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Volume 7, Issue 1, April 2010

COMPULSORY LICENSING PROVISION UNDER TRIPS: A STUDY OF ROCHE VS NATCO CASE IN INDIA VIS-À-VIS THE APPLICABILITY OF THE PRINCIPLE OF AUDI ALTERAM PARTEM

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Abstract

In keeping with the relatively new waiver of the requirement of domestic production under Article 31(f) of TRIPS, the Indian Patents Act 1970 was amended allowing for compulsory license in certain exceptional circumstances.

Unlike in other sections relating to compulsory licensing in the Indian Patent Act, there is no reference to a patentee being extended the "opportunity of being heard". This appears surprising since it is the generic version of patentee's patented drug which is intended to be manufactured and exported to other countries by a third party. Despite this exclusion, the Indian Controller in the relatively recent Roche vs Natco compulsory licensing case upheld the merit of one of the basic tenets of common law, i.e. no one's interest should be prejudiced without such person being provided with an opportunity of presenting his or her case. In fact, the Controller held that, besides it being fair that the party whose interest is at stake be heard, the submissions of such parties could be of extreme value in arriving at a decision regarding the terms and conditions of grant of a compulsory license.

This article enquires whether giving a plain or literal interpretation to a relatively unambiguous statute is all that is expected from an adjudicating authority, or whether it is equally important for such authority to give effect to the cardinal principle of audi alteram partem as far as a patentee when such interpretation could yield results liable to be construed ultra vires the primary intention of the amended provision.

DOI: 10.2966/scrip. 070110.135

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1. Introduction

In keeping with the relatively new waiver of the requirement of domestic production under Article 31 (f)[1] of Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the 30 August 2003 agreement that Section 92 A[2] of the *Indian Patents Act 1970* (as amended) was enacted. S 92 A, in essence, deals with provision of compulsory license (CL) - in certain exceptional circumstances - for the manufacture and export of pharmaceutical products patented in India to countries which have no or insufficient manufacturing capacity in the pharmaceutical sector so as to address their public health concerns.

Interestingly, unlike in other sections relating to compulsory licensing in the Indian Patent Act, there is no reference whatsoever for provision of an "opportunity of being heard" to a patentee under s 92 A. Even though the rights of the patentee are determined under this provision, an adjudicating authority is not compelled to hear the patentees' side of story. This *prima facie* appears surprising since it is the generic version of patentee's patented drug which is intended to be manufactured and exported to other countries by a third party (generic company) subject to their securing a CL. Despite such relatively unambiguous exclusion – intentional or otherwise - in S 92 A, the Indian Controller in the relatively recent *Roche vs Natco* compulsory licensing case went ahead to uphold the merit of one of the basic tenets of common law, i.e. no one's interest should be prejudiced without such person being provided with an opportunity of presenting his or her case. In fact, the Controller held that besides it being fair that the party whose interest is at stake is heard, the submissions of such parties (the patentees) in a CL case could be of extreme value in arriving at a decision regarding the terms and conditions of grant of a compulsory license.

This piece – in the light of the *Natco* case and the amended Article 31 (f) of the TRIPS – enquires into whether giving a plain or literal interpretation to a relatively unambiguous piece of a statute i.e. s 92 A of the *Indian Patents Act 1970* (as amended) is all that is expected from an adjudicating authority. Or is it equally important for such authority to give effect to the cardinal principle of *audi alteram partem* as far as a patentee in a CL case is concerned even when such interpretation could yield results liable to be construed *ultra vires* with the primary intention of amended Article 31 (f) along the lines of which s 92 A was enacted.

2. The Paris Convention and TRIPS Provisions: WTO Compulsory Licensing

The Paris Convention of 1883 envisaged provision for each contracting state to take legislative measures for the grant of compulsory licences. Article 5A (2) of the Paris Convention reads:

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[1] As originally worded, Article 31 (f) read: "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use".
[2] See the Appendix at the end of this piece.

> Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.[3]

Therefore, the Paris Convention provided for grants of compulsory licenses by the member countries at least in cases of the non-working of a granted patent in a country of union. This implies that the concept of compulsory license is very much a pre-TRIPS phenomenon.

The (TRIPS) agreement allows compulsory licensing as part of the agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. But the term "compulsory licensing" does not appear in the TRIPS Agreement. Instead, the phrase "other use without authorization of the right holder" appears in the title of Article 31. Compulsory licensing is only part of this since "other use" includes use by governments for their own purposes.[4]

However, the World Trade Organisation (WTO) website offers a definition of the expression "Compulsory License". According to the WTO website, "compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement".[5]

Under TRIPS Article 31, a WTO Member may in its domestic law provide for compulsory licensing in situations of national or extreme emergency or in cases of public non-commercial use. Procedural safeguards require that the measure is used for essential products and that prior negotiations with the rights-holder have failed to obtain a reasonable result. TRIPS waives the requirement of prior negotiation in emergency cases or when the subject matter of the patent is required for public non-commercial use. The scope and the duration of the license shall be limited to the purpose for which it was authorised.[6]

The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. However, the Doha Declaration[7] on TRIPS and Public Health confirms that countries are free to determine the grounds for granting compulsory licences. In Article 31, the TRIPS Agreement does prescribe a number of conditions which ought to have been fulfilled before issuing compulsory licences. In particular, such conditions require that:

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[3] Article 5A (2) of the Paris Convention.

