# **Notes**

# SECTION 107A(B) OF THE PATENTS ACT: WHY IT MAY NOT REFER TO OR ENDORSE DOCTRINE OF INTERNATIONAL EXHAUSTION?

J. Sai Deepak\*

### ABSTRACT

The specific and limited objective of this article is to interpret Section 107A(b) of the Patents Act, 1970 in order to evaluate the validity of the popular assumption that the provision embodies the doctrine of international exhaustion. The corollarial popular assumption is also that "parallel import" invariably connotes "international exhaustion". The Author has primarily relied upon principles of statutory interpretation to question these popular assumptions, and has placed adjunctive reliance on legislative debates and other *travaux* preparatoires to corroborate his line of enquiry and his conclusions. The underlying broad objective of this exercise is to dissuade a populist approach to the law of patents, and to advocate the use of principles of statutory interpretation as primary guiding lights to understand the Statute, as opposed to preconceived notions based on word-of-mouth. The Author categorically states that the opinions presented in the article reflect his personal academic opinions, and are not representative of the opinion of any professional organization of which he was or is or may be a part.

### Introduction

Ever since the Patents Act, 1970 (hereinafter referred to as "the Act") was amended in the year 2005¹ after two sets of amendments in the years 1999 and 2002, one of the most highlighted and discussed amendments to the Act is the one effected to Section 107A(b) of the Act. Section 107A is part of Chapter XVIII of the Act which is titled "Suits Concerning Infringement of Patents"; Section 107A is preceded by Section 107 which spells out the grounds of defence available to a defendant in a suit for infringement², and is followed by Section 108 which enumerates the reliefs available to a patentee in a suit for infringement.

However, that Section 107A does not strictly constitute a "defence" too becomes apparent; what this means is that although Section 107A may be invoked by a defendant to "defend" himself against an allegation of infringement, it essentially identifies a "patent null" realm which places it at a higher pedestal

<sup>\*</sup> Advocate, High Court of Delhi

<sup>1</sup> The Patents (Amendment) Act, 2005

<sup>2</sup> The grounds of defence available under Section 107 are strictly circumscribed by the grounds of revocation available under Section 64 of the Act.

than the defences available under Section 107. In other words, the patent-free niche protected by Section 107A preserves an ostensibly "larger" interest, namely "public interest". This is evident from, besides the title of the provision which is "Certain Acts Not to be Considered as Infringement", the nature of non-infringing acts identified in the provision such as (i) use of a patented invention for development and submission of information to regulatory Authorities (Section 107A(a)), and (ii) conditional import of patented products (Section 107A(b)).

The latter act i.e. conditional import of patented products, forms the very subject-matter of rumination of the instant article. The popular assumption is that Section 107A(b) refers to the doctrine of international exhaustion. What is also assumed is that "parallel imports" must necessarily translate to or be synonymous with international exhaustion. In the following parts of this article, the Author attempts to question these assumptions since a clear unbiased reading of the provision does not give a practitioner of the subject or a student of law the impression that it has anything to do with international exhaustion, although it may have something to do with conditional parallel imports. This line of enquiry has been elaborated in detail in the following portions.

# Territoriality of Patent Rights and Exhaustion

All forms of Intellectual Property Rights such as Patents, Copyright, Trademarks and Industrial Designs are territorial in nature, which means they are vested by, and exercised and enforced under national legislations. This, despite the fact that the national legislations which govern the grant of such IP rights have been subjected to global harmonization pursuant to Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO). The concept of territoriality applies with greater vigour to the law of patents since under TRIPS, despite promulgation of certain minimum standards and obligations, every member nation has been permitted "national flexibilities" to set its own standards of patentability, and create certain exceptions/limitations to the rights of patentees. Further, the fundamental jurisprudence of patents envisages situations where patents over the same invention may be held by two completely unrelated entities in two different jurisdictions. Also, it is possible under the law of patents that the same invention is granted a patent in one jurisdiction, and denied in another, based on the standards followed in each jurisdiction. Each of these situations is firmly rooted and grounded in the territorial nature of patent jurisprudence. This territorial nature also has a bearing on the doctrine of "exhaustion".

