a prima facie presumption that Parliament does not intend to act in breach of international law, including therein specific treaty obligations; and if one of the meanings which can reasonably be ascribed to the legislation is consonant with the treaty obligation and another or others are not, the meaning which is consonant is to be preferred.’* In the context of Section 107A(b) therefore, where the terms of the statute are not clear, it is likely that the courts will interpret the section in a manner consistent with TRIPS.

### **Harmoniously Interpreting Section 107A(b)**

From the above, it is clear that a plain literal reading of Section 107A(b) detrimentally impacts a patentees’ exclusive rights under Section 48 and also runs the risk of violating TRIPS. Alternative interpretations (such as construing ‘law’ to mean Indian law) might help preserve the exclusive rights of a patentee, as they do not permit imports from anyone apart from the patentee or his authorized agent. However, as we have demonstrated, such an interpretation is beset with logical inconsistencies and results in an undue curbing of the scope of the principle of exhaustion.

How then ought a judge to interpret 107A(b), so as to balance out competing interests of the patentee on the one hand, and the desire to make cheaper goods available to the consumer on the other? We argue that one of the ways in which to harmoniously construe Section 107A(b) is to interpret ‘patented product’ to mean ‘product patented in the exporting country’ and not ‘in India’.

To recapitulate Section 107A(b), it exempts from infringement an *‘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.* If 'patented products' are read to mean products patented in the exporting country (Bangladesh), then the section automatically excludes any 'non patented' imports from Bangladesh. In other words, Cipla cannot avail of the provision to import generic versions of Tarceva manufactured by Beximco. Any such import by Cipla would be violative of the exclusive right to import guaranteed to Roche.

This interpretation complies with TRIPS and fits well within the overall framework of the section. If the term 'law' is taken to mean the law of the exporting country (e.g. Bangladesh), then the term 'patented product' appearing in close conjunction with 'law' has to necessarily mean a product patented in such exporting country.<sup>33</sup>

Also, this interpretation furthers Parliamentary intent i.e. to permit international exhaustion and the buying of low priced patented goods, once the patentee has already sold them anywhere else in the world.<sup>22</sup> Therefore, imports from jurisdictions where there are no patents and the patentee has not yet sold his/her goods there ought not be permitted. However, under the interpretation we offer, any goods sold by the patentee in a jurisdiction where there is no 'patent' in force, cannot be imported, despite there being a 'first sale' by the patentee.<sup>34</sup>

One may cast some doubt on the above interpretation by pointing to the definition of 'patented article' in Section 2. This section defines the term to mean an 'article patented in India'. Therefore, one may argue that the term 'patented product' in Section 107A(b) has to mean a product patented in India. Such an argument however ignores a well established canon of statutory interpretation that *'where the context makes the definition given in the interpretation clause inapplicable, a defined word when used in the body of the statute may have to be given a meaning different from that contained in the interpretation clause; all definitions given in the interpretation clause are therefore enacted subject to the qualification - 'unless the context otherwise requires.'*<sup>35</sup> In fact, section 2 of the Patents Act, which is the definitional Section, also begins with such a qualification.

Based on all of the above, it is argued that in the light of TRIPS compliance issues, as also to preserve the exclusive right to import under Section 48, a judge is likely to interpret the term 'patented products' in

Section 107A(b) to mean products patented in the 'exporting country'.

#### **Expanding the Scope of Exhaustion: Method/Process Patents**

The United States Supreme Court recently dealt with principles of national exhaustion in *Quanta v LGE*.<sup>5</sup> This case involved a licensing arrangement between LGE, the patentee, and Intel in relation to chipsets. The key issue was whether or not LGE's patent rights had been 'exhausted' after the sale by Intel (the licensee) to Quanta (one of Intel's customers), leaving Quanta free to do what it wished with the chipsets. Intel was required under one of the contracts with LGE to give notice to customers that they could not combine the chipsets with devices by other manufacturers. For the purpose of this paper, the discussion is limited to the 'patent' issue (as to whether or not there was exhaustion) and excludes the contractual issue (as to whether or not there had been a breach of contract).

