FICCI's POSITION ON COMPULSARY LICENSING

INTRODUCTION

FICCI lauds the efforts of the Department of Industrial Policy & Promotion (DIPP) in bringing out a discussion paper on Compulsory Licensing. The invitation in its current form to various stakeholders is certainly a welcome step and will prove to be helpful in accomplishing the objective of developing a predictable environment for use of such measures and will eventually enable the Government to take an appropriate policy decision at the appropriate time.

Pursuant to the objective of the discussion paper, given below is FICCI's position on various contours of compulsory licensing as enlisted in Schedule XVII of the discussion paper.

GENERAL COMMENTS

1. CL provisions in Indian patent law appear to be liberal and make use of the flexibilities provided in the TRIPS Agreement almost fully.
2. The effectiveness of these provisions in the post TRIPS era has not yet been tested properly. There have been no applications for CL except two requests under Sec 92 A. But those two requested suffered from initial infirmity in that they did not have minimum essential documentation such as notifications by the least developed country concerned.
3. There has been no instance of any application on account of either national emergency or non-availability of an essential drug or on account of the price of an essential drug.
4. There has been no empirical study to find out the reasons for non-resorting to CL by Indian pharmaceutical sector. Only a thorough investigation into the whole matter can bring out the shortcomings of the existing provisions on CL including the procedural aspects. This study should look into the legal, economic and public health aspects of the issue. This study should particularly examine whether public health in India suffered for want of use of CL and whether it would have been better had the CL provisions been used. It should also bring out the reasons for Indian pharma companies not exploring the CL route.
5. CL procedure should be simple and easy to follow.
6. It is not necessary to have CL for all diseases. For common sicknesses without any significant health impact and for which multiple medicines are available, it is not necessary to go for CL.

7. It is also ordinarily not necessary to go for CL for generic medicines, unless there is an acute shortage of such medicines or they are priced very high.

8. CLs should be reserved for health emergencies such as epidemics and non-availability of essential drug at a reasonable price.

9. Use of CL should not serve as a disincentive to investment in drug discovery.

10. Individual cases will have to be examined on their own merits.

11. Guidelines should not make things more constrictive. The objective should be facilitation of entry of newer and better drugs in the market and their easy availability at an a reasonable price. Therefore, CL should not be used routinely, but only in exceptional circumstances.

12. In the absence of an application procedure, selection of a company to manufacture a CL product will lead to many complications. For one a company should be capable and willing to manufacture the product and for another there should not be any discrimination among companies.

XVII. Issues for Resolution:

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?*

Though guidelines do provide support giving an aura of predictability to the interested parties who need to know how an agency would respond to the matter at hand but such guidelines cannot take away the discretionary power when it comes to law enforcement. Further, such guidelines do not have a legal sanctity. Given that TRIPS (Article 31(a), reproduced below) agreement gives enough flexibility to member countries on granting of compulsory licenses but it does put a condition for giving it on a case by case basis. Since one is required to evaluate each case on its individually own merits one would argue as-to what purpose would a uniform set of instructions serve and how they can be universally applied in each case.

If guidelines are issued, more often than not, the Controllers would heavily rely upon these guidelines and would try to fit each and every case into these guidelines and reject or grant the License based on these guidelines. In other words, they would hardly use their discretion.

Assuming for arguments sake that guidelines are issued and the Controllers use them, the orders passed by the Controller would be challenged before the High Court, who would in any case issue directions that may override the guidelines.

It would however be worthwhile to supplement the Manual of Patent Practice and Procedures (MPPP) with exhaustive reference and learning materials, i.e. in the form of a booklet, which will contain cases of grant of compulsory license abroad, the conditions under which such licenses were issued, the royalty paid, the method of calculating royalty, etc. Such materials would not only educate the Controller but would be exhaustive enough and give wide space for the Controller to issue his discretion.

Since so far India has not witnessed any case of issuance of Compulsory Licensing in the pharmaceutical sector, it would therefore be very difficult to cite any cases in the manual whereby an applicant for the issuance of compulsory license could get some idea about how Government in past has applied her wisdom in grant of compulsory license. Reference may be made to the Patent Office manuals of Japan, Europe, Canada and UK which provide useful tips and guidelines on grant of compulsory license.