"Exhaustion" essentially relates to the limits on the scope of rights of a right holder, which concept is applied to all major forms of IPR such as patents,

copyrights, trademarks and industrial designs. Exhaustion refers to that point where the rights of the IP right holder end, and the realm of commons begins. The concept is based on the premise that upon the first sale of the product which embodies the right of the right holder, and upon the product being put in circulation, the ability of the right holder to dictate further movement of the product ends since he has already reaped the benefits of his right through the act of first sale. Depending on the territorial extent to which the concept of exhaustion applies, it is further classified into 3 categories/doctrines, namely (1) National Exhaustion, (2) Regional Exhaustion and (3) International Exhaustion.

**National Exhaustion**- National Exhaustion refers to a situation where the law of a country recognizes, that upon the first sale of the product which is protected by an IP right, the right holder loses the right to control its movement only within the territory of the country. However, the law still guarantees his right to prevent unconsented import of his own genuine goods from a foreign territory, by a third party. This is to ensure that his own goods which have been put in circulation by him/his agents with his consent in a foreign territory do not disrupt the movement of his goods in other jurisdictions. For instance, an Indian entity may own patents over the same invention in India and China. The doctrine of national exhaustion does not let the Indian entity control the movement in India of the goods protected by the Indian patent after the act of first sale in India. However, the Indian entity still retains the right to prevent unconsented import (by third parties) into India of its own goods protected by its own Chinese patent. This is to ensure that there is no cross-contamination of markets since the Indian entity is entitled to reap the benefits of its Indian and Chinese patents from the respective markets. It is critical to bear in mind that in the absence of a legislative intent to the contrary, national exhaustion is the default or standard rule which applies. This is because a departure from the doctrine of national exhaustion is also a limited yet critical departure from the default rule of territoriality, and therefore requires express legislative intent which is manifest in the wording of the statute. A departure from the doctrine of national exhaustion has the effect of recognizing as valid, acts of sale committed outside the territory of a country. Therefore, according to well-settled principles of legislative drafting, recognition of extra-territorial acts in the context of a strictly territorial right per force carries with it the indispensable necessity of clear and express statutory language.

**Regional Exhaustion-** Regional Exhaustion is clearly a broader variant wherein the law under a regional or bilateral treaty such as the EU recognizes regional exhaustion. This means that once the goods are put in the stream of

commerce after the act of first sale, the right owner cannot control its movements in the entire region i.e. in the States which form members of the regional treaty/arrangement. As stated earlier, for regional exhaustion to apply, there must be a clear expression/provision to that effect since it is a limitation on the rights of an IP right holder by recognizing acts committed in the region, but outside the territory of a member country.

International Exhaustion- International Exhaustion is the broadest variant wherein the law of a country takes the clear, express, unambiguous and unequivocal position that regardless of where the goods are sold, so long as they are not counterfeit, and have been "lawfully acquired/sold/purchased" from an agent or licensee or distributor of the right owner, the right owner cannot prevent its import into the country. This is the position India has taken with respect to trademarks as clearly and unequivocally reflected by Section 30 of the Trademarks Act, 1999. However, the this is not the position of Indian law with respect to patented products and products made from patented processes under the Patents Act, 1970. The ensuing portions of the Article will elaborate further on the arguments of the Author.

# **Dissecting Section 107A(b)**

The right of a patentee under the Patents Act, 1970 is spelt out under Section 48 of the Act, which is the exclusive right to prevent third parties, who do not have his consent, from the act of making, selling, using, offering for sale, selling or importing for those purposes the patented invention into India. It must be noted that the right granted is essentially a negative right i.e. an exclusive right to prevent third parties. This right is granted subject to other provisions of the Act, such as but not limited to Section 47 and Section 107A of the Act. The latter provision deals with certain acts which are not to be treated as infringement of patent rights, which forms the subject-matter of the Article.

Section 107A was originally introduced in the Patents (Amendment) Act, 1999. In the 1999 Act, the provision read as follows:

107A. Certain acts not to be considered as infringement: For the purposes of this Act,-

(a) any act of making, constructing, using or selling a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, us or sale of any product;

(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 a infringement of patent rights.