The Supreme Court held in favour of Quanta's right to deal with the product as it wished i.e. Quanta could combine Intel chipset with other products. Specifically, it disagreed with LGE that 'exhaustion' applied only to product patents. It categorically held that it applied to process patents or method patents as well.

It is interesting to note here that the Indian provision does not speak about 'process patents' or method patents at all. This is a glaring gap and merits immediate rectification by an amendment.

#### **Conditional Sales**

The *Quanta* decision is notable for another reason: it leaves open the question of whether or not a 'conditional sale' precludes exhaustion. In other words, if the patentee or her licensee imposes a condition on the sale, such as the fact that the product can be used only once,<sup>36</sup> can it be said that the rights in the patented good are still 'exhausted' and a buyer is free to ignore the condition? There is a distinction between a suit for patent infringement and a suit for breach of contract.<sup>37</sup> US case law is almost unanimous in accepting that there could be a breach of contract claim in such cases. However, the Court in *Quanta* did not explicitly decide as to whether the breach of such a condition would constitute a patent infringement as well.

The Court simply stated that in this particular case, the sale was an 'unconditional' one. Therefore under US law, it may well be possible to introduce 'conditions' to accompany sales and thereby erode the



principle of 'exhaustion'.<sup>38</sup> Indian law ought to prevent against such a possibility by expressly indicating that exhaustion will prevail, notwithstanding any condition attached to the sale.

#### **Repair v Reconstruction**

The courts of many countries draw a distinction between 'repair' and 'reconstitution/reconstruction' when determining the applicability of the doctrine of exhaustion. Specifically, most countries' laws provide that the doctrine of exhaustion permits the buyer of patented goods to repair them, but not to reconstitute/reconstruct them.<sup>39</sup> The rationale for this distinction seems to be that while a repair may be necessary even for a single 'use' of the article in the manner intended by the patentee, a reconstitution would potentially permit more than a single use even though the patentee would have obtained remuneration only for a single item and not for use of this single item multiple times.<sup>40</sup> It is proposed that Indian law also strike this distinction between reconstitution and repair, and permit repairs.

#### **Proposed Amendment to Section 107A(b)**

The authors proposed to amend Section 107A(b) to remove the ambiguities discussed above. And in particular to prevent the possibility of a judge construing section 107A(b) so as to permit imports from an exporting country (Bangladesh), when there is no patent in such exporting country. The amendments also seek to fill the following gaps:

Section 107A(b) does not recognize 'national exhaustion'

Section 107A(b) does not recognize 'process' patents or 'method' patents

Section 107A(b) does not preclude the possibility of introducing 'conditional sales' to thwart the scope of 'exhaustion' and consequent resale/redistribution.

Therefore the following amendment are proposed:

*"107B. Parallel Importation and Exhaustion of Rights. (a) For the purposes of this Act, the rights of a patentee or anyone claiming through such patentee shall stand exhausted after an article covered by a patent has been sold once anywhere in the world (including within India), by or with the authorization of such patentee.*

*(b) The provisions of section 107B(a) shall apply in case of sale of any patented article, notwithstanding:*

- (i) any contractual stipulation to the contrary by the patentee or her authorized representatives.*
- (ii) The specific form of the transaction between the patentee or her authorized representative and the buyer.<sup>41</sup> In particular, any attempt to classify what is in essence a 'sale' of an article as a license shall be ignored for the purpose of this section.*
- (iii) any notice in relation to the article placed by the patentee or her authorised representatives or any other party selling the patented article; unless such notice is absolutely essential to ensure public health or safety."<sup>42</sup>*

*Explanation 1: (a) The term 'exhaustion' (and its cognates), in relation to a 'patented article' means that the exclusive rights of the patentee and any/all her authorized representatives (under Section 48) vis-à-vis such article stand terminated after the first sale of such article any where in the world, provided such first sale is made by or with the authorization of the patentee.*

*(b) Exhaustion shall also occur when there is a sale of a component that 'substantially embodies' or 'essentially embodies' any patent/s granted under this Act, provided the manufacture and first sale of such component was made by or with the authorization of the patentee.*

