

Comments
on
Discussion Paper
on
Compulsory Licensing

Indian Pharmaceutical Alliance
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PREFACE

The Department of Industrial Policy and Promotion, Ministry of Commerce has published a Discussion Paper dated 24 August 2010 on Compulsory Licensing. The paper has identified 13 issues for resolution and has invited public comment.

The Indian Pharmaceutical Alliance (IPA) acknowledges the openness of the Government of India in inviting public comment and wishes to place on record its appreciation of the admirable summary provided in the Discussion Paper of the background to the issues involved.

The IPA has always been deeply conscious of the need to generate consensus on Intellectual Property issues which are often contentious. The IPA has commented on the issues identified with the national interest in mind. Comments are accompanied with summaries of opposing viewpoints and background material where appropriate, to facilitate discussion and informed consensus on the use of compulsory licensing provisions in accordance with the Patents Act.

25 September 2010

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COMPULSORY LICENCES: COMMENTS ON ISSUES FOR RESOLUTION

1. *Are guidelines necessary or required for the issue of compulsory licenses? Can it be argued that it is inadvisable to fetter the discretionary power of government relating to the circumstances in which compulsory licenses should be issued, and thus such guidelines should not be applied to Category I CLs but be restricted to Category II CLs? Even the latter are issued through the exercise of quasi judicial powers by the Controller. Will the issue of guidelines to trammel her subjective satisfaction be desirable? Should therefore such guidelines be restricted to the royalty payment to be awarded while issuing a CL?*

1.1. Preliminary

1.1.1. Approach to analysis

It is possible to view the issue from two perspectives to aid analysis:

- Legal considerations
- Policy considerations

The Discussion Paper calls for comments from the policy perspective. However the legal considerations are also discussed in this response as they inform and influence policy in the context of compulsory licensing in two main ways:

- The need and scope for guidelines are in part determined by the scope and content of the statutory provisions.
- The challenge to the grant or refusal of compulsory licenses will be judicially adjudicated and an appreciation of legal considerations relating to the exercise of discretionary power will be useful.

The IPA view follows from the above.

1.1.2. Category I and Category II Licenses

For convenience, the categorisation of Compulsory Licences (CLs) adopted in the Discussion Paper is recapitulated below:

- Category I CLs are those issued on application to any person interested in certain special circumstances:
 - under Sec 92, on notification in respect of a patent by the Central Government in circumstances of national emergency or extreme urgency or public non-commercial use;
 - under Sec 92A for the manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity for such products to address public health problems provided a CL has been granted by such country or import from India is permitted.

- Category II CLs are those issued:
 - under Sec 84, on application to any person interested, on any of three grounds: (i) the “reasonable requirements of the public with respect to the patented invention have not been satisfied”; or (ii) “the patented invention is not available to the public at a reasonably affordable price”; or (iii) “the patented invention is not worked in India”;
 - under Sec 91, on application of any patentee or licensee, who is prevented or hindered on working his patent by some other patent; a CL may be granted for such other patent.

The legal considerations for Category II CLs are discussed first as this is the more general category; the Category I CLs are the special category and are dealt with subsequently.

1.2. Legal considerations

1.2.1. *The legal inquiry*

The starting point of any inquiry into the legality of the provisions governing the grant of CLs is whether they are violative of Art 14 of the Constitution which prohibits the State from denying any person equality before the law or the equal protection of laws within the territory of India. It is useful to briefly outline certain well settled legal propositions to aid the discussion:

- A legislation may fall foul of the fundamental right of equal protection if it confers an unguided discretionary power on the administrative authority in applying the law.¹
- Discretionary power, though wide, is not necessarily discriminatory when the legislative policy is clear from the statute² as also the principles or factors to be considered for the exercise of discretion.³
- The mere fact that a particular word or phrase is not defined does not render an Act unconstitutional as it can be judicially interpreted on a case-by-case basis.⁴
- If the legislative policy is clear, a discretionary power that is to be exercised with regard to the particular circumstances of the case is not discriminatory.⁵
- Executive guidelines cannot remedy an unconstitutional conferment of unguided discretion in a Rule.⁶
- It would be competent for the authority that exercises discretion to lay down guidelines in conformity with legislation to ensure fairness and exclude arbitrariness.⁷