The provision was subsequently amended as follows by the Patents (Amendment) Act, 2005:

- 107A. Certain acts not to be considered as infringement: For the purposes of this Act,-
- (c) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product;
- (d) importation of patented products by any person from a person who is duly Authorized under the law to produce and sell or distribute the product, Shall not be considered as a infringement of patent rights.

The first principle of statutory interpretation is to give due attention and respect to the wording of the statute. This requires us to peruse with care Section 107A. In understanding the provision, what must be borne all through is that the reference to a "patent"/"patented" in the provision is to an Indian patent<sup>3</sup>. The first limb of the provision relates *to any act which is done in India* with respect to a "patented invention" with the intent of developing and submitting information to regulatory Authorities in India or outside India; such an act would not be considered as infringement. The reference to "patented invention" is broad enough to include a "patented product", a "patented process" and "product made from a patented process", the support for which may be drawn from the definition of "patented article" in Section 82 of the Act.<sup>4</sup>

The second limb of the provision, which refers to importation of patented products, does not use "patented invention". This difference is of no consequence since the definition of "patented article" may be used to understand "patented product" as well. Further, there is no apparent logic to support the other interpretation that the application of the second limb of the provision is restricted to product patents alone. Simply put, the second limb of the provision, which relates to importation, must necessarily apply to product patents, and

<sup>3</sup> Section 2(1)(m) defines "patent" as a patent for any invention granted under this Act

<sup>4</sup> In Section 82(a), "patented article" includes any article made by a patented process.

products which are produced from patented processes as well. This clarifies the scope of application of Section 107A(b).

The next step is to interpret the provision in entirety. The prevalent literature on the provision pays excess attention to the word "importation", instead of reading the provision as a whole to make complete sense of it. For the sake of convenience, Section 107A(b) is reproduced below:

(b) importation of patented products by any person from a person who is duly Authorized under the law to produce and sell or distribute the product, Shall not be considered as a infringement of patent rights.

The provision does not exempt any and all importation; it places certain restrictions. If re-stated, the first part of the provision categorically states that a patented product may be imported "by any person". In other words, there are no fetters on who may import the patented product into India. However, the concluding portion of the provision is where the catch lies, and which in the Author's opinion, holds the key to understanding the true import of the provision.

Although the patented product may be imported into India by any person, let's call him "X", X may not source the patented product "from any person". X may source the product *only from a person who is duly Authorized under the law to produce and sell or distribute the product*. The use of the language in this portion of the provision is unorthodox, and certainly does not lead to a straight-forward or simplistic conclusion of "international exhaustion". The person from who X imports the patented product into India, let's call him "Y", must:

- 1. Have been "duly Authorized under the law"; and
- 2. Have been "duly Authorized under the law" for the specific purpose of producing and selling or distributing the patented product.

Unless and until these twin conditions are satisfied by Y, X may not import the patented product from Y. The questions that need to be asked here are:

- 1. What does "duly Authorized under the law" mean?
- 2. Which law is referred to in "duly Authorized under the law"?
- 3. Why is there a specific reference to "produce and sell or distribute"? How is "produce and sell or distribute" to be interpreted?

The first two questions may be addressed together. The words "duly Authorized under the law" have not been used in connection with importation

of the patented product. Instead, they have been used in connection with "produce and sell or distribute". The words "duly Authorized under the law" carry with it a certain degree of formality, which effectively translate to express permission or "Authorization under the law" to produce and sell or distribute the patented product. It is critical to note here that "Authorized under the law" is not the same as "Authorized by law" or "permitted by the law". In other words, "duly Authorized under the law" cannot be an allusion to any "soft" or "implied" principle of exhaustion or tacit consent. The reference in "duly Authorized under the law" cannot be to a foreign law for reasons given below.

Established rules of legislative drafting require that if a reference is made to foreign law, the reference must be crystal clear and apparent from a plain literal reading of the provision. This is simply not the case with Section 107A(b). An unconstrained reading of Section 107A(b) tells us that "under the law" is an implicit reference to Indian law. Explained below are a few scenarios to advance this argument.