*Provided that the 'exhausted' rights envisaged under this section shall include the right to repair but not the right to reconstitute the product.*

*Explanation 2: The terms 'article covered by a patent' and/or 'patented article' as used in this section, include, without limitation, articles covered by product patents or articles resulting from the practice of process or method patents, all such patents being patents granted under this Act.*

*Explanation 3: In this section, the term 'authorized representatives' shall include, without limitation, licensees, assignees, subsidiaries, business partners, agents or any other person selling the patented product with the consent of the patentee, whether express or implied.*

*Explanation 4: The determination of every term as used in this section shall be solely in accordance with Indian law, including the issue of whether or not there has been a first sale.<sup>43</sup> In particular, the term 'sale' shall be interpreted in accordance with the Sale of Goods Act.*

## Acknowledgement

The authors would like to thank numerous readers of the Spicy IP Blog for providing their comments to our posts dealing with parallel imports. These comments greatly enriched our understanding and appreciation for the various interpretative nuances relating to Section 107A(b) <http://spicyipindia.blogspot.com/2008/05/parallel-import-debate-in-india-some.html>. The authors would also like to thank Karan Bharihoke (J Sagar Associates), Swathi Sukumar (Anand and Anand) and Sneha Jain (ILS.Pune) for their inputs and comments.

## References

- 1 The Patents (Amendment) Act, 2005, published as law in the Gazette of India on 5 April 2005, Prior to these amendments, the Patents Act, 1970 (Act No. 39. Of 1970) was also amended by the Patents (Amendments) Act, 1999 and the Patents (Amendment) Act, 2002 in order to comply with TRIPS mandates.
- 2 *F Hoffmann-La Roche Ltd. and Anr v Cipla Limited* 48 (2008) DLT 598, MIPR 2008 (2) 35 (*Roche v Cipla*). For an extensive analysis of this decision, Basheer Shamnad and Reddy Prashant, *Roche v Cipla: The 'Price' of a Patent Injunction in India*' (draft on file with authors).
- 3 Article 27.1 of TRIPS, which represents the common minimal standard that WTO members are mandated to implement in their domestic patent regimes, provides that 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.'
- 4 Article 28(1) of the TRIPS Agreement which states in pertinent part that 'a patent owner shall have the exclusive right to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product'
- 5 *Quanta Computer Inc v LG Electronics Inc* (No. 06-937) 453 F. 3d 1364, reversed (Supreme Court, 9 June 2008).
- 6 This principle is also commonly referred as the 'first sale doctrine', a doctrine which '...stands for the proposition that, absent unusual circumstances, courts infer that a patent owner has given up the right to exclude concerning a patented article that the owner sells.' *Glass Equipment Development Inc v Besten Inc* 174 F.3d 1337 as quoted in Words and Phrases (Permanent Edition Vol. 17), 'First Sale'.
- 7 The 'use' of a patented product that had been legitimately purchased from a patentee or her authorized representative may be exempt from patent infringement under an implied license theory, *Anton/Bauer Inc v PAG Ltd* No. 3:01 CV 577 (CFD), 2002 US Dist. LEXIS 11583, (D. Conn. 12 June 2002). In view of express statutory provisions to the contrary, one may not be able to import implied license theories into India. See discussion and text to Ref 21 and 22.