¹ State of WB v Anwar Ali Sarkar, AIR 1952 SC 75

² Ramakrishna Dalmia v Tendulkar Justice SR, AIR 1958 SC 279

³ Tika Ramji Ch v State of UP, AIR 1956 SC 676

⁴ Benila v State of Maharashtra, 1995 Supp (1) SCC 235, para 4

⁵ Balbir Singh v MCD, AIR 1985 SCC 339, paras 9-10

⁶ Senior Supdt of Post Office v Izhar Hussain, AIR 1989 SC 2262

⁷ Union of India v Sangameshwar CK, AIR 1994 SC 612, para 21

Chapter XVI of the Patents Act confers discretionary powers on Controller to grant CLs and under certain special circumstances, to the Government to notify patents for which CLs may be granted. The general considerations for the exercise of these powers are set out in Sec 83 in sub- clauses (a) to (g). The legislative policy and the desired objectives sought to be achieved with regard to the working of patents in the context of the exercise of the discretionary power for the grant of CLs are clearly set out therein. It states that patents are granted to encourage inventions and to secure their working to the fullest practical extent in India and consistent with the TRIPS agreement, recognises that they contribute to technology innovation, transfer and dissemination to the mutual advantage of producers and users of technological knowledge and to social and economic welfare. The section also states that patents are granted to make the benefit of the patented innovation available at reasonably affordable prices to the public. What are not the objectives of the grant of patents are also clearly set out: a monopoly for the importation of the patented product, impeding public health or allowing abuse of patent rights by practices that restrain trade or transfer of technology.

1.2.2. *Category II CLs*

Sec 84 applications

The discretionary power of the Controller to grant CLs under Sec 84 is limited to cases which are founded on any of three grounds as outlined in 1.1.2 above.

The exercise of the discretion is guided by the considerations of Sec 84(6), namely the nature of the invention, the time elapsed from the granting of the patent, the steps taken by the patentee to work the invention and his ability to do so to public advantage, the financial ability of the applicant to work the patent if the CL is granted and the efforts made by the applicant to obtain a licence from the patentee.

Sec 86 provides further guidance for assessing the time that has elapsed from the granting of the patent while considering the grant of a CL. The Controller is required to consider whether the elapsed time was insufficient for any reason for the working of the patent to the fullest extent and he is empowered to adjourn the consideration of the grant of the CL, should he determine that further time is justifiably required by the patentee to do so.

Sec 89(a) reiterates the guiding principle of Sec 83(a) for grant of CL under Sec 84, namely that patented inventions are worked in the territory of India to the fullest extent that is reasonably practicable. Very importantly it provides a balance in favour of the interests of the patentee working or developing the patent in India by requiring that his interests are not unfairly prejudiced.

Sec 90 lays down the policy and relevant considerations for settling the terms and conditions of the CL. The procedure for dealing with applications for CLs under Sec 84 is set out in Sec 87 and includes notice to the patentee and the requirement of hearing the patentee or any other person opposing the application for CL. Rules 96 to 98 further specify the procedure to be followed.

Sec 91 applications

The discretionary power of the Controller to grant CLs under Sec 91 is limited to the ground outlined in 1.1.2 above. Sec 91(2) requires that the applicant satisfies the Controller:

- That the applicant is willing to grant or procure the grant of license of the patent that is intended to be worked by him on reasonable terms.
- That such patented invention (the working of which is hindered by the other patent for which he is applying for a CL) has made “a substantial contribution to the establishment or development of commercial or industrial activities in the territory of India.”

Sec 89 setting out the guiding principles for the grant of CL under Sec 84 is equally applicable to grant of CL under Sec 91. Sec 90 which deals with the terms of the CL and the procedure prescribed under Sec 87 and Rules 96-98 discussed above for dealing with applications under Sec 84 apply to applications under Sec 91 also.

In sum therefore, the only guidance governing the grant of CL under Sec 84 that is not applicable to licences under Sec 91 are those under Sec 83 and 84. This appears to be so as these considerations are not relevant or material to applications under Sec 91.

1.2.3. Category I CLs

Sec 92 applications

Sec 92 provides that if the Central Government is satisfied that CLs should be granted because of any of the special circumstances outlined in 1.1.2 in respect of any patent in force, it may make a declaration to that effect by notification in the Official Gazette.

The policy, guidelines and relevant considerations for the grant of CLs under Sec 91 also apply to the grant of CLs under Sec 92. In addition, the general considerations under Sec 83 are also specifically made applicable.

It is important to note that notification under Sec 92 can be issued only in the case of national emergency or extreme urgency or public non-commercial use. The question that arises is whether any additional guidance required for the Central Government itself to notify a patent under Sec 92 to exclude arbitrariness.

There are several reasons to think that there is no legal necessity to prescribe guidelines:

- The discretionary power of the Central Government under Sec 92 is not absolute, but restricted to national emergency, extreme urgency or for public non-commercial use, which are special circumstances in extreme situations and are normally clearly recognizable. The sphere is very limited and legislative policy and intent is spelt out.

- A case-by-case consideration is not necessarily arbitrary.
- The discretion is vested with the Central Government and not any single individual or minor functionary and such vesting is permissible in law.⁸

Sec 92A applications

This is the only provision in the Patents Act for grant of CL that relates solely to pharmaceuticals and is very limited in scope. The section is largely mandatory as CL 'shall be available' and the Controller 'shall...grant' a CL on receipt of an application for the manufacture and export of a pharmaceutical product under the conditions specified in the section and summarized in 1.1.2 above.