- A. If the reference were to be to foreign law, it would be possible for an importer to eviscerate and defeat the rights of an Indian patentee by importing the patented product from a foreign producer who has been Authorized by the law of his country to produce and sell the patented product. In others words, Y may be authorized by his country to produce and sell or distribute a product over which there exists a patent in India. This Authorization cannot be a sufficient basis for permitting import of the product into India since it would render nugatory the rights of the owner of the Indian patent;
- B. The second scenario is where a third party holds a foreign patent over the same invention as the Indian patentee, which is theoretically conceivable and practically possible in the law of patents. If the reference were to be to a foreign law, the foreign patent held by the third party could also be treated as falling within "duly Authorized under the law", thereby paving way for import of the patented product into India at the expense of the Indian patentee. An identical factual matrix was encountered in the case of *Strix Limited v. Maharaja Appliances* before the High Court of Delhi.<sup>5</sup> In that case, the defendant had invoked Section 107A(b) under the pretext that its products were protected by a Chinese patent held by a China-based party. In other words, according to the defendant in that case, since the production of the imported products

was "duly Authorized under the law" by way of a Chinese patent, importation of the products into India did not infringe the rights of the Indian patentee. The High Court in that case was not convinced by the Defendant's submission because the Defendant could not furnish the name of the Chinese supplier, and hence did not inspire confidence. However, it is unfortunate that the Court did not seize the opportunity to clarify whether the existence of a Chinese patent, if at all it existed, would have indeed justified the import of the patented product under Section 107A(b). It is the Author's opinion that the existence of a foreign patent in the name of a third party cannot be treated as falling within the meaning of "duly Authorized under the law" since it would undermine the grant of a patent by the Indian State. In other words, there is no merit in the argument that the rights of the Indian patentee are inferior to the rights of the holder of a foreign patent;

- C. The third scenario could be where a foreign patent over an invention is held by the party which also holds an Indian patent over the same invention. Would such a foreign patent constitute "duly authorized under the law"?
- D. The fourth scenario could be one, where even though the holder of the Indian patent may not hold a patent over the same invention in a foreign country, he or his licensee could still be manufacturing the product in such foreign country. Can the products of such party or his licensee be imported into India under Section 107A(b)?

Scenarios C and D are the ones typically used by proponents of international exhaustion to make their case. However, the language of the provision forces us to move away from scenarios C and D for reasons enumerated as under.

### INTERNAL AIDS OF INTERPRETATION - SECTIONS 84 AND 90 OF THE PATENTS ACT

That the reference to law in Section 107A(b) cannot be to foreign law and that the provision does not relate to parallel imports is borne out from the interpretation of Section 84 of the Patents Act, which relates to grant of Compulsory Licenses. An application for a Compulsory License is made under Section 84 of the Act on the grounds that:

- (E) the reasonable requirements of the public with respect to a patented invention have not been satisfied; or
- (F) that the patented invention is not available to the public at a reasonably affordable price or

(G) that the patented invention is not being worked in the territory of India.

In particular, the Author's line of interpretation may be supported using Section 84(7)(e). According to Section 84(7)(e), a patentee would be deemed to have not satisfied the reasonable requirements of the public if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by-

- (i) the patentee or persons claiming under him; or
- (ii) persons directly or indirectly purchasing from him; or
- (iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement.

Since, according to Section 84(7)(e), importation of the patented invention into India by persons directly or indirectly purchasing from him could amount to prevention of or hindrance to working of the patented invention by the patentee, it makes little sense to argue that Section 107A(b) embodies international exhaustion and permits parallel importation of the patented invention. Stated otherwise, how can something which adversely affects the working requirements of a patentee under Section 84(7)(e), be granted a *carte blanche* under Section107A(b)? It is one of the cardinal principles of statutory interpretation that a statute must be interpreted as a whole, and that interpretation of a provision must be upheld which gives due and consistent meaning to the rest of the statute. It follows that (i)territorial exhaustion and (ii) importation from a person duly Authorized under Indian law to produce and sell or distribute, facilitate harmonious interpretation of the rights of the patentee under Section 48, his working requirements under Section 84 and non-infringing importation under Section 107A(b).

Similarly, the terms and conditions under which a Compulsory License is granted are enumerated under Section 90 of the Act. Of specific relevance to the issue at hand are sub-sections 2 and 3 of Section 90. Sub-section 2 of Section 90 is reproduced as follows:

"90(2).No license granted by the Controller shall Authorize the licensee to import the patented article or an article or substance made by a patented process from abroad, where such importation would, but for such Authorization, constitute an infringement of the rights of the patentee."