[4] "Obligations and exceptions Under TRIPS, what are member governments' obligations on pharmaceutical patents?" available at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (accessed 6 Nov 2009).

[5]The question answer series is provided in the WTO website available at http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (accessed 6 Nov 2009).

[6] Hans Henrik Lidgard and Jeffery Atik "Facilitating Compulsory Licensing under TRIPS in Response to the AIDS Crisis in Developing Countries" available at http://ssrn.com/abstract=794228 (accessed 6 Nov 2009).

[7] See Appendix.

- normally the person or company applying for a licence has to have tried to negotiate a voluntary licence with the patent holder on reasonable commercial terms. Only if that fails can a compulsory licence be issued, and
- even when a compulsory licence has been issued, the patent owner has to receive payment; the TRIPS Agreement says "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization", but it does not define "adequate remuneration" or "economic value".

There is more. Compulsory licensing must meet certain additional requirements: it cannot be given exclusively to licensees (e.g. the patent-holder can continue to produce) and it should be subject to legal review in the country.[8]

Importantly, TRIPS Article 31(f) adds (read formerly added) that any use of a compulsory license shall be predominantly for the supply of the domestic market of the member state authorising such use. Article 31(f) had been read to prohibit the manufacture of generics in third countries for export to countries experiencing a public health crisis. Thus, countries lacking indigenous pharmaceutical manufacturing capacitie could not effectively access medicines in compliance with TRIPS Article 31.[9]

2.1. The Amendment to the Scope of Article 31 (f) of TRIPS: The Doha Declaration

It was not until 30 August 2003 that the TRIPS Council was finally able to reach a decision[10] ("the 30 AugustAgreement") shortly before the Cancún Ministerial Conference.[11] What was changed was a provision that formerly said that compulsory licences must be granted mainly to supply the domestic market (paragraph (f) of Article 31). The 2001 Doha Ministerial Conference decided that this should be changed so that countries unable to manufacture pharmaceuticals could obtain cheaper copies elsewhere if necessary.[12]

Under the 30 August Agreement, the requirement of domestic production in TRIPS Article 31(f) is waived on the following conditions:

- The importing country must make an application to the WTO.
- The compulsory license granted in the exporting country shall also be notified to the WTO and be limited to the amount necessary to meet the needs of the importing country.

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[8] *Ibid*.

[9] *Ibid*.

[10] WTO, "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" WT/L/540.

[11] WTO, Ministerial Conference Fifth Session Cancùn, 10 – 13 September 2003, available at www.WTO.org (accessed 6 Nov 2009).

[12] See note 7 above.

- Products shall furthermore be distinguishable through specific labelling and marking and information must be published on the internet.[13]

Individual states have thereafter declared that they intend to amend national patent laws in order to facilitate production by compulsory licensees for subsequent exportation. Canada took steps in this direction in November 2003, when a proposed amendment to the Canadian Patent Law was introduced. Compulsory licensing would be granted to Canadian generic manufacturers to produce and export patented products to least developed countries lacking production capacity.[14]

Unfortunately, the early experience of the implementation of this provision showed that the mechanism devised by the 30 August 2003 decision to make necessary drugs available to the least developed countries is quite complicated.

2.2. The Rwanda Case

On 17 July 2007, Rwanda notified the WTO's Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) that it planned to import the HIV-drug TriAvir from the Canadian company Apotex and would not enforce any patents granted in that respect in Rwanda. Two months later, Canada issued a compulsory license allowing Apotex to use nine patented inventions for manufacturing and exporting TriAvir to Rwanda. On 4 October 2007, Canada notified the Council for TRIPS of the compulsory license.[15]

These actions constitute the first application of the mechanism set up by the WTO to safeguard access to medicines for countries lacking the capacity to manufacture drugs. The mechanism was meant to balance countries' obligations to grant patents under the TRIPS Agreement with their ability to provide cheap drugs to their populations.[16]

This first application of the mechanism shows that it is too cumbersome to work effectively. Rwanda could have imported a similar combination drug from India, which was available at $0.14 per tablet and was not yet affected by India's new patent legislation. It would only have had to impose a compulsory license in its own territory, and would possibly not even have needed this step, as it is not clear whether any of the nine inventions had been patented in Rwanda.[17]

Apotex (the Canadian company) concluded that the mechanism would have to be changed to work effectively. The process proved cumbersome and the generic

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[13] In an attachment to the statement made by the chair a "best practices guideline" for distinguishing products was initiated. This suggestive list also referred to the practice of prohibiting re-exportation. See the General Council's Chairperson's statement (30 August 2003) available at www.WTO.org (accessed 6 Nov 2009). The statement is regarded as an integral part of the Agreement and it specifies that the Agreement must not be an instrument to pursue industrial or commercial policy objectives and that several developed countries have opted out of benefiting from the Agreement as importers. See note 6 above.