The inquiry of the Controller is therefore restricted to finding of fact – whether the specified conditions exist or not – and discretion is limited to the terms of the CL. While Sec 90 provides for the consideration of factors relevant to the terms and conditions for CLs granted under Sec 84, no guidance is available for CLs granted under Sec 92A.

It must also be noted that appeals to the Appellate Board are not provided for against orders of the Controller under Sec 92A. However, such orders are subject to judicial review under Art 226 of the Constitution.

1.2.4. Summary legal position

The legal position is summarised below with respect to the need or otherwise for further Rules or guidelines to govern the exercise of discretionary power to grant CLs under Chapter XVI of the Patents Act.

Grant of CL

It is obvious from the above that the discretion of the Controller to grant CLs under Sec 84, 91 and 92 or a notification of the Central Government under Sec 92 is not absolute, unguided or unfettered. It has to be exercised in the light of the principles, legislative policy, consideration of relevant factors and procedure laid down in the statute and Rules, which in effect constitute adequate guidance for the grant of CLs under these sections.

The patentee who may be adversely affected by the grant of a CL as well as any other person who may oppose its grant will necessarily have to be heard before any order is passed.

There are sufficient safeguards by way of appeal under Sec 117A against any order of the Controller or Central Government under Sec 84, 91 and 92.

The question of discretion does not seem to arise for *grant* of CLs under Sec 92A.

⁸ Matajog Dubey v Bhari HC, AIR 1955 SC 44 at p 48

Taken as a whole, the provisions relating to the *grant* of CLs cannot be said to be arbitrary or violative of Art 14 of the Constitution and no further Rules or executive guidelines are necessary from a legal perspective.

Terms and conditions other than royalty

The terms and conditions of the CLs granted under Sec 84, 91 and 92 are to be determined by the Controller in accordance with the provisions of Sec 90. Clauses (iv) to (ix) describe the relevant circumstances and factors for the various conditions and limitations that may be imposed by the Controller. These include conditions that the CL is non-exclusive, non assignable, for the remaining term of the patent unless a shorter term is desirable in the public interest and predominantly for supply to the Indian market but exports could be permitted if needed to develop or supply the export market.

The power of the Controller is therefore not absolute and unguided. Based on similar reasoning as in the case of grant of CL, it can be said that no further Rules or executive guidelines are necessary from the legal perspective with respect to CLs granted under Sec 84, 91 and 92.

There are no corresponding provisions for CLs under Sec 92A and understandably so, as the conditions of the grant are only for export to countries with insufficient or no manufacturing capacity on the ground of public health and where the destination country has already issued a compulsory licence or permitted the import (with conditions and limitations under the applicable national law) of the patented product. There is thus no material discretion to be exercised by the Controller in this regard.

Royalty

A contentious aspect of the grant of CLs is likely to be royalty. Sec 90(1) provides that the Controller “shall endeavour to secure” that the royalty or the remuneration awarded to the patentee is “reasonable”. Some of the relevant considerations have also been set out in clauses (i) to (iii):

- The nature of the patented invention and the expenditure incurred in making and developing it.
- The need to ensure that it is worked to the fullest extent possible by the applicant for the CL, at a “reasonable profit” to him.
- That the patented article is available to the public at “reasonably affordable prices”.

The Controller is required to consider the fixation of royalty in the light of the legislative intent summarized above, the general considerations and guiding principles in Sec 83 and 89 and taking into account other relevant factors.

From a legal perspective, it cannot be said (as reasoned earlier) that the provisions for determining royalty are absolute, unguided or arbitrary.

Additionally, there is persuasive justification for not framing any further Rules or executive guidelines for fixing royalty as this is obviously and eminently a situation that demands a case by case consideration of what is “reasonable”. The relevant considerations detailed above are specific to each case and best determined accordingly, including for CLs granted under Sec 92A.

1.3. Policy considerations

While there may be no requirement under law to provide any further Rules or executive guidelines for the exercise of discretion to grant CLs under Chapter XVI, it is doubtless open to the Central Government or the Controller (as appropriate) to issue guidelines consistent with the Patents Act and the Rules thereunder to exclude the possibility of arbitrariness or unfairness.

The issue for discussion is therefore whether executive guidelines are warranted by policy considerations.

It must be remembered that the power to grant CLs is applicable to all fields of technology. The field is so vast and unrestricted that conceptually, guidelines can only be general in nature. This is achieved by the statute itself. For example, if one analyses the scope of the discretion for grant of a CL under Section 84, the possible grounds are already limited to just three and the residual discretion is necessary as a practical matter:

- The first ground is that “reasonable requirements of the public” are not satisfied. The circumstances under which it will be deemed not to have been satisfied are specifically set out in 5 sub clauses (a) to (e) of Sec 84(7). The further determination specific to a case has to be necessarily determined on the facts and circumstances of that case.
- The third ground is one of fact – whether the “the patented invention is not worked in India.” While the meaning of “worked in India” could be a matter of controversy, that is a matter of one-time interpretation, not a matter of discretion.
- In effect therefore the Controller’s discretion is relatively wide only with respect to the second ground, namely to determine whether the patented article is available at a “reasonably affordable price”. This is obviously very specific to the circumstances of every case and it would be arguably counterproductive to set out guidelines, beyond those available in the statute itself, to determine this issue.