It is clear from the above reproduced portion that a Compulsory License does not authorize the Licensee to import the patented invention. Further, it

clarifies that without an Authorization under Section 90 to import the patented invention, the importation would amount to infringement of the rights of the patentee. The question that needs to be asked here is if Section 107A(b) permits parallel imports by way of international exhaustion, why would Section 90(2) state that import of the patented invention by the Compulsory Licensee without such Authorization would amount to infringement of the patentee's rights? In other words, if the right of parallel import is otherwise available under Section 107A(b), why would the Legislature require Authorization under Section 90 and thereby curtail and abridge the rights of Compulsory Licensee by preventing him from exercising his right to import under Section 107A(b)? This clearly establishes that the only logical conclusion that a holistic reading of the Statute gives rise to is that Section 107A(b) does not refer or allude to unauthorized parallel imports or international exhaustion. Further, Sub-section 3 of Section 90 clarifies this interpretation. The sub-section allows the Controller of Patents to Authorize import of the patented article by the Compulsory Licensee, subject to conditions which the Controller deems fit such as quantum of royalty payable to the Patentee. Therefore, it becomes clear that imports from a person who is not authorized under Indian law are prohibited by the Patents Act.

# **External Aids of Interpretation**

One point of reference is the originally proposed amendment to Section 2(m) of the Copyright Act, 1957 in the Copyright (Amendment) Bill, 2010, which has now been dropped in the version that was passed by the Rajya Sabha on May 17, 2012. In the said version of the Bill, the following Proviso was sought to be inserted in Section 2(m) of the Copyright Act:

"(v) in clause (m), the following proviso shall be inserted, namely:—

"Provided that a copy of a work published in any country outside India with the permission of the Author of the work and imported from that country into India shall not be deemed to be an infringing copy;";

It is apparent from the clear language of the above-reproduced Proviso that it embodied the doctrine of International Exhaustion. A comparison with Section 107A(b) of the Patents Act informs us that the language in the latter is nowhere similar or close to the said proposed Proviso. Therefore, the direct and logical consequence of the Petitioner's interpretation of Section 107A(b) is that Indian Patent law follows territorial exhaustion, which proscribes and prohibits parallel imports from a person who is not duly Authorized under Indian law.

### INDIA'S COMMUNICATION TO URUGUAY ROUND OF GATT

As mentioned earlier, if the legislative intent was to give effect to the doctrine of international exhaustion, the language of the provision would have been as straight-forward and as clear as it is in Section 30 of the Trademarks Act, 1999 which is reproduced below:

- 30(3). Where the goods bearing a registered trade mark 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—
- (H) the registered trade mark having been assigned by the registered proprietor to some other person, after the acquisition of those goods; or
- (H) the goods having been put on the market under the registered trade mark by the proprietor or with his consent.

Section 30(3) of the Trademarks Act has been rightly construed as embodying the doctrine of international exhaustion since it refers to a good bearing the registered trademark which is "lawfully acquired". In other words, it refers to a product bearing the registered trademark which is acquired from a lawful/legal channel. The adoption of international exhaustion with respect to trademarks is consistent with India's representation to Uruguay Round of General Agreement on Trade and Tariffs (GATT). In its communication dated July 10, 1989 and titled "Standards and Principles Concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights", India elaborated on its position with respect to intellectual property rights (hereinafter referred to as "the Uruguay Communication"). Relevant to the instant Article are Parts II and I of the Uruguay Communication where India has clarified its stance with respect to Trademarks and Patents respectively.