[14] See note 6 above.

[15] HP Hestermeyer, "Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines" *American Society of International Law* available at http://www.asil.org/insights071210.cfm (accessed 6 Nov 2009).

[16] *Ibid.*

[17] *Ibid.*

manufacturer had few incentives to go through with it. It is not economical to produce for merely one importing country, and it is difficult to convince countries to notify the WTO of their need to import. Additionally, Canada imposes a maximum term of two years for a compulsory license and this is not enough to recoup the investment of producing a generic drug.[18]

As per Canadian regulations, products can only be exported to eligible countries under Canadian Access to Medicines Regime (CAMR) and cannot be sold in Canada until the relevant patents expire. "If other critical medicines are to go to Africa in a reasonable timeframe, the federal government must change the CAMR Legislation," Apotex President, Jack Kay said in press statement. "CAMR is unworkable as it now stands. Apotex decided to do this because it was the right thing to do for the people dying from AIDS in Africa."[19]

While the WTO's goal of increasing access to medication during public health emergencies is a good one, the terms of this provision have led to unfettered discretion by nations to dictate the terms of their own compulsory licensing programmes. The WTO intended through this agreement to ensure that countries facing public health crises that lacked the ability to pay for pharmaceuticals at patent prices, would be able to invoke these terms to ensure that their citizens had access to medication. Because member nations may dictate when they are entitled to compulsory licensing for a wide range of pharmaceutical products, however, countries have invoked compulsory licensing for a range of conditions that may go beyond the definition of a "public health crisis" the WTO intended. This unchecked discretion has created a negative association with compulsory licensing, and may be hurting the very countries that need access to life-saving medications most: underdeveloped countries facing severe public health crises that lack domestic pharmaceutical production capacity.[20]

Given the defects of the mechanism, the Director General of the European Generic Medicines Association concluded at a hearing of the European Parliament that it is unlikely that any company in Europe would make use of the mechanism.[21]

3. Ss 92 and 92 A of Indian Patents Act 1970 (as amended)

It is in keeping with the new waiver of the requirement of domestic production under TRIPS Article 31 (f) that s 92 A of the *Indian Patents Act 1970 (as amended)* was enacted.

In order that the provisions of s 92 A are comprehended more clearly, let us first attempt to figure out the scope and extent of the preceding s92[22] of the *Patents Act*

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[18] *Ibid.*

[19] Aafrol News, "Canada sells combined AIDS drugs to Rwanda" (8 May 2009) available at http://www.afrol.com/articles/28848 (accessed 6 Nov 2009).

[20] AM McGill, "Compulsory Licensing of Patented Pharmaceuticals: Why a WTO Administrative Body Should Determine What Constitutes a Public Health Crisis under the Doha Declaration" available at http://works.bepress.com/cgi/viewcontent.cgi?article=1000&context=aileen_mcgil (accessed 6 Nov 2009).

[21] See note 15 above.

[22] See Appendix.

1970 which dealt with the "Special provision for compulsory licenses on notifications by Central Government".

Sub-section (2) of s 92 essentially clarifies that even with respect to "Special provisions for compulsory license" the procedure stated in s 84[23] *inter alia* shall apply i.e. the patentee shall have the opportunity to oppose any application made to the Controller for issue of a compulsory license. It is only in the non-obstante clause of sub-section (3) of s 92 that the power is given to the Controller not to follow the principle of *audi alteram partem* specified in s 87[24] (4) if situations mentioned in paragraphs (i) or (ii) or (iii) of sub-section (2) of s 92 including the situation of a public health crisis with respect to specified diseases such as AIDS, HIV or other epidemics. The expression is broad enough to include any and all kinds of diseases envisaged by the Controller.

A further proviso to sub-section (3) of s 92 makes it clear that once a decision is arrived at by the Controller, the provision of s 87 would not be applicable. In fact, there is an express obligation upon the Controller to inform the patentee regarding non-applicability of the provision of s 87. It is important to note that s 92 envisages situations which occur inside India, i.e. where the patent has actually been granted to a patentee.

3.1. Natco Compulsory Licensing Case in India

The first ever compulsory license application made in India was by Natco Pharma for the manufacture and exportation of Roche's patented anti-cancer drug Erlonitib to Nepal, the sub-Himalayan kingdom. Besides Erlotinib, Natco Pharma had also applied for the issue of a second compulsory license to the IPO for manufacture and export of Sunitnib [Sutent], also an anti-cancer drug.