The futility of attempting to prescribe further guidelines also follows from the above. For example, how does one further ‘guide’ the exercise of discretion to determine “reasonably affordable price”? The price of a piece of complicated machinery may be in crores of rupees. It may be reasonable, given the costs and affordable to that segment of industry that uses it, but can hardly be the basis of a generalisation. To develop a more specific framework relating costs, price, income levels of the relevant customer segments and the like to arrive at what is a “reasonably affordable price” is a practical impossibility.

In sum, the concept of reasonableness is easier to comprehend in general and is more capable of consistent application to individual cases, than when it is sought to be ground down to finer detail. This is also consistent with Art 31(a) of the TRIPS agreement which requires the consideration of grant of CLs “on individual merits”.

It is certainly possible that individual decisions can be flawed. But the safeguard is that it can be appealed or judicially reviewed.

Other countries have also chosen not to provide any more detailed guidelines than those contained in the Indian Patents Act. For example, the Patents Act, 1977 in the UK bears a close resemblance with respect to the ambit of the discretion allowed to the comptroller to grant Licences of Right or CLs, though there are differences in the specific grounds and conditions prescribed. Policy considerations have not warranted the issue of further executive guidelines in the UK. It has been left to the judicial process to develop a body of precedent that further refines the application of the law on a case by case basis.

1.4. The IPA view

- The discretion of the Controller to grant CLs under Sec 84, 91 and 92 and 92A or a notification of the Central Government under Sec 92 is not absolute and has to be exercised in the light of the principles, legislative policy, consideration of relevant factors and procedure laid down in the statute and Rules, which in effect constitute adequate guidance for the grant of CLs under Chapter XVI of the Patents Act.
- Within this framework, the residual discretion is necessary for the equitable determination of the grant of CLs and the terms and conditions of such grant on a case by case basis. This is consistent with Art 31(k) of the TRIPS agreement which requires such consideration on the basis of “individual merits”.
- Relevant legal and policy considerations do not warrant the issue of further executive guidelines, including for the fixation of royalty, for the exercise of the discretionary power of the Controller or the Central Government.
- There are adequate safeguards provided by way of appeal or judicial review to an aggrieved party.
- The experience of the UK where the Patents Act, 1977 has conferred discretionary power to the comptroller for the grant of Licenses of Right and Compulsory Licenses, similar in ambit to the Patents Act in India, supports the continuance of the present statutory and administrative scheme.

2. ***Do the requirements for issue of a notification by the Central Government (national emergency; extreme urgency; public non commercial use) under Section 92 require amplification through issue of guidelines? Further are these grounds sufficient to meet all the circumstances and exigencies that may necessitate issue of a compulsory license? Does the term public non commercial use necessarily imply free distribution? Should such distribution be confined to government channels? Should drugs for treating diseases like cancer or diabetes should also fall within the ambit of CLs? Should such notifications be confined to public health emergencies? Are there other valid circumstances when such provisions can be invoked?***

- 2.1. As argued in 1.2.3 above, the circumstances of national emergency, extreme urgency and public non-commercial use enumerated in Sec 92 are clearly recognizable and require no further amplification through guidelines.
- 2.2. 'Public non-commercial use' requires that the patented article is not compulsorily licensed for commercial use in the normal course of business. There is no requirement that it should be distributed for free, though the price at which such article is distributed in relation to its cost, the section of the public to which it is distributed and the purpose as well as other relevant considerations would determine whether such use is 'public non-commercial use'.
- 2.3. Whether the three grounds for grant of CLs under Sec 92 are exhaustive of all circumstances or not is relevant only for a review of the statute and not for the purpose of determining the desirability or otherwise of issuing executive guidelines under the section.
- 2.4. It is not necessary that the articles covered by a CL granted under Sec 92 should be manufactured, imported or distributed only by Government. The channel of distribution may not necessarily be the determining factor of whether the article is being put to 'public non-commercial use'.
- 2.5. Whether patents for cancer and diabetes drugs (or for that matter any other article) can be notified under Sec 92 will depend on the justification relating to its use in conditions of national emergency, extreme urgency or public non-commercial use.
- 2.6. There are only three grounds, as enumerated in the section itself, for invoking powers under Sec 92. Public health crises relating to the specified diseases and other epidemics are deemed to be within the scope of one or more of the grounds specified.
3. ***How should recourse to issue of a compulsory license under section 92 and recourse to use by the Central Government of an invention under Section 100 be differentiated in the matter of use? Under what circumstances should each be invoked?***
- 3.1. Under Sec 92, a patent can be notified by the Central Government for issue of CL under three circumstances: national emergency, extreme urgency and public non-commercial use.