- 8 The exhaustion doctrine, thus, serves to allow the patentee to extract full consideration for a patented article, but no more, Paul J C *et al*, US patent exhaustion: Yesterday, today, and maybe tomorrow, *Journal of Intellectual Property Law & Practice*, 3(7) (2008) 461-469.
- 9 *US v Moore* 604 F. 2d 1228 as quoted in Words and Phrases 'First Sale' (n. 6).
- 10 In fact, the rules in relation to copyrighted works are likely to differ, depending upon the kind of work in question. Thus, in relation to a computer program, one would be prevented from further resale of such program if the 'single use' license under which it has been bought, has been utilized by the first buyer. If the single use license is not 'exhausted,' resale would be permissible.
- 11 International Patent Exhaustion and the Global Semiconductor Industry (<http://semiconductorlawblog.com/blog/?p=18>). In the context of Japan, see *BBS AG v Racimex*, Case No. Heisei, 7(o)1988, Collected Civil Cases vol. 51, Section 6, p. 2299 (1 July 1997) (Supreme Court of Japan, Third Petty Bench).
- 12 For the Brazilian position, AIPPI Report: International Exhaustion of Intellectual Property Rights (Brazil) available at <http://www.aippi.org/reports/q156/gr-q156-Brazil-e.htm>. For the Chinese position, see Xiang Yu, The Regime of Exhaustion and Parallel Imports in China: A Study Based on the Newly Amended Chinese Laws and Related Cases, *European Intellectual Property Review*, 26(3) (2004) 105-112.
- 13 TERRELL (Ref 5) at 228 who notes that 'The Doctrine of exhaustion of rights developed under EC law serves to restrict the right of a patentee to bring proceedings for infringement in this country where the patentee has already consented to the marketing of the goods in question in another member State. The principle of free movement of goods must then prevail.'
- 14 Act No. 47 of Year 1999 dated 30th December 1999. The Trademarks Act, 1999 came into force in September 2003.
- 15 CS(OS) No. 2285/2006; Unreported Order dated 20.02.2007.
- 16 To this extent, the defendants relied on the *Notes on Clauses* under the Trademarks Bill, 1999 (Bill No. XXXIII of 1999) which, in relation to Sections 30(3) and 30(4), states: 'Sub-clauses (3) and (4) recognize the principle of 'exhaustion of rights' by preventing trademark owner from prohibiting on ground of trademark rights, the marketing of goods in any geographical area, once the goods under the registered trademark are lawfully acquired by a person. However, when the conditions of goods are changed or impaired after they have been put on the market, provision will not apply.'
- 17 The latter part of the order appears to be based on a straightforward application of Section 30(4), which provides that 'Sub-section (3) shall not apply where there exists legitimate reasons for the proprietor to oppose further dealings in the goods in particular, where the condition of the goods, has been changed or impaired after they have been put on the market.'
- 18 Section 48 of the Indian Patents Act grants exclusive rights to a patentee, including the right to 'use' the patented product. One might argue that such a buyer could 'use' the patented product under an implied license theory. However, a strictly technical reading of the Act would dictate a different result. Section 68 of Indian law categorically states that no license or assignment or creation of any other interest in a patent is valid unless it is set out in writing and duly executed.
- 19 In *State Bank of Travancore v Mohammad*, AIR 1981 SC 1744, the words 'any debt due before the commencement of