This issue of grant or non-grant of the compulsory license was still under consideration when Natco filed an interlocutory petition before the Controller of Patent asserting that since the application for grant of compulsory license was made by them under s 92 A of the *Patents Act 1970*, the patentees should not be provided with an opportunity of being heard. In other words, Natco Pharma requested the Controller to disallow Roche (the patentees) the right to actively represent them in the compulsory license proceeding before him.

4.1.1. The Issue in Interlocutory Petition: Audi Alteram Partem

It was natural for the Controller to dispose first of the interlocutory petition before he took up the main matter. As will be appreciated, the interlocutory petition dealt more with necessity of the applicability or non-applicability of the principle of natural justice and fair dealing under specific circumstances envisaged in the Indian Patent law. Of course, the provision which was of direct relevance on this matter was the scope and interpretation of s 92 A.

The matter came up for hearing before the Controller on 19 March 2008. After listening to the arguments from both sides, i.e. from Natco (the generic manufacturer) and Roche (the patentee), the Controller observed that there was nothing in s 92 A

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[23] See Appendix.
[24] *Ibid*.

which specifically prohibited an adjudicating authority from affording the patentees an opportunity of being heard. In other words, the Controller felt that the law did not forbid him from allowing the patentees to present their case before he eventually decided the fate of the third party's application for issue of a compulsory licence on the patentees' invention. The Controller, therefore, in effect, upheld the relevance and applicability of one of the basic tenets of the common law that no one's interest should be prejudiced without such person being provided with an opportunity of presenting his or her case. In fact, the Controller went on to observe that in addition to it being fair that the party whose interest could be harmed is heard, the submissions of such party (the patentees) could be of extreme value in arriving at a decision regarding the terms and conditions of the grant of a compulsory license.

While this interpretation has been welcomed by many, there is no dearth of the critics, who in view of the intended scope of the s 92 A, find the line of reasoning of the Controller out of sync with the letter of the law in question as well as with the provisions of the amended Article 31 (f) of TRIPS. The incongruence becomes discernible when a categorical distinction between the ambit of the expression "hearing" and "consultation" is drawn more so, since s 92 A of the *Indian Patent Act* is conspicuously silent on the issue of affording a hearing to a patentee. However, it appears that if it is possible to interpret the expression "hearing" in a manner that it refers merely to a "discussion" or a "consultation" or even to a "conference" rather than it referring to a full blown trial procedure, perhaps a balanced approach could then be achieved. The approach of harmonious construction acquires significance in view of the fact that, on the face of it, it appears that the *mens rea* behind the Controller's decision and order to allow the patentees, i.e. Roche in the present instance, to be present at a CL hearing under s 92 A was to impart justice and fair play.

Although, it envisages the framing of terms for the grant of compulsory licenses, s 92 A does not however spell out the modalities of the same in utmost detail. The section being in compliance with TRIPS has witnessed the Controller award a hearing to the Patentee. The term "hearing", having been omitted both from the provision of the Patents Act and the TRIPS document, leads to the question "if a 'hearing' would merely mean 'consultation' or does it go beyond the scope of the term, invading into arenas and practices that associate themselves greatly with traditional litigation?" [25]

The question one ought to ask and try to answer is whether in a situation where, for the first time, a piece of legislation, e.g. s 92 A of the *Patents Act 1970*, comes up for construal and/or interpretation before an adjudicating authority, it is appropriate to consider merely the letters of the section to be the absolute governing force. Alternatively, should an adjudicating authority (the Controller) also follow say, for example, the tenets of the maxim "justice should not only be done but it should appear to have been done" while giving effect to the section.

In other words, can a judgment or an order which apparently does not strictly adhere to the letters of the law but nonetheless upholds one of the most cardinal principles of justice and equity, i.e. *audi alteram partem* or hear the other side valued by most modern legal systems be said to be overreaching in its effect. There is no dearth of

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[25] D Subramanian,"TRIPS and Compulsory Licensing: The NATCO Nuance" available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1289992 (accessed 6 Nov 2009).

judgments across legal systems upholding the importance of the principles of justice and fair play. In fact, relatively recently, the principle of *audi alteram partem* was referred to by even the International Court of Justice (ICJ) in the *Nuclear Tests* case[26] in view of the concerns regarding France's non-appearance at the judgment. Having said that, it has to be admitted that instances of divergence from strict adherence to the principle of *audi alteram partem* leading to conviction of individuals *in absentia* under specific set of circumstances, have also been considered equally acceptable by quite a few modern legal systems.

2.2. The Overall Scope and Implications of S 92 A vis-à-vis Applicability of the Principle Audi Alteram Partem for a Patentee

Now, let us critically examine the provisions envisaged in above-quoted s 92 A. This section deals primarily with the issue of compulsory license intended purpose which is the exportation of "pharmaceutical products" in certain exceptional circumstances to a relatively underprivileged country other than the country where the patentees secured their patent protection, i.e. India. Interestingly, the expression "pharmaceutical product" has been defined under explanation to s 92 A to relate to any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and is inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use. Therefore, noticeably not only the finished patented pharmaceutical product but also the ingredients necessary for their manufacture is included in the ambit of the expression "pharmaceutical products".