With specific reference to trademarks, India categorically favoured the adoption of doctrine of international exhaustion which is borne out from the following excerpts from Part II of the Uruguay Communication:

# "QUALITY ASSURANCE FUNCTION OF TRADEMARKS"

37. Quality assurance is an important function of trademarks and it should receive as much attention as protection in any trademark regime. Very recently, in a "parallel imports" case, the import of a product bearing a well-known trademark from the subsidiary of a transnational corporation located in a developing country was prevented by another subsidiary of that transnational corporation manufacturing the same

product with the same trademark in a developed country on two grounds, namely (a) the product manufactured by the subsidiary in the developing country was of an "inferior" quality (although it carried the same trademark), and (b) the export of the product from that developing country had been prohibited by the transnational corporation. This shows that even where a product is manufactured in a developing country with this well-known trademark of a transnational corporation, there is no guarantee that its quality is the same as that of the product manufactured by the parent company or its subsidiary in an industrialized country, and on that ground alone, the export of the product from the developing country can be questioned in a litigation. Therefore, the trademark law should have a clear stipulation that the foreign trademark owner should give a categorical assurance that the quality of the product manufactured by the licensor himself in his own country and that in any litigation or proceeding concerning the quality of the product, he will give an assurance to that effect. In particular, developing countries should have the freedom to regulate the quality assurance aspect of the use of trademarks which may extend not only to the quality control responsibilities of the trademark licensor but also to quality certification vis-à-vis products bearing the same trademarks in other countries.

# Exhaustion of rights

38. The doctrine of "Exhaustion of Rights" is linked to "parallel imports". The exhaustion of the exclusive rights of the trademark owner should not be limited to the same country or the same free trade area, but should extend globally. In other words, the principle of international exhaustion of rights should apply to trademarks."

Paragraph 38 of the Uruguay Communication leaves nothing to imagination since it contains an unambiguous reference to adoption of international exhaustion with respect to trademarks. In fact, the very quality requirements, that have been sought for in Para 38 of the said Communication, form part of the requirements under Section 30 of the Trademarks Act, 1999. It is critical to note that the clear language used in Section 30 of the Trademarks Act is in stark contrast to the use of "from a person who is duly Authorized under the law" in Section 107A(b) of the Patents Act. If the legislature had indeed intended to give effect to the doctrine of international exhaustion in the Patents Act, the language of Section 107A(b) would have been broader and as express as Section 30 of the Trademarks Act.

Part I of the very same Uruguay Communication also clarifies the Indian position with respect to patents. Specifically, Paragraphs 5 to 31 of the Uruguay

Communication deal with all major aspects of patent law such as Basic Approach, Working of Patents, Compulsory License, Licence of rights, Exclusions from Patentability, Product versus Process Patents, Duration of Patents, *Government use of Patents in Public Interest*, Revocation of Patents and Restrictive and Anti-competitive Business Practices. It is critically pointed out by the Author that nowhere in the Communication is there a reference or remote allusion to international exhaustion with respect to patents. In fact, the discussion with respect to exhaustion is limited to trademarks alone.

Of particular relevance is the portion titled *Government use of Patents in Public Interest* in Paragraph 28 of the Communication. The said Para is reproduced as follows:

"28. As explained earlier, the patent system of developing countries should strike a rational and reasonable balance between the private monopoly interests of the patent owner and the larger public interest of the society. Therefore, where the public interest, and in particular, national security, food production, poverty alleviation, nutrition, health care or the development of other vital sectors of the national economy so requires it, the host country government or any third person designated by it should be free to work and use the patented invention in the country, including the importation of the patented product if necessary, without the consent of the patent owner on such terms and conditions as the host country government may decide."

The above reproduced Paragraph broadly relates to work and use of the patented invention by the Government in public interest. The underscored portion of the Uruguay Communication supports the Author's interpretation of Section 107A(b) of the Patents Act. The underscored portion of Para 28 of the Uruguay Communication states that the Government could import or *permit importation* of the patented product if necessary, without the consent of the patent owner on such terms and conditions as the government may decide. This supports the line of interpretation of Section 107A(b) that the Author puts forth below, and which is a restatement of Section 107A(b):

"Unless the patented product is imported from such a person who has been specifically "designated or Authorized under the (Indian) law" to produce and sell or distribute the patented product, importation of the patented product by any person would amount to infringement of the patent"

The fact that the wording of Section 107A(b) is consistent with the Indian intent clarified in the Uruguay Communication cannot be dismissed as mere

coincidence. What is even more clinching is the second aid of external interpretation, which is elaborated below.