Under Sec 100(1), the Central Government and any person authorized by it may use the patented invention in accordance with the specified conditions. Sec 99 states that "an invention is said to be used for the purposes of Government if it is made, used, exercised or vended for the purposes of the Central Government, a State Government or a Government undertaking." It may also be noted that this includes, under Sec 100(6), "the right to sell on a non-commercial basis".

It is thus clear that Sec 92 is invoked under special conditions of emergency, urgency and public non-commercial use. Sec 100 is invoked for Government use. While the notification under Sec 92 is restricted by the existence of the three circumstances listed therein (and possibly uses that have a nexus with the

circumstances) irrespective of who uses it, the restriction under Sec 100 is Government use irrespective of the circumstances.

4. *Can products manufactured under a Category I license be effectively distributed solely through government channels? Does issue of Category I CL envisage sale of the compulsory licensed goods outside the ambit of government and in the market?*

4.1. Category I licenses have been defined in the Discussion Paper to include CLs issued under Sec 92 and 92A. The above question would not normally arise for CLs issued under Sec 92A as they relate to manufacture and export under the specified circumstances.

Whether Government can effectively distribute an article under a CL under Sec 92 will have to be evaluated by Government on a case by case basis. However, there is no restriction as to the use of private channels for the mitigation of the circumstances which led to grant of CL.

5. *The Competition Act 2002 does not explicitly provide for issue of Compulsory Licenses as a remedy for anti competitive practices. However, Section 27(g) empowers the Competition Commission to pass ‘such other order or issue such other directions as it may deem fit’. Further Section 90(ix) of the Patents Act recognizes that CLs can be granted to remedy a practice determined, after judicial or administrative process to be anti competitive. Should CLs be issued on the basis of anti competition law – if it is determined that companies have abused their dominant position in the market or engaged in unfair competition?*

5.1. Article 31 of the TRIPS agreement recognizes that the use of a patented article may be allowed under national law without the authorization of the right holder and sets out the conditions of such use that “shall be respected”. Clause (a) of Article 31 requires that such uses should be considered on individual merits. Clauses (b) to (f) set out the conditions under which such use can be permitted. Clause (b) requires that prior efforts must have unsuccessfully been made by a proposed user to obtain authorization from the right holder on commercial terms and clause (f) stipulates that such authorization shall be predominantly for domestic use.

5.2. Article 31(k) of the TRIPS agreement reads as follows:

“Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.”

Under Sec 51 of the UK Patents Act, 1977, a License of Right may be granted by the comptroller on application of the concerned Minister when a report of the Competition Commission is tabled in Parliament of a finding of certain anti-competitive practices. The national law of the UK clearly allows and permits Licenses of Right to be granted by the comptroller for certain anti-competitive practices.

5.3. In the absence of a corresponding provision in the Patents Act in India, the question that arises is whether Indian law allows or permits CLs to be issued for

monopolistic or anti-competitive practices under the competition law. There could be two views in the matter.

- 5.3.1. One view could be that abuse of dominant position, monopolistic and anti-competitive practices would inevitably lead to the patented articles not meeting the reasonable requirements of the public or not being available at reasonable affordable prices, or both. Therefore, just as a public health crisis is deemed to warrant the notification of the Central Government under Sec 92, a finding of anti-competitive practices should be deemed to satisfy the requirements of Sec 84(1). This would entitle an applicant to rely upon a finding of anti-competitive practices under the Competition Act to apply for a grant of a CL without further needing to establish the grounds in Sec 84(1). It will be argued that Sec 90(1)(ix) is supportive of legislative intent to this effect and additionally allows the Controller to permit exports under the CL, consistent with Article 31(k) of the TRIPS agreement.
- 5.3.2. The other view could be that even conceding that Art 31 of the TRIPS agreement permits the grant of CLs to remedy anti-competitive practices, India has not made use of this flexibility and a finding of abuse of dominant position or unfair competitive practices under the Competition Act is no ground to issue a CL under Sec 84. Sec 90(1)(ix) would be explained as a provision whereby exports may be permitted when there is a concurrent and independent determination of anti-competitive practices under the Competition Act.
- 5.4. As a practical matter, it is most likely that the abuse of dominant position or unfair competitive practices will result in satisfaction of the grounds specified in Sec 84 and justify the grant of a CL in accordance with that section.
6. ***Should working of a patent in the territory of India be interpreted to mean that it should be manufactured within the territory of India? Under what circumstances should the provisions of Section 84(7) (e) regarding working of the patent being prevented or hindered by importation from abroad be applied?***
- 6.1. Para 66 of the Discussion Paper sums up the opposing views on the meaning of working of a patent in India from a TRIPS perspective. As stated in para 66, one view is that Art 27(1) does not permit discrimination between articles manufactured locally and those that are imported. There has been significant debate on the issue as reflected in the extensive literature on CL.⁹ As also mentioned in para 66, there is the opposing view that the proper interpretation of TRIPS would allow CL if there is no local manufacture, mainly on the ground that Art 31, read with Art 7 and 8 would prevail over Art 27(1).¹⁰
- 6.2. As pointed out in para 67-68 of the Discussion Paper, the issue came up before the WTO Dispute Settlement Body (DSB) on a complaint by the US against Brazil, but as it was eventually withdrawn, there was no occasion for the issue to be adjudicated. The closest that the DSB has come appears to be in the *Canada*