It is worthwhile to note that sub-section (3) of s 92 A makes it apparent that the right to export products for which a compulsory license under sub-sections (1) and (2) of such section has been secured is notwithstanding the extent to which a product has secured a compulsory license under any other provisions of the Act.

A close reading of s 92 A makes it apparent that the two alternative conditions required be fulfilled by a party seeking to secure a compulsory license under s 92 A is that:

> (1) such party has been granted compulsory license in the country to which it intends to export the products (licensed to be manufactured to them); or
>
> (2) such party has been allowed (secured permission) to import such product to the said country from India.

In the Natco compulsory license matter, since Nepal qualified as one of the Least Developed Countries (LDC) under WTO classification, it was not mandatory for Nepal to establish that it had insufficient manufacturing capacities and/or facilities. Additionally, a product patent regime for pharmaceutical products was and is non-existent in Nepal. Therefore, the requirement to grant a license to Natco (in Nepal) to import the requisite drug(s) into Nepal was also not a necessary.

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[26] *Nuclear Tests* [1974] 265(ICJ).

As far as s 92 A is concerned, there is not even a reference to offer an "opportunity of hearing" to a patentee in a CL proceeding. Therefore, is it safe to presume that such a critical exclusion or omission by the legislature was accidental or unintentional? Some light is thrown on this issue when a comparison of the provisions of Section 92 - wherein patentees' rights to be heard have in general been taken care of - is carried out with the provisions of s 92 A. Perhaps the right of the patentee to be heard has been considered suspended - arguably, appropriately or inappropriately - under the exceptional circumstances envisaged in s 92 A. One interesting difference between sub-section (3) of s 92 and sub-section (1) of s 92 A is the use of the expressions "public health crises" and "public health problems", respectively in these sections. One can perhaps argue that expression "crisis" denotes a graver situation than the expression "problem" but under the situations stated in both sub-clauses, i.e. in sub-section (3) of s 92 as well as sub-section (1) of s 92 A, the principle of *audi alteram partem* has been considered not applicable or suspended by the legislature as far as a patentee is concerned.

Interestingly enough, Rule 97 of *Patents Rules 2003* envisages that if, upon consideration of evidence, the Controller is satisfied that a *prima facie* case has not been made out for the making of an order under ss 84, 91 or 92 or 92 A, he shall notify the applicant accordingly, and unless the applicant requests to be heard in the matter within one month from the date of such notification, the Controller shall refuse the application. So Rule 97 provides for an opportunity of being heard for an applicant of a CL - as opposed to a patentee or a licensor - before his application is rejected subject to such applicant making a request to the Controller within stipulated time. Therefore, even under the Rules, it was not considered worthy by the legislature to provide a patentee an opportunity of being heard in a CL proceeding under essentially Section 92 A.

The non-inclusion of the provision of "opportunity of being heard" in s 92 A, therefore, appears purposeful rather than of an unintentional omission on the part of legislature. What lends more credence to this inference is the fact that there is no provision for appeal from the decision of the Controller to grant or not to grant compulsory license under s 92 A. This bar is specifically laid down in Sub-section (2) of s 117A[27] - which in general lays down which sections of the *Patents Act* are appealable - of the *Patents Act 1970* as amended. Interestingly, decisions, orders or directions of the Controller under ss 91, 92 and even 94 are appealable before the relatively recently established Intellectual Property Appellate Board (IPAB) but not the Controller's decision/order under s 92 A. Incidentally, in a recent decision or order of Delhi High Court in *W.P. (C) Nos. 332 of 2010 & 13295, 12006, 8393, 8392 & 8389 of 2009*, the rejection of a patent application under Section 25 (1) – which deals with pre-grant opposition and is not included in the list of appealable sections in Sub-section (2) of s 117A - of Act was held appealable before IPAB. Until this

[27] *117 A. Appeals to the Appellate Board.*
(1) Save as otherwise expressly provided in sub-section (2), no appeal shall lie from any decision, order or direction made or issued under this Act by the Central Government, or from any act or order of the Controller f r the purpose of giving effect to any such decision, order or direction.
(2) An appeal shall lie to the Appellate Board from any decision, order or direction of the Controller or Central Government under s 15, s 16, s 17, s 18, s 19, s 20, sub-sections (4) of s 25, s 28, s 51, s 54, s 57, s 60, s 61, s 63, s 66, sub-section (3) of s 69, s 78, sub-sections (1) to (5) of s 84, s 85, s 88, s 91, s 92 and s 94.

decision, the IPAB had maintained that rejection of an application under a pre-grant opposition under s 25 (1) was not appealable before this body.

Therefore unless the appealability of s 92 A is interpreted otherwise by a court, once a decision to grant or not to grant a compulsory license under s 92 A is taken by a Controller, such decision is *prima facie* final. The only foreseeable cause of action out of such decision appears to be filing of a writ petition in the High Court of respective jurisdiction under Article 226[28] of the constitution of India.