- this Act to any banking company*, was interpreted to mean *'any debt due at and before the commencement of this Act'*. Chandrachud J., delivering the judgment of the court opined that: 'The plain language of the clause, if interpreted so plainly, will frustrate rather than further the object of the Act. Relief to agricultural debtors, who have suffered the oppression of private moneylenders, has to be the guiding star which must illumine and inform the interpretation of the beneficent provisions of the Act.... We would have normally hesitated to fashion the clause by so restructuring it but we see no escape from that course, since that is the only rational manner by which we can give meaning and content to it, so as to further the object of the Act. (para. 19)'.
- 20 The South Asian Association for Regional Cooperation (SAARC), is an association of countries seven countries (Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka) and aims to accelerate the process of economic and social development in Member States.' See <<http://www.saarc-sec.org/main.php>>. The Commonwealth is an association of 53 sovereign nations, most of whom were former British colonies, that support each other and work together towards international goals. Countries such as India, Sri Lanka, Australia and New Zealand are members of the commonwealth, <http://www.thecommonwealth.org>.
- 21 This amendment was first introduced under the Patents (Amendment) Ordinance, 2004 promulgated by the President in order to meet the deadline of January 1, 2005 required by the TRIPs Agreement to introduce product patents. Section 107A(b) of the Ordinance provided that there would be no infringement if there has been an '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'. This language was retained in the Patents (Amendment) Bill, 2005, which eventually became the Patents (Amendment) Act, 2005.
- 22 Debates in the Rajya Sabha (upper house of Indian Parliament) ([http://rajyasabha.nic.in/rsdebate/deb\\_ndx/204/23032005/3to4.htm](http://rajyasabha.nic.in/rsdebate/deb_ndx/204/23032005/3to4.htm)) where Shri Jairam Ramesh, the Minister of State for Commerce and Industry, states that '... the relevant sections are Section 47, Sections 82-84 and Section 107 (a) and (b) which deals with parallel imports. .... The short point that I want to make is that, on the issue of prices, on the issue of availability of patented medicine, on the issue of ability of the Government to retain right of ensuring that the patent is translated into a product, there are enough safeguards in the existing legislation both in the 1970 legislation, but more importantly in the revised Patents Act of 1970 reflecting new provisions for compulsory licensing, reflecting new provisions for parallel import particularly; and also reflecting new provisions for enabling the Government to import; and use and distribute for its own use either through itself or through the third party.'
- 23 A press release from the Press Information Bureau (the nodal agency of the Government of India tasked with disseminating information on government policies, programme initiatives and achievements.) (<http://pib.nic.in/release/release.asp?relid=8096>), which notes in connection with the amendment to Section 107A (b) that '...this has been amended to say that the foreign exporter need only be 'duly authorised under the law', thus making parallel imports easier. A parallel import is a mechanism that helps in price control.' See also Official website of the Ministry for Commerce and Industry, which carries a short note on this aspect: [http://commerce.nic.in/pressrelease/pressrelease\\_detail.asp?id=1633](http://commerce.nic.in/pressrelease/pressrelease_detail.asp?id=1633).
- 24 Bangladesh recently amended its patent regime to remove pharmaceutical patents altogether. A news report in the Daily Star (<http://www.thedailystar.net/story.php?nid=27621>) stated that 'A circular issued by the Department of Patent, Design and Trademarks in January said as per the TRIPS agreement all applications for patents of medicines and agricultural chemicals will be kept suspended until January 01, 2016. It said the previous applications as well as fresh applications relating to patents for medicines and agricultural chemicals will be preserved in a 'mail box' and will be considered after the expiry of the deadline.'
- 25 It must be noted that Bangladesh has yet to reach a similar technological capability as India, in so far as the manufacture of drugs is concerned. Although their current strength is limited to the manufacture of formulations, it is only a matter of time before they gain proficiency in Active Pharmaceutical Ingredients (API's) as well. By setting up base in Bangladesh, Indian companies could help Bangladeshi industry acquire the skills necessary for making API's, Gehl Sampath P. Intellectual property rights and innovation in a least developed country context: The case of Bangladesh (May 2007), for the least developed country report 2007 of the UNCTAD.
- 26 It is relevant to note here that it is possible that a patentee (i.e. a person who has a patent in India) may voluntarily choose to sell in a market where she doesn't have a patent. In this situation, notwithstanding the absence of a patent in this market, the patentee's rights over the goods are, arguably, exhausted. Imports from such markets must therefore be permissible under Indian law. AIPPI report on the UK position in this regard: '...patent rights are exhausted if a patented product is put on the market by or with the consent of the patentee anywhere within the EEA. This applies even when the patentee does not have an equivalent patent in the country of first marketing, when there is no patent protection available there or where the local legislation fixes an artificially low sales price for the products there.' See 'International Exhaustion of Industrial Property Rights.' International Exhaustion of Industrial Property Rights: United Kingdom (AIPPI Congress in Melbourne 2001), <http://www.aippi.org/reports/q156/gr-q156-United%20Kingdom-e.htm> (Hereinafter, AIPPI Reports: United Kingdom).
- 27 As noted earlier, under section 48 of the Indian Patents Act, a patentee has the exclusive right to make, use, distribute and sell the patented good.
- 28 Ref 20, for a discussion on this, *H C Suman and another v Rehabilitation Ministry Employees Co-operative House Building Society Ltd, New Delhi and others AIR 1991 SC 2160* and *Hameedia Hardware Stores v B. Mohan Lal Sowcar AIR 1988 SC 1060* where the Supreme Court discussed various situations in which words can be added to a Statute for a meaningful interpretation.
- 29 *Report of the Panel WT/DS114/R* (17 March 2000).
- 30 *Report of the Panel WT/DS114/R* (17 March 2000), para 7.29.
- 31 *Novartis AG v Union of India* (2007)4 MLJ 1153 (Madras HC) (MANU/TN/1263/2007).