We would also like to highlight here that, while it is a laudable effort on the part of Government to seek public inputs on how Compulsory licensing provision may be modeled in such a way so that there is upsurge in its usage by the relevant set of stakeholders so that affordable drugs are made available to public at the earliest, the existing provisions/regulations (such as Drug Controller General of India approves the marketing of generic drugs, during the term of patent grant, in case it is safe and effective) and judicial pronouncement (There have been instances where the Judiciary has decided the cases on grounds of public interest attributing high cost of drugs) are also harmonious with the objectives of issuance of Compulsory License.

Para 27 - 30 of the discussion paper on compulsory license, made available on the website of Department of Industrial Policy and Promotion, brings to the public notice a recent trend of takeovers of the Indian companies by foreign MNC majors which has potential to orient the Indian companies away from the Indian market. Keeping in view the recent trend one might argue as to what purpose would it solve in case the issuance of CLs is made more user-friendly. We attach (annexure I) the list mergers & acquisitions and strategic alliance which have taken place, as per which:

- Out of the top 39 Indian pharma companies, six have been acquired by foreign MNCs namely, (matrix, Piramal Health care, Ranbaxy, Wockhardt, Ventex, and orchid Pharma) and 17 Indian companies are in strategic alliance with the foreign MNCs

- Out of the 15 top biotec companies, two of the company Shanta Biotec and Tibo tech have been acquired by a foreign MNC.

- The key suppliers in Ayurveda are Dabur, Baidyanath, and Zandu, which together have about 85% of India's domestic market. Rest all are very small manufacturers. Out of these three companies the pharma arm of Dabur has been taken over by a German Company Frescenius Kabi.

There is a need to analyze the impact of this especially on the generic industry in India and possible effect on availability of medicines currently under price control.

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?*

We are of the opinion that amplification of the requirements u/s 92 will not serve any purpose unless the compulsory license granted under Section 92 of the Patent Act, 1970 is kept out of the blanket coverage of other provisions mentioned u/s 92(2) dealing with the grant of compulsory license. As per section 92(2), for the grant of compulsory license (in case of national emergency, extreme urgency or public non-commercial use), one is obliged to follow a very cumbersome procedure which involves serving upon of application to the patentee followed by complete opposition procedure. Emergency situations require expediency and to go through the usual cumbersome and long procedures for grant of compulsory license would defeat the very purpose of compulsory license in such cases of emergency i.e. to give the public timely access to essential medicines. Instead of following the usual procedures of opposition for compulsory licenses we feel that it would be enough if the government may just notify the patent holder of the grant of compulsory license and at the same time affixing an adequate rate of royalty which will be paid to him as is usually done under such circumstances. It wouldn't be rational to follow the same procedures as one has to go through for a grant of a normal compulsory license u/s 84. Until and unless the long delays and time lags are removed from the above-mentioned section, even the amplification of requirements mentioned will not serve any purpose. This stance also finds support in Article 31(b) of TRIPS which allows member states to let go of the requirement of following the usual compulsory licensing procedures under circumstances of an emergency. Thus, to bring in effect the above made assertions, a suitable amendment will have to be made in the Act itself in this regard.

The grounds cannot be amplified without amendment in law, i.e. amendment of the Act. Notifications that are issued under Section 92 must be confined to cases of national emergency,

extreme urgency and public non-commercial use. Public non-commercial use is a term with wide amplitude in the sense that any product (irrespective of the therapeutic area) can be covered under this category. For instance, a drug useful against brain tumor or renal cancer could also come under this category.

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?*

Grant of compulsory license under Section 100 and under Section 92 has different implications as explained hereunder:

Description	*Section 92*	*Section 100*
Circumstances	*Under circumstances of national emergency, extreme urgency, public non-commercial use*	*Use of the invention for purposes of government.*
When CL can be issued	*After a patent is granted*	*After an application is filed or after a patent has been granted*
To whom the license may be issued	*To any party, i.e. any company for retail supply*	*To any party, i.e. to any company for supply to the government and not for retail supply.*
Whether commercial use permitted	*Yes, commercial use by third parties is permitted. In fact, the license is issued by the government to third parties for commercial use.*	*Use is exclusively by government for its own purpose, i.e. distribution through government hospitals at a certain reasonable price.*
Royalty	*Reasonable royalty to be paid to patentee*	*The license issued is free of royalty or any remuneration to the patentee.*

As can be seen from the table above, the power vested with the Government under Section 100 is very wide and can be employed under any conditions for any disease, whereas the power under

Section 92 can only be exercised under conditions of extreme urgency or national emergency. Thus, there is a fundamental difference in the approach of the two provisions.