⁹ See Kapczynski A, *Harmonization and its discontents: A case study of TRIPS implementation in India's pharmaceutical sector*, California Law Review, Vol 97, No 6, December 2009, 1586-87, fn 99 for an extensive listing. <http://www.californialawreview.org/assets/pdfs/97-6/2KapczynskiFINAL.pdf>

¹⁰ Citing Attaran A, and Champ, P: *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 Yale J. Int'l L. 365 (2002)

Pharmaceuticals case¹¹ where India was also an intervenor and the decision was that Art 27(1) is not derogated by Art 30 or 31. While not directly on the point of compulsory licensing and the local manufacturing requirement, this would imply that the major contention supporting CL on the ground of a local manufacturing requirement has not found favour with the DSB.

- 6.3.** If local manufacturing was indeed the policy intent of Parliament, the problem is also compounded by the amendment to the Patents Act with effect from 20.5.2003 Prior to its amendment, Sec 90(a) setting out when the reasonable requirements of the public were deemed not satisfied had this clause (ii):

“the demand for the patented articles is not being met to an adequate extent or on reasonable terms from manufacture in India” (emphasis added)

Subsequent to the amendment, the corresponding Sec 84(7)(ii) of the present Act reads as follows:

“the demand for the patented article has not been met to an adequate extent or on reasonable terms”

The deletion of the term “from manufacture in India” would suggest that importation would be permissible to meet the reasonable requirements of the public. On the other hand, Sec 83(b) which sets out the general principle applicable to working of patents, that “they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article” has been retained as is, without any amendment and non-working of the patent has been added as an independent ground for the grant of a CL under Sec 84. There is thus considerable ambiguity in whether the local working requirement is satisfied by local availability by way of importation or is restricted to local manufacture.

- 6.4.** Attaran and Chap believe that the decision of the DSB in *Canada Pharmaceuticals* is incorrect and suggest that a way over this difficulty would be for Member states amend their law in a manner which would take advantage of TRIPS flexibilities and restrict working of the patent to local manufacture:¹²

“Even if we assume, for the sake of argument, that Article 27(1) is paramount, non-derogable, and imposes limitations of non-discrimination on the exercise of Article 31, none of this forbids a law purporting to grant compulsory licenses in the “public interest.” Of course, there might be questions later if the wide discretion granted by that law were exercised discriminatorily, but that is a separate matter concerning the legitimacy of administrative decisions, rather than the substantive law itself. So far as the statute itself goes, what is to prevent Brazil from amending its law to read exactly like Section 24 of the German Patent Law:

If the . . . patentee refuses to permit the exploitation of the invention by another . . . offering to pay reasonable compensation and to furnish security therefore, that person shall be given authority to exploit the invention if the permission is indispensable to the public interest.

Permitting compulsory licensing on public interest grounds such as these is not irregular; at least nine of twelve Western European countries do so. The Brazilian courts would likely have little difficulty in determining that technology transfer, economic development, and possibly even cheap

¹¹ Panel Report on Canada—Patent Protection of Pharmaceutical Products, WT/DS114/R, 7.88-7.93 (Mar. 20, 2000), available at <http://www.wto.org> See Mota, SA: *TRIPS—Five Years of Disputes at the WTO*, 17 *Ariz. J. of Int'l & Comp. L.* 533, 545 (2000) for an extensive discussion on this case. The Panel ruling was not appealed.

¹² Attaran, A and Chap P, *op cit*, pp 392-3.

AIDS drugs, are “indispensable to the public interest”—all this and more could fit that elastic criterion. Far from conferring excessive latitude, a compulsory licensing law based on the public interest comports with the WTO Ministers’ recent Doha Declaration, which states that WTO members have “freedom to determine the grounds upon which [compulsory] licenses are granted”.....