- 32 1966-3-All E. R. 871.
- 33 This follows a statutory rule of construction that goes by the Latin name of *noscitur a sociis*, which, as explained by Lord Macmillan means: ‘*The meaning of a word is to be judged by the company it keeps.*’ As quoted in Justice G P Singh, *Principles of Statutory Interpretation*, 9th edn, 2004, 415.
- 34 Compare this with the position in the UK which, in the context of the EU rules on ‘regional exhaustion’ permit imports even where there is no ‘patent’ in force in the country of first sale, AIPPI Reports: United Kingdom.
- 35 Singh G P, *Halsbury’s Laws of England* (Butterworths, London), 4<sup>th</sup> edn, vol 35, 1994, reprinted 2000, p.174; *State of Maharashtra v Indian Medical Association* AIR 2002 SC 302, 307.
- 36 *Mallinckrodt Inc v Medipart Inc*, 976 F.2d 700 (Fed. Cir. 1992). It appears therefore that under older decisions of the courts in UK, the rule of international exhaustion applied only if there was no express condition to the contrary; Singh G P, *Halsbury’s Laws of England* (Butterworths, London), 4<sup>th</sup> edn, vol 35, 1994, reprinted 2000, p.250, 412.
- 37 This distinction is an important one as has been observed by a scholar; Mark R Patterson, Reestablishing the Doctrine of Patent Exhaustion, Patently-O 19 November 2007, <http://www.patentlyo.com/patent/2007/11/reestablishing.html>; who suggests that while the ‘patentee could still impose limitations on buyers’ uses of the products,... those limitations would be solely matters of contract. They could not be enforced through patent infringement actions, and they would be subject to antitrust law limitations.’
- 38 Singh G P, *Halsbury’s Laws of England* (Butterworths, London), 4<sup>th</sup> edn, vol 35, 1994, reprinted 2000, where it is stated that: ‘...if at the time of sale, the purchaser has notice of some restriction, imposed by the proprietor or those representing him, that restriction will bind the purchaser, although the Court will not presume that purchaser knew of the restriction merely because notice of it was marked on the article, if marking was not such as to be apparent under ordinary conditions to a customer at the time of sale.’
- 39 *Dunlop Pneumatic Tyre Co Ltd v Neal*, 1899(1) Ch. D. 807 where it was held that ‘the purchaser of a patented article can carry out repairs to it; however, he cannot manufacture a new article and claim that he had not infringed the patent because in the manufacture he had used an article derived from a patented article sold by its patentee’. The principles in *Dunlop* were endorsed by the House of Lords in *British Leyland Motor Corporation and Others v. Armstrong Patents* [1986] UKHL 7 (27 February 1986).
- 40 *Aro Manufacturing Co v Convertible Top Replacement Co*, 365 U.S. 336, 346 (1961) where the US Supreme Court held that ‘although there is no right to ‘rebuild’ a patented combination, the entity ‘exists’ notwithstanding the fact that destruction or impairment of one of its elements renders it inoperable; and that, accordingly, replacement of that worn-out essential part is permissible restoration of the machine to the original use for which it was bought.’
- 41 The form of a transaction does not determine whether exhaustion applies, so the doctrine may apply even though a transaction is not characterized as a conventional sale. See *United States v Masonite Corporation*, 316 US 265, 278 (1942); J C Paul *et al*, US patent exhaustion: Yesterday, today, and maybe tomorrow, *Journal of Intellectual Property Law & Practice*, 3(7) (2008) 461-469.
- 42 This is to cater to concerns that arise out of a *Mallinckrodt Inc v Medipart* kind of situation.
- 43 This is to ensure that any ‘conflict of law’ issues are resolved relatively quickly and easily.