4. The Practical Obstacles in Implementation of the Altered Provision of Article 31 (f).

Despite the clear language of the Doha Declaration, finding a solution to securing access to medicines (for the least developed country members) has turned out to be a difficult task. Countries were acting in their own self-interest either because they felt essential values were at stake (as with the United States) or because they saw opportunities for domestic industry to expand into new fields (India and Brazil).[29]

Accordingly, a combined reading of TRIPS Article 31 and the 30 August Agreement requires that a number of steps be carried out before a compulsory license can be granted. First, negotiations for a voluntary license on commercially reasonable terms must have failed. Only then can an application for a compulsory license be introduced to the WTO. In its application, the importing country must demonstrate an emergency situation and its own inability to produce the product locally. The potential exporter must also seek a voluntary license and needs an approval from its own national government. Royalties must be established and a distinguishable product produced and approved. These procedures must be repeated for each export transaction. Each step does not in itself present an insurmountable hurdle – but cumulatively they constitute a real obstacle.[30]

In fact, there are not sufficient examples of countries unable to manufacture the pharmaceuticals obtaining cheaper copies of such drugs from elsewhere if necessary. Interestingly, The Netherlands appears to a positive example by allowing for NGOs to act for an importing state without requiring some undefined "permission" from the government of the importing country. NGOs, particularly those with operational experience in the procurement of medicines, may be the best bet in terms of getting drugs to those in need expeditiously Norway does not go beyond the WTO Decision and defines eligible "pharmaceutical products" as those "covered by paragraph 1(a) of the General Council Decision". The EU establishes a 30 day period for negotiating a voluntary licence but waives the need to negotiate with the patentee in the event that the generic product is needed for an emergency or other circumstance of extreme urgency or for public noncommercial use. The importing countries need the pharmaceutical products to be safe and effective; there should be a regulatory review requirement. However, because the product is destined primarily for export, it should be up to the importing country to determine whether it wishes to avail itself of the regulatory approval process of the exporting country or of the WHO pre-qualification

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[28] See Appendix.

[29] See note 6 above.

[30] A Valach, "Protecting the rights of patent holders and addressing public health issues in developing countries" (2005) 4 *Chicago-Kent Journal of Intellectual Property* 156-185, at 168.

project. These measures help to ensure a rapid and effective response to global public health crises, while remaining compliant with WTO obligations.[31]

Therefore, even though a European country like The Netherlands is taking proactive step to utilise the 30 August Agreement to provide essential medicines to needy countries, such efforts have miniscule effects because of the essential complexity of the procedure involved. They are almost as good as negligible.

4.1. The Canadian Royalty Model

Sub-section (2) of Section 92 A envisages that the Controller shall grant a CL solely for manufacture and export of concerned pharmaceutical product(s) to a needy country "under such terms and conditions" as may be specified and published by the Controller. Therefore, according to the above quoted provision of law, it is almost at the sole discretion of the Controller to fix the terms and conditions including the period for the CL and the amount of royalties to be paid by the licensee to the licensor or patentee. No set formula and/or royalty guideline is provided for under s 92 A or any rules thereunder which a licensee or a licensor or even a Controller while deciding the terms and conditions of a license agreement ought to follow. Such wide discretionary power to an adjudicating authority in a law is liable to interpreted and given effect to in almost any manner thought reasonable by such authority.

In this respect, a look at the Canadian royalty guidelines published in a WHO publication titled "Remuneration guidelines for non-for non-voluntary use of a patented on a medical technology" is worthwhile.

In 2005, Canada proposed royalty guidelines for the export of medicines under the Jean Chrétien Pledge to Africa Act, which implements the WTO waiver of Article 31(f) of the TRIPS Agreement. The Canadian royalty guidelines are a sliding scale of the generic sales price. The rate depends entirely upon the location of the importing market and the rank of the importing country in the United Nations Human Development Index (UNHDI). The formula is one, plus the number of countries on the UNHDI, minus the importing country's rank on the UNHDI, divided by the number of countries on the UNHDI, multiplied by 0.04. The rate is then applied to the generic sales price.[32]

With 177 countries currently in the UNHDI index, the royalty rate can be expressed as:

$$\text{Royalty rate} = 0.04 * [(178) - \text{rank importing country}]/177$$

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[31] E Ng and JC Kohler, "Finding flaws: the limitations of compulsory licensing for improving access to medicines - an international comparison" *Health Law Journal* (1 Jan 2008) available at http://www.thefreelibrary.com/Finding+flaws:+the+limitations+of+compulsory+licensing+for+improving...-a0200915335 (accessed 6 Nov 2009).

[32] WHO, "Remuneration guidelines for non-for non-voluntary use of a patented on a medical technology" available at http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf (accessed 6 Nov 2009).