# Legislative Debate on the Patents (Amendment) Act, 2005

The Patents (Amendment) Act, 2005 was passed on April 4, 2005. A combined discussion was held in the Lok Sabha, the Lower House of the Parliament, on March 22, 2005 under the Statutory Resolution regarding disapproval of Patents (Amendment) Ordinance, 2004 (No.7 of 2004) and the Patents (Amendment) Bill, 2005. This was a motion moved by Mr.Kamal Nath, then Minister of Commerce and Industry. In the said debate, the Minister of State for Parliamentary Affairs, Mr.Pawan Kumar Bansal (a cabinet colleague of Mr.Kamal Nath), stated thus:

"The second point, Madam, which has now been incorporated in the present Bill and as also in the Ordinance, is an amendment to Section 107A(b), providing for parallel import. Here, this amendment says: "On import of patented commodity from anywhere in the world, the Government reserves the right." Despite the fact that a particular medicine may be patented here by any other company, we have the right to import that patented commodity from anywhere in the world, where it is cheaper, even though it is patented here. Earlier however, this required that the foreign exporter was duly Authorised by the patentee. That was the condition earlier. I may remind my hon, friends on the other side that it has been taken off. Now, the law would be, as it has been included here in the Bill before us now, that 'no longer do we only need to stick to that condition that the foreign exporter was duly Authorised by the patentee to sell and distribute the products.' The position now would be that 'the foreign exporter be Authorised under the law, thus making the parallel imports easier.' This mechanism, as you know, would help in price control."

The above-reproduced paragraph amply clarifies the true meaning and scope of Section 107A(b) and supports the interpretation put forth by the Author. It bears noting that nowhere in the legislative debate is there a *carte blanche* to permit "importation from any person". The reference in the debate is expressly to the "Government's right" to import or to Authorize imports. It is no coincidence that this position is similar to the position taken by India in the Uruguay Communication. Therefore, the interpretation that Section 107A(b) refers to untrammelled and unauthorized parallel imports is incorrect and has no basis in facts and law.

The long and short of the provision is that it vests the Government with the power to import on its own, or authorize and facilitate imports into India. Simply put, instead of the patentee Authorizing imports into India, it is the Government which has the power to import from a foreign entity or Authorize/recognize a foreign entity to produce and sell/distribute the patented product. Such importation would not be considered as infringement under Section 107A(b).

In a way, this mechanism is the reverse of the one envisaged under Section 92A of the Act; under Section 92A, a compulsory license may be issued by the Indian Government to a "person interested", to satisfy the pharmaceutical requirements of another country. One of the circumstances in which the mechanism under Section 107A(b) could be employed is probably one where no player in India has the wherewithal to meet a particular exigency which is related to the supply of a product protected by an Indian Patent.

# Price Control Mechanism under Section 107A(b)

The mechanism envisaged under Section 107A(b) is a lesser known but equally legitimate form of parallel import wherein the Government of a country identifies the jurisdiction with the best international price and quality possible for its country with respect to a patented product and sources/imports the products from that jurisdiction. This is a price control mechanism that is to be invoked when the price of the patented product becomes unaffordable to the consuming public in India. In fact, the mechanism under Section 107A(b) could serve as the first gear in controlling prices of patented products before switching gears to invoke the compulsory licensing provision under Section 84 of the Act. The advantage offered by Section 107A(b) is that one need not wait for a period of three years from the date of grant of the patent to lapse as required under Section 84 of the Act.

Also, under Section 107A(b), it is possible for the Government to choose a manufacturer in a jurisdiction where the cost of manufacturing the patented product is the cheapest, and thereafter import or authorize import of the products into India. In a way, this means that the Act envisages a two different ways of keeping the prices of patented products under check, one under Section 84 of the Act and the other under Section 107A(b). This interpretation of Section 107A(b) also addressed another eventuality. It is perfectly possible that even when a patentee does not fulfil his working obligations under the Act, no "person interested" may apply for a compulsory license under Section 84 for multifarious valid reasons. Under Section 85 of the Act, the Government may not revoke a patent for non-working until expiration of two years from the date of grant of

the first compulsory license. This means that if no compulsory license is applied for by a "person interested", it is not permissible for the Government to revoke the patent for non-working under Section 85. Does this mean the Government has no alternative course of action available under the Act? The interpretation of Section 107A(b) put forth by the Author ensures that in the absence of any "person interested" who can act as a compulsory license, the government is not bereft of options to secure public interest in critical areas such as public health and nutrition. Is there a precedent for such a mechanism anywhere in the world?

