JAPAN INTELLECTUAL PROPERTY ASSOCIATION

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30h September, 2010

Shri Anand Sharma
Minister of Commerce and Industry
DEPARTMENT OF INDUSTRIAL POLICY & PROMOTION,
Udyog Bhawan,
New Delhi -110011,
India

Dear Shri Anand Sharma,

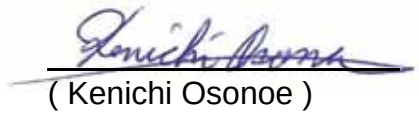
Re: Discussion Paper on Compulsory Licencing

The Japan Intellectual Property Association (JIPA) is a non-governmental organization that was established in 1938, which represents users of intellectual property systems. As an association having about 900 Japanese leading companies, JIPA submits recommendations and proposals to the relevant authorities and organizations with regard to the establishment of intellectual property systems overseas and improvements in the implementation thereof.

As for recruiting comments "Discussion Paper on Compulsory Licencing " on your website, we have often discussed since 2005 with Indian Patent officials in New Delhi, Mumbai and Tokyo. And we still continue to maintain an awareness of this issue today.

Therefore, we reviewed Indian Compulsory Licencing, and submit important issues for IP stakeholders.
Your deeply consideration on these matters will be appreciated.

Yours faithfully,



(Kenichi Osonoe)
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JIPA's Opinions on the Compulsory Licence in India

Japan Intellectual Property Association

JIPA hopes that the Indian patent authority will make clear in what circumstances compulsory licences for patents will be issued for public interest, and that it will give due consideration so as not to issue such licences in inappropriate situations.

In the event of a public health emergency on a national scale, such as an epidemic of HIV/AIDS, tuberculosis or malaria, compulsory licences should be issued for the purpose of providing effective new drugs at low prices for people suffering from these diseases. JIPA fully understands such necessity.

At the same time, however, it is also true that protecting patentees' interest is important. In particular, research and development of pharmaceutical products requires large investment. If drug manufacturers cannot recoup their R&D investment during the period of protection based on patents, they would not be able to further carry out research and development of new drugs, which leads to a concern that a number of people in need of such new drugs would not be relieved from their suffering. From this viewpoint, JIPA considers that compulsory licences for patents should be issued only in the event of a national emergency or any other equivalent extreme urgency.

JIPA requests that the Indian patent authority should fully exchange opinions with the relevant industries and corporations of other countries when considering the issue of a compulsory licence, and also requests that it should provide in the Patents Act or related rules and regulations that a compulsory licence shall be issued only in the event of a national emergency, giving due consideration so as not to issue a compulsory licence in an inappropriate situation.

In the section below, JIPA indicates its opinions on the specific issues addressed in Chapter XVII.

1. *Are guidelines necessary or required for the issue of compulsory licences? Can it be argued that it is inadvisable to fetter the discretionary power of government relating to the circumstances in which compulsory licences 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?

[JIPA'S opinion on Question 1]

In order to avoid the issue of a compulsory licence (CL) in an inappropriate situation, it is necessary to put in place guidelines regarding the requirements for the issue of a CL, the procedure for pre-issue negotiations, and the conditions for the Controller's decision. Even granting that the issue of Category I CLs is inevitable, JIPA considers that negotiations on a CL to be issued should be held with the patentee under the government's responsibility based on proper conditions on par with international and reasonable commercial conditions, and that the goods manufactured with the use of the compulsorily licensed patent and the quantity thereof should be controlled based on the conditions as agreed between the parties and under the control of the government. The issue of CLs should be limited to Category I.

The guidelines should not be restricted to royalty payment but JIPA requests that they should also include a provision that other types of compensation, such as a tariff reduction for the products relevant to those of the patentee for a certain period, may be available by option or negotiation.