.... Bearing all this in mind, the United States and other WTO members should concede that any grievance against local working requirements is probably not worth fighting. Any member risking a fight might get exactly what it asks for: the end of local working requirements, but in their place, far more aggressive “public interest” compulsory licensing laws.” (internal citations omitted)

- 6.5.** The notion of allowing compulsory licensing on the ground of public interest has found strong support from a public health perspective. A study commissioned by the Commission on Intellectual Property Rights, Innovation and Public Health (an independent Commission set up by the WHO) sets out the rationale of compulsory licensing:¹³

“The grant of patent rights enables the patent holder to prevent a third party from exploiting his invention. However, when reasons of public interest justify it, national authorities may allow for the exploitation of the patent by a third party without the patent holder’s consent or authorization. In such cases, the public interest of ensuring broader access to the patented invention is deemed to be more important than the interest of the patent holder in retaining his exclusive rights. Compulsory licenses can therefore play a crucial role in ensuring that patent laws are able to meet public health needs, and that patent rights do not unnecessarily holder or prevent access to affordable medicine.”

The study also reports on the implementation and desirability of compulsory licensing on the ground of public interest in developing countries:¹⁴

“A general public interest ground featured in most patent legislation of the Asian and Latin American countries. The Andean Community Decision 486 also provides for public interest as a ground for the grant of a compulsory license. In most cases, the public interest ground is broadly defined, leaving governments with the discretion to determine public interest in the particular circumstances. However, the term “public interest” does not appear to be a common feature in the laws of the African countries nor is it in the Bangui Agreement of OAPI. In Africa, the commonly-found ground adopted language incorporating “failure to exploit” a patent, or the “failure to supply or meet demand on reasonable terms”.....

In those cases where a public interest ground is broadly framed, it may be sufficient to encompass the public health needs in terms of ensuring access to medicines. Where the public interest ground is not available, it would be advisable for countries to review their laws to ensure that the compulsory licensing provisions are not unnecessarily restrictive.”

- 6.6.** As a practical matter, whether local needs are met through import or local manufacture may not be of significance in the context of compulsory licensing if the goods are available at a reasonably affordable price and the reasonable requirements of the public are met, as there is limited incentive or commercial justification for an applicant to apply for a CL under such circumstances. However, if the patented article is imported and highly priced, it is likely that one or both the other grounds of Sec 84(1) will be available, namely that the imported patented article is not reasonably affordably priced or that the reasonable requirements of the public are not met. No doubt, the burden on the applicant is heavier as he would need to prove

¹³ Musungu, SF and Oh, C: *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?* Study 4C, Commission on Intellectual Property Rights, Innovation and Public Health, August 2005, p 15

¹⁴ *Ibid*, p 18

the existence of these circumstances, than when importation is deemed to be non-working of the patent in India.

7. *How should the essential elements of a Category II CL outlined in Para 54 and 55 above be proved by the applicant to the satisfaction of the Controller?*

7.1. The onus is upon the applicant to show the grounds exist for the grant of a CL. Para 54 of the Discussion Paper notes that while Sec 84(7) sets out the conditions that need to be satisfied to establish that the reasonable requirements have not been satisfied, “there is no guidance available in the Act for determining” whether the patented article is available at a reasonably affordable price or the patent is worked in India.

7.2. As argued in 1.2.2 and 1.2.4, there is adequate guidance for the exercise of discretionary power under Sec 84 and 91 in the various provisions of the Patents Act itself. If there were no guidance, and the discretion is absolute, the power to grant CLs would be arbitrary.

7.3. The specific issue of exercising discretion to determine the existence of the ground of the patented article not being available at a reasonably affordable price has been discussed in 1.3 above. The onus is on the applicant to prove the existence of the ground and the patentee or licensee has the opportunity to put forth his case. Thus, there will be enough material available before the Controller to exercise discretion with respect to this ground on a case by case basis, guided by the provisions in the Act. To attempt to prescribe further guidance beyond what is available in the Act may be counterproductive. It is noteworthy that in the UK also, the implementation of legislative policy with respect to Licenses of Right has evolved over time in the light of judicial determination in a number of cases. The approach of considering each case on its “individual merits” is a salutary one, particularly in view of Article 31(k) of the TRIPS agreement.

7.4. Whether or not a patent is worked in India is a finding of fact and not a matter of discretion for the issue of guidelines. The main dispute will be with respect to whether importation will be deemed to be local working the patent. The Controller will need to take a view on this in general, rather than on a case by case basis. This aspect has been discussed in 6.1- 6.3 and 6.6 above.

8. *What should be the basis for royalty payments to compensate for CLs? Should a uniform stance be taken for Category I CLs; Category II CLs and Central Government use of inventions? Or should a differential approach be adopted?*

8.1. The issues and options have been summed up in Section XIV of the Discussion Paper (paras 56-63). In addition, the UK law has also evolved to identify three approaches to determination of royalty for Licenses of Right¹⁵:

- The so-called ‘Article 41’ (as it was the method of determining royalty under Sec 41 of the UK Patents Act, 1949) which took into account the recoupment of

¹⁵ *Terrel on the Law of Patents*, Sweet & Maxwell, London, 2000, 11.88-11.91. See also Khader, Feroz Ali: *The Law of Patents*, Lexis Nexis Butterworths, New Delhi, 2007, 22.79-22.86

research and testing costs, promotion costs and profit on the capital investment made in the project by the patentee.