### TRICOLOUR DRAWS COLOUR FROM THE RAINBOW

It must be pointed out that the mechanism envisaged under Section 107A(b) is not peculiar to India. Other developing countries which share similar concerns to that of India too have put in place similar mechanisms. In December 1997, the government of South Africa amended its Medicines and Related Substances Control Act (MRSCA) which, inter alia, permits the Minister of Health to suspend patent rights where it was deemed necessary to offset a high price of patented drugs. The law legalized parallel imports of patented medicines in such cases. In particular, the new Section 15C of the Medicines and Related Substances Control Act permitted such Authorized Government-sanctioned parallel imports. The said provision reads as follows:

Section 15C: The minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-

- (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
- (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported:

(c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

The constitutionality of Section 15C was challenged by 39 pharmaceutical companies in South Africa as an association, however the provision was subsequently upheld by South African Courts after a vigorous and spirited defense was put up by the Government of South Africa. The above-reproduced provision makes it abundantly clear that the mechanism provided for in Section 107A(b) is not unheard of, and is certainly a plausible one.

What is also borne out is that Section 107A(b), in effect, refers to conditional parallel import, which stands distinguished from parallel import by way of international exhaustion. The mechanism envisaged under Section 107A(b) of the Indian Patents Act and Section 15 C of the South African Medicines Act is a lesser known but equally legitimate form of parallel import wherein the Government of a country identifies the jurisdiction with the best international price and quality possible for its country with respect to a patented product and sources/imports the products from that jurisdiction. James Packard Love, a reputed IP policy analyst and the Director of US-based NGO "Knowledge Ecology International", earlier known as "Consumer Project on Technology", an organization founded by consumer activist, humanitarian and environmentalist Mr.Ralph Nader, had the following to say on Government-Authorized parallel imports in connection with Section 15C of the South African Medicines Act<sup>6</sup>:

"In the beginning, the South Africa government was trying to expand use of off-patent generic drugs, and also to permit the import of patented medicines, in cases where the patent owner was selling the medicine cheaper in another country. South Africa was then facing higher prices for several medicines than were found in neighboring countries, or in several cases, than in the US and European markets......This is very important, but almost entirely misunderstood—contrary to popular misconception, parallel imports does not involve buying from generic suppliers, but rather just shopping around for the best price a company charges internationally...... Put another way, if South Africa permits parallel imports, it will be able to import an Indian version of Glaxo's AZT, but not CIPLA's generic version of the same drug."

The above-reproduced Paragraph captures the heart and soul of the Author's contention i.e. "parallel imports" need not always refer to or be a consequence of international exhaustion. It could also refer to those situations where a country's Government decides to shop or enable import of patented products from a particular jurisdiction which meets its demands. This is precisely the mechanism provided for in Section 107A(b).

# IMPLICATIONS OF THE AUTHOR'S INTERPRETATION OF SECTION 107A(B)

The obvious consequence of the Author's interpretation of Section 107A(b) is that it is possible to argue realistically that Indian Patent law follows territorial exhaustion. It could be legitimately argued that:

- (a) in the absence of an express provision which recognizes international exhaustion, and
- (2) subject to the right of import from a Government Authorized person under Section 107A(b)

the importation right of the patentee under Section 48 of the Act remains sacrosanct, thereby alluding to the doctrine of territorial exhaustion.

### Conclusion

The unquestioned assumption that Section 107A(b) refers to international exhaustion, points to a disturbing trend where rigorous legal research takes a back seat in interpreting the law, and politico-economic arguments and biases dictate the course of law and logic. This does not augur well for a developing patent regime like India where a clear and reasoned approach to the law of patents is the need of the hour, particularly when the opportunities for the judiciary to set the law are far and few in between. Therefore, it is imperative to shun herd mentality since the interpretation of patent law or the application of logic is no one individual's sole propriety. Finally, it is critical that we revisit long-held beliefs since it is not uncommon in a developing field of law to find that practice, which is based on consensus, is often at variance with the letter of the law, and hence express legislative intent.