The Canadian royalty guidelines result in relatively low royalties. The top rate is 4% of the generic sales price, and the lowest rate for 2004 was 0.02%, for Sierra Leone. Weighted by global population, the average rate is 1.9%. Weighted by global rates of HIV infection, the average rate is 1%. Selected royalty rates based upon the 2004 UNHDI rankings are presented in Table R-3. A complete list is given in Table A-1 of the appendix.[33]

Table R-3: Royalty Rates under Canadian Royalty Guidelines - based upon UNDP 2004 HDI [34]

Country 2004	HDI Rank Royalty Rate
Norway	1 4.0
United States	8 3.8
Chile	43 3.1
Brazil	72 2.4
Philippines	83 2.2
Indonesia	111 1.5
India	127 1.2
Swaziland	137 0.9
Mozambique	171 0.2
Sierra Leone	177 0.02

[33] See note 32 above.

[34] *Ibid.*

Interestingly, according to certain reporting,[35] Natco apparently offered to pay royalty as high as 5%, i.e. one of the highest in the WHO guideline referred to hereinabove with respect to a developing country. If this was the situation, the question of settling the royalty issue should not have been a point of contention between the patentee and the CL seeker.

However, in most circumstances relating to CL issues either under Article 31 (f) or otherwise, percentage of royalties to be paid to a patentee – in the absence of a standard guideline or format – remains a contentious issue and a further impediment towards the grant of a CL. At least on this issue, as correctly pointed out by the Controller in the *Natco* decision, the role of a patentee and their submissions could be very crucial.

In the circumstances, studying the Canadian Royalty model/guideline and perhaps customising such a model for the needs of the individual countries such as India could be beneficial.

5. Conclusion

It will be appreciated that the overall procedure which is required for securing medicines through importation by compulsory license is cumbersome. Although it is agreeable that proper checks and balances for this exclusion under TRIPS are necessary lest the provision is misutilised for vested interests. However, unintentionally creating a further layer of practical hindrance i.e. of providing for an opportunity of being heard to a patentee, towards achieving the ultimate aim of securing access to medicines for the least developed countries might make the already burdensome procedure a little more cumbersome. Therefore, the question why the cardinal principle *of audi alteram partem* should not necessarily be adhered to and honoured while dealing with the singular situation of compulsory license envisaged under s 92 A of *Indian Patent Act* is something which ought to be examined in the backdrop of the intention behind creation of this provision in the Decision of the General Council of TRIPS on 30 August 2003. This appears to be one of the crucial considerations which instigated the Indian legislature not to provide expressly for the provision of a hearing to the patentees in a compulsory license situation envisaged essentially in s 92 A.

Noticeably, on the issue as to how much royalty ought to be paid to a patentee as opposed to the issue whether a "compulsory license" ought to be granted or not, there is nothing in s 92 A or as a matter of act, in any other section of the Patent *Act 1970* dealing with compulsory license which specifically or even impliedly prohibits the Controller from consulting a patentee. Therefore, at least on this issue, it does make sense that – as an interim arrangement - the patentees who have invested substantive amounts of research time, manpower, energy and money to arrive at an invention and protect it be given an opportunity – be it in the form of consultation or conference or meeting – to present their concerns, reservations and/or financial implications before the Controller. When the interest of a section of a nation – poor and deprived – is

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[35] Generic Pharmaceuticals and IP blog available at http://genericpharmaceuticals.blogspot.com/2008/02/india-compulsory-license-hearings-tart.html (accessed 6 Nov 2009).

against the interest of a patentee, a balanced approach ought to be adopted in keeping with the intention behind adoption of a particular piece of legislation and its over all implication. Until the time a set formula for calculation of royalty is established or a pattern along the lines of the Canadian scheme of calculation of royalty is adopted, a consultative approach towards patentees could very well be adopted and pursued.

The *Roche vs Natco* compulsory license case was the first opportunity wherein a complex compulsory license situation came up for hearing before the IPO and therefore, one cannot expect that a settled principle of law should emerge from a single instance. Rather, like any field of law, this crucial issue will also reasonably settle through perhaps a series of divergent and concurring orders and/or decisions given by the IPO and/or the IPAB and/or even the Indian Courts in time. Unlike the legislature, the courts or adjudicating bodies do not have the flexibility to uphold, overrule or even lay down a legal principle unless a matter comes up for hearing before it. Therefore, if left to the judiciary or adjudicating bodies only time will tell how long it eventually takes to evolve a settled principle of law as far as the issue of affording or not affording an opportunity of being heard to a patentee in a compulsory licence related matter under s 92 A is concerned. In the interim, what is referred to as "literal construction" – primarily under judicial interpretation of statute - of the provisions of s 92 A of *Patents Act 1970* as amended should, to a large extent, solve the broad purpose of the amendments brought into force in the *Indian Patent Act* in conformity with the 30 August 2003 TRIPS declaration. This approach should, more importantly, help in facilitating the actual motive behind bringing out the 30 August declaration i.e. to make patented pharmaceutical products readily available to the populations of countries which have no or insufficient manufacturing capacity in the pharmaceutical sector so as to address their public health concerns.