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 licence? 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?*

[JIPA'S opinion on Question 2]

Amplification should not be allowed for any requirement. In accordance with Section 92 A (Category II) and thereafter, CLs should be issued under strict requirements regarding the disclosure of the name of the pharmaceutical product, export volume, and destination of export, the strict ban on parallel import, and the submission of the proof of recognition of the guidelines by the importing country.

The term “public and non commercial use” should not be construed to mean free (or gratuitous) distribution but should be construed to mean use for the public under the government’s responsibility.

Such distribution of the licensed drugs should not go beyond the bounds of the CL and therefore should be confined to government channels.

Such notifications should be confined to public health emergencies.

JIPA considers that the provisions on CLs should be applied only in limited cases such as national emergency and extreme urgency, but the issue of CLs may be inevitable in the event of risks of bioterrorism attacks or an epidemic of a new influenza virus.

3. *How should recourse to issue of a compulsory licence 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?*

[JIPA’S opinion on Question 3]

JIPA has no particular comment on this issue.

4. *Can products manufactured under a Category I licence 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?*

[JIPA’S opinion on Question 4]

As stated above, such products should be effectively distributed solely through government channels. The issue of Category I CLs does not envisage sale of such goods outside the ambit of government but in the market.

5. *The Competition Act 2002 does not explicitly provide for issue of Compulsory Licences 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?*

[JIPA'S opinion on Question 5]

CLs should not be issued on the basis of anti-competition law. Since anti-competition law and patent law protect different legal interests, JIPA finds a problem with issuing CLs on the basis of the former law.

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?*

[JIPA'S opinion on Question 6]

As the "export" of the patented article is included in the scope of "working of a patent" under the Indian Patents Act, the definition of "working of a patent in the territory of India" should not be limited to domestic manufacturing. Also in accordance with the purport of Article 5A(1) of the Paris Convention, the application of Section 84(7)(e) on the grounds that the domestic working of the patent is prevented or hindered should be avoided.

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?*

[JIPA'S opinion on Question 7]

From the viewpoint in line with the answer to Question 6, JIPA considers that such proof should be required only with regard to the elements outlined in Para. 54 a), and should be produced based on objective evidence through quasi-judicial proceedings in which the patentee takes part.

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?*

[JIPA'S opinion on Question 8]

The principal basis for compensation for CLs should be the amount equivalent to the royalty payable for the products manufactured with the use of the licensed patent and the quantity manufactured, and the amount equivalent to the royalty payable for the volume of products imported and sold in the importing country. Licences for patents held by third parties that are requisite for the working of the patented invention covered by the CL should be treated separately. CLs should be limited to Category I, and even when Category II CLs are issued, the approach to be taken in terms of compensation for Category II CLs should be different from that for non-commercial Category I CLs.

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?*

[JIPA'S opinion on Question 9]

Payments for a CL should be negotiated with the patentee based on proper conditions on par with international and reasonable commercial conditions, and solatium may be one of the components of such payments. Since the prices of Indian generic drugs are often extremely low as compared to international standards, the total of the royalty and solatium should not be fixed at a certain percentage of the prices of generic drugs in India, but should be determined separately through proceedings involving the parties (e.g. the patentee), while taking into account the prices in other

countries and various other circumstances.

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?*

[JIPA'S opinion on Question 10]

An application to be made to obtain export permission from the TRIPS Council must be objectively persuasive, and the parties concerned should be notified of such application promptly.

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?*

[JIPA'S opinion on Question 11]

JIPA considers that there is no necessity to meet the request for further disclosure of information because the information disclosed in the specifications is sufficient for third parties to carry out follow-up experiments, and generic products have been manufactured without such problem of insufficiency of information.

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?*

[JIPA'S opinion on Question 12]

Even granting that such time period, by nature, should be specified depending on

the degree of urgency, due process must be guaranteed for the parties concerned (e.g. the patentee). This time period should depend on the degree of urgency, rather than the categorization of CL applications (Category I or Category II).

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?*

[JIPA'S opinion on Question 13]

Under the principle of freedom of contract, the contract details on this issue should be decided between the parties concerned.

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