CUTS INTERNATIONAL

COMMENTS ON DISCUSSION PAPER
SUBJECT: COMPULSORY LICENCING

S No.	Issues for Resolution	Comments
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?	1. The Patent Law has created a robust and comprehensive compulsory licensing system in India. Compulsory licensing provisions are envisaged as striking a delicate balance between the needs of technology consumers and producers. In a developing country such as India, compulsory licensing is probably the most effective safeguard against the potential abuse of monopoly by patentees. However, government discretion should not be fettered with in case of grant of CL category I given that CLs in this category can be resorted to in case there is a national emergency, extreme urgency or for non commercial use. 2. Patients would benefit if the Government has effective system for granting and implementing compulsory licensing, this is an important move as it will ensure that consumers in India are assured of affordable drugs. Indian drug companies will also benefit as they will be able to produce drugs ahead of the patent expiry which will give them a headstart in other markets. 3. Under Section 84 of the Patents Act, an application for the grant of compulsory licence can be made to the Controller of Patents only after the expiration of three years from the date of the grant of a patent. In a world where diseases spread in epidemic proportions, a monopoly to manufacture and market a life-saving drug for three years can result in certain havoc. The Section also requires the person making the application to set out the nature of interest and provides an opportunity for the patent holder to oppose the application. All this may sound fine in the interest of natural justice, but as compulsory licensing would be resorted to in emergency situations (this is besides grounds provided under section 92); any difficulty in seeking a

		grant would unnecessarily delay the process. Delay in getting access to life saving drugs would literally be a matter of life and death. 4. The procedure under section 84 & 85 may therefore result in prolonged litigation through opposition by patentee and may lead to be more cumbersome. Whereas the patentee may be paid royalty, his opposition should be dispensed with in case of CL category I. 5. Provisions such as section 87 (2) read with Rule 98 should be simplified and the time prescribed for notice of opposition stated in Rule 98 (1) as well as the hearing be reduced in order to facilitate quicker sanction of CLs in category II. 6. The process must be changed to facilitate routine and expedited compulsory licensing of important medicines. A strictly enforced deadline of one to three months should be established for the grant of a compulsory license, and rights of appeal should not include permission for injunctive relief that would impede the use of the license.
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	1. TRIPS Agreement of the WTO does not provide for guidelines, and jurisprudence has upheld public interest including in particular availability of affordable medicines. Therefore, guidelines may constrain juridical interventions in public interest. However, guidelines can be issued in procedural aspects of implementation of CLs such as royalty etc. 2. Similarly guidelines are not essential as mentioned especially in case of CL in category II with respect to grant of CL as the standards and conditions have been laid down sufficiently in the Act. Nonetheless, guidelines may serve a purpose only where subjectivity is involved and therefore guidelines may be provided in setting time period for grant of CLs or in other procedural aspects. 2.Public non commercial use should necessarily mean supplies through

		government authorised outlets for free distribution and may also includes lowest price if not free distribution especially in case of CL in category I. The term can also mean government subsidising purchased medicines as non commercial can also be interpreted to mean where welfare state provision of good sis ensured. 3. Yes, CLs should include drugs for cancer, diabetes etc and it is in line with the Doha Declaration on TRIPS and Public Health which states that the TRIPS Agreement does not and should not prevent Member countries from taking measures to protect public health. Thus chronic diseases can also be addressed by way of these provisions. Confining such notifications only to public health would be restrictive especially when the word 'public health' has wider meaning.
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?	CLs under section 92 can be obtained on application made at any time after the patent is granted. It is meant to be issued on grounds of national emergency, extreme urgency and in case of public non commercial use. Further as mentioned above such CLs should be operated through a government manufacturing unit/outlet or a public sector undertaking and that such provision under section 92 is invoked in case of public health and should be applied to essential drugs. Section 100 states that the rights to make, use, exercise and vend an invention for the purposes of government which includes the right to sell on non-commercial basis. This means the government is empowered to manufacture or cause to manufacture patented products and sell them without profits. This also means that in case of absence of any government units/PSUs or second manufacturer for manufacturing of essential drugs, section 100 of the Act can be invoked.
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	The products under CL category I should be effectively distributed through government channels by putting in place proper and efficient distribution system. However, the circumstances for sale of compulsory goods outside the ambit of government and in the

	and in the market?	market should be provided only under special circumstances as it may in usual parlance have likelihood of contravening the TRIPS Agreement.
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?	In a developing country such as India, compulsory licensing is probably the most effective safeguard against the potential abuse of monopoly by patentees. Sec 27(g) has to be given ejusdem generis interpretation (general words following specific should be interpreted accordingly). This implies "other order or issue such directions", have to be interpreted in light of foregoing penalties mentioned in subsections (a) to (f). Consequently, it would not be within the powers of Competition Commission to grant CL, as a remedy for anti competitive practices. However, Commission may ordain delinquent enterprise to slash down the cost of their product, this is within the mandate provided by the legislature. CLs must be given as a result of indulgence in anti –competitive behaviour by firms. But to avoid frictions between the departments and effective enforcements of laws. Competition Commission can carry out such investigations and then can make a direction to patent authorities to grant CL Grant of CL as a penalty for anti-competitive behaviour should not be construed or given effect to in light of Sec 84 of Patents Act. This implies that action can be taken before expiry of three years from the date of ceiling of patent and a license holder should not be provided any opportunity to defend licence. The reason for grant of CL under Competition Laws and Patent Laws although have same greater objective of Common welfare, they differ in as much as the scope of these two laws and authorities under them are concerned
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	According to the available IP literature and development economists, working refers to 'availability' which includes imports as long as the availability is ensured credibly. Based on this literature, it may be useful to use 84 (7) (e) only to ensure that imports are credibly going to make drugs available. CL is

	patent being prevented or hindered by importation from abroad be applied?	precisely the route through which inadequate imports can be taken care of. Further, India's compulsory licensing provision is now more important than ever since India passed the revised Act. India needs to encourage the continued success of the generic drug industry by allowing compulsory licenses. Like all the other developed and developing countries India should take some reasoned protective measures for the domestic industry.
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?	Availability, accessibility and affordability should be construed as satisfactory elements for granting of CLs in Category II. However, judicial discretion should not be constrained for reasons mentioned in 1 & 2 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?	A differential approach could be adopted for royalties in case of Category I and II of the 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?	No comments
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?	Section 92A provides for compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. Thus, this section is an "enabling provision" for export of pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector in certain exceptional circumstances, to address public health problems. Such country has either to grant compulsory license for importation or issue a notification for importation into that country. However, unless cumbersome notification procedures contained in the TRIPS and Public health para 6 system are reconsidered by the WTO membership, existing provision should not be disturbed
11.	While originally applying for a patent, the	Private Public Partnership could be

	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?	effectively used in this regard wherein the process or product could be developed jointly and such situations can be handled
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?	Yes, the controller should examine and should take final view on all CL applications within a specified time. The time period should be reasonable keeping in view that the objective of CL especially in category I Is not defeated. There should be different for both types of CLs.
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?	Yes, in case of mergers and acquisitions of Indian companies in future with MNCs, value of patents could be calculated on the basis of original research costs, royalty for the life of patent.