Appendix

1. - 92A. Compulsory Licence for Export of Patented Pharmaceutical Products in Certain Exceptional Circumstances.

> (1) Compulsory licence shall be available for *manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector* for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.
>
> (2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.
>
> (3) The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under any other provision of this Act.

> Explanation.—For the purposes of this section, "pharmaceutical products" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use."

2. The Doha Declaration

> 5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognise that these flexibilities include: …
>
> (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
>
> (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
>
> (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

Available at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

3. - 92. Special Provision for Compulsory Licences on Notifications by Central Government"

> (1) If the Central Government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licences should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette, and thereupon the following provisions shall have effect, that is to say,-
>
> (i) the Controller shall, on application made at any time after the notification by any person interested, grant to the applicant a licence under the patent *on such terms and conditions* as he thinks fit;
>
> (ii) in settling the terms and conditions of a licence granted under this section, the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentee deriving a reasonable advantage from their patent rights.

(2) The provisions of sections 83, 87, 88, 89 and 90 shall apply in relation to the grant of licences under this section as they apply in relation to the grant of licences under section 84.

(3) Notwithstanding anything contained in sub-section (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub-section (1) that it is necessary in-

(i) a circumstance of national emergency; or

(ii) a circumstance of extreme urgency; or

(iii) a case of public non-commercial use, which may arise or is required, as the case may be, including public health crises, relating to Acquired Immune Deficiency Syndrome, human immunodeficiency virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in sec ion 87 in relation to that application for grant of licence under this section:

Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section 87.

4. - 84. Compulsory Licences

(1) At any time after the expiration of *three years* from the date of the sealing of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:-

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

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

(2) An application under this section may be made by any person notwithstanding that he is already the holder of a licence under the patent and no person shall be estopped from alleging that the reasonable requirements of the public with respect to the patented invention are not satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price by reason of any admission made by him, whether in such a licence or otherwise or by reason of his having accepted such a licence.

(3) Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.

(4) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may grant a licence upon such terms as he may deem fit.

(5) Where the Controller directs the patentee to grant a licence he may, as incidental thereto, exercise the powers set out in section 88.

(6) In considering the application filed under this section, the Controller shall take into account,-

(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

(ii) the ability of the applicant to work the invention to the public advantage;

(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

(iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit: Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.

Explanation.—For the purposes of clause (iv), "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months.

(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied-

(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,-

(i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or

(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii) a market for export of the patented article manufactured in India is not being supplied or developed; or

(iv) the establishment or development of commercial activities in India is prejudiced; or

(b) if, by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or

(c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing, or

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable, or

(e) 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.

5. - 87. Procedure for dealing with applications under sections 84 and 85

(1) Where the Controller is satisfied, upon consideration of an application under section 84, or section 85, that a prima facie case has been made out for the making of an order, he s all direct the applicant to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the application is made, and shall publish the application in the official journal.

(2) The patentee or any other person desiring to oppose the application may, within such time as may be prescribed or within such further time as the Controller may on application (made either before or after the expiration of the prescribed time) allow, give to the Controller notice of opposition.

(3) Any such notice of opposition shall contain a statement setting out the grounds on which the application is opposed.

(4) Where any such notice of opposition is duly given, the Controller shall notify the applicant, and *shall give to the applicant and the opponent an opportunity to be heard before deciding the case.*

6. - 226. Power of High Courts to issue certain writs

(1) Notwithstanding anything in Article 32 every High Court shall have powers, throughout the territories in relation to which it exercise jurisdiction, to issue to any person or authority, including in appropriate cases, any Government, within those territories directions,

orders or writs, including writs in the nature of habeas corpus, mandamus, prohibitions, quo warranto and certiorari, or any of them, for the enforcement of any of the rights conferred by Part III and for any other purpose.

(2) The power conferred by clause (1) to issue directions, orders or writs to any Government, authority or person may also be exercised by any High Court exercising jurisdiction in relation to the territories within which the cause of action, wholly or in part, arises for the exercise of such power, notwithstanding that the seat of such Government or authority or the residence of such person is not within those territories

(3) Where any party against whom an interim order, whether by way of injunction or stay or in any other manner, is made on, or in any proceedings relating to, a petition under clause (1), without

(a) furnishing to such party copies of such petition and all documents in support of the plea for such interim order; and

(b) giving such party an opportunity of being heard, makes an application to the High Court for the vacation of such order and furnishes a copy of such application to the party in whose favour such order has been made or the counsel of such party, the High Court shall dispose of the application within a period of two weeks from the date on which it is received or from the date on which the copy of such application is so furnished, whichever is later, or where the High Court is closed on the last day of that period, before the expiry of the next day afterwards on which the High Court is open; and if the application is not so disposed of, the interim order shall, on the expiry of that period, or, as the case may be, the expiry of the aid next day, stand vacated.

(4) The power conferred on a High Court by this article shall not be in derogation of the power conferred on the Supreme Court by clause (2) of Article 32.