- The ‘comparables’ approach, determining the royalty with reference to comparable licenses negotiated at arms length.
- The ‘profits available’ approach, which would lead to a division of profits between the patentee and the licensee, but is a method of last resort.

8.2. No distinction has been made in the payment of royalty between the grant of CL under Sec 84, 91 and 92 and all of them are subject to Sec 90. For CLs under Sec 92A, the terms and conditions may be specified by the Controller under sub-section (2), but without further elaboration. There does not seem to be any provision for the adoption of a differential approach.

8.3. Sec 90(1)(i) requires the “royalty and other remuneration” to be “reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors.” It is therefore incumbent on the Controller to take into account the specified factors as well as other relevant factors. This implies that the relevance or otherwise of every factor pleaded in the proceedings, both by the applicant and patentee have to be determined and assessed by the Controller.

8.4. It may not be immediately required to further specify the relevant considerations or basis of royalty at this stage. The patentee and applicant will advance their cases and cite all the available guidelines, the decisions in other jurisdictions and the principles insofar as they are relevant that have developed in the UK or elsewhere. The Controller will have sufficient material available to him to exercise his discretion equitably, having regard to the circumstances in each particular case.

9. *Should payments to the patent holder include a component of solatium as indicated in Para 62? How should such a solatium be arrived at? Should the aggregate royalty and solatium be fixed at say 10% of the generic price?*

9.1. Sec 90(1)(i) allows the payment of “royalty and other remuneration” and it may therefore be viewed as permitting solatium. However, this has to be decided on a case by case basis.

9.2. There may be no need to pre-determine an aggregate rate (or a maximum of such aggregate) of royalty and solatium, nor the basis that it should be related to the generic price. While the objective of CL is to make available a patented article at reasonably affordable prices and therefore the generic price is anticipated to be reasonable, it may nevertheless vary substantially from product to product and the “economic value”, costs incurred in development, anticipated size of the market and other relevant factors may also vary considerably. It may thus be appropriate for the Controller to determine royalty and other remuneration on the basis of the circumstances in the particular case.

10. *How can the operational constraints in the implementation of the August 30 decision be resolved during the course of issue of CLs under Section 92A?*

- 10.1. The situation has been summed up in paras 46-49 of the Discussion Paper. The operational constraints are materially in the country of import as it is necessary that they issue a CL or allow the import of the drug under patent to enable the issue of a CL under Sec 92A. The Controller has no ability to resolve these constraints in the importing country.
11. *While originally applying for a patent, the applicant is required to disclose complete specifications of the invention, as well as the best method for working it. However, there may be an incentive for the patentee to limit the description in the patent resulting in critical portions of the technology remaining undisclosed. This may cause delay in working of the CL. should such a problem of insufficiency of information in the Patent application arise in relation to the issue of a CL, how should it be addressed?*
- 11.1. The non-disclosure of the ‘best method’ or insufficient disclosure for working the patent would be a ground for revocation of the patent under Sec 64(1)(h) of the Patents Act. It is not anticipated that this problem will arise on account of a fear of compulsory licensing and even if it does, the remedy is revocation.
12. *Should the Controller be obligated to examine and take a final view on all CL applications within a specified time period? What should be this time period? Should this time period be the same for Category I and Category II CL applications?*
- 12.1. Category I licenses are issued under very special conditions which will be associated with extreme urgency. The Controller is a high functionary and it is not anticipated that the Controller will be indifferent to this urgency. It may therefore be unnecessary to provide any time limit for the grant of Category I licenses.
- 12.2. Category II licenses are where there is a significant public interest involved of satisfying reasonable requirements of the public at reasonably affordable prices. It is axiomatic that discretionary power carries with it a concomitant responsibility to exercise it promptly and without unconscionable delay. The discretionary power includes a power to adjourn applications for grant of CLs under Sec 86. It may therefore be unnecessary to provide time limits. Any such prescription in a statute will usually have provisions built into it that enable delays for reasons beyond the control of the Controller and cynics would say these provisions can be used to justify delays beyond a specified time limit.
- 12.3. As a practical matter, the most important factor that will ensure timely disposal of applications is the availability of an adequate number of expert personnel to assist the Controller. The IPA urges that this be accorded the highest priority in the first instance. One of the disincentives for the application of a CL is sometimes said to be the expectation that it would take an inordinate amount of time. This can be allayed by suitable announcements of intent of timeliness and allocations of adequate personnel to realize the intent.
13. *Should publicly funded Indian research organizations stipulate while selling/transferring patents to Indian private sector companies that the ownership of*

patents will revert to these organizations in case the ownership of those companies passes on to foreign hands?

13.1. This is in the domain of commercial licensing of patents and not related to compulsory licensing.