Further, the license granted under Section 100 would only enable sale of the generic version of the drug through Government channels, whereas license under Section 92 would enable sale of the product in the open market.

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?*

Yes, the issue of Category I CL does envisage sale of goods outside the government, i.e. in commercial market. Moreover, the products manufactured under a Category I CL can be effectively distribution through government as well as non-government channels.

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?

Yes, compulsory license should be granted if it is determined that companies have abused their dominant position in the market or engaged in unfair competition.

It is true that Competition Act and the Patents Act have no direct link with each other i.e., cross-referencing provisions. However, certain commercial transactions could be scanned by the watchful eyes of the Competition Commission and could be called in question.

The Federal Trade Commission of USA as well as the European Commission is very vigilant against anti-competitive practices and in many cases that have come up before the Commission, the FTC as well as the EU commission has issued compulsory license on the grounds of abuse of dominant position. To that extent, the FTC as well as the EU have issued guidelines for the authorities to examine anti-competitive practices and issue licenses if circumstances so warrant. There are cases (e.g. the Kodak case), when the patentee refused to issue license and the Court has held that such refusal is anti-trust violation; similarly, the European Court of Justice has held in the IMS health case that refusal to issue compulsory license by copyright owner is an abuse of its dominant position. These propositions are yet to be tested in India under the Indian laws. It has also been reported that compulsory licensing was a frequently applied remedy in US in the 1940s and 1950s, with 107 antitrust settlements between 1941 and 1959 calling for such

licensing or dedication of between 40,000 and 50,000 patents[1]. In 1956 alone, IBM and AT&T were required to license more than 9,000 patents, many royalty-free.

There is no reference in the Patents Act to the Competition act and vice-versa.

In a case where the patent holder charges higher prices, it may be argued as an abuse of dominant position.

Assuming for arguments sake that a case of abuse of dominant position is made out or a case under Section 27(g) is made out, then the Competition issuing a license Commission has to hold an enquiry, pass a reasoned order, which is subject to appeal and after it is finally decided by the Supreme Court, that there has actually an abuse of dominant position or a case under Section 27 is made out, then with such order the Applicant can approach the Controller for issuance of compulsory license. As you can see it is a long drawn process.

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?

Throughout the Act the word used is "working of a patent". Nowhere has it been specifically stated that "working" means manufacture of the product within India. However, one can take a nationalistic view that working should be interpreted as working within India, i.e. manufacture within India.

TRIPS:

Article 27.1 of TRIPS states that patent rights will be enjoyed without discrimination as to whether a product is imported or produced locally. Further if one were to examine Art 30 and 31 of TRIPS a harmonious reading would enable a country to maintain a provision requiring local working. Hence as per TRIPS which is ambiguous in wording, it does not matter whether a patented product/process is imported or produced locally, the question is whether it is being used in India. An article by Paul Champ & Amir Attaran which is published in the Yale Journal of International law (YJIL) provides an in-depth look into the question of TRIPs compatibility. In the YJIL article the authors go through the entire negotiating history of the TRIPs agreement and point out how the same is inconclusive in establishing whether or not the member states actually wanted the insertion of a 'local working requirement'. The authors conclude stating that TRIPs does permit members states to maintain a 'local working' requirement.

[1] Michael A. Carrier, Unravelling the Patent-Antitrust Paradox, University of Pennsylvania Law Review, Vol 150. No. 3, 2002.

Brazil: Brazil had amended its IP laws, especially the patent law, providing that working requirement would mean 'local working'. Brazil was taken to WTO by USA- India joined the dispute as an interested party. Eventually, US found out that one of its own local provided for mandatory local working in case of publicly funded invention, and US withdrew the complaint, reserving its rights to file a fresh one later. Turkey: Same is the case with Turkey. There is a provision in Turkish law that the working of patent be complied with strictly. It does not expressly state that working means 'local working' but the Patentee has to demonstrate that the requirement is met by importation or by local working and in absence of either, the patent is subject to compulsory licensing.

Hence from the above it can be concluded that India can take the view that 'working' means local working as this would also facilitate in Tech Transfer. However, consideration should be given in such cases where it is difficult to manufacture a particular drug in India owing to the climatic conditions. Research needs to be carried out in this area.

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?

Yes, it is correct that the essential elements outlined in para 52 and 53 should be proved by the applicant to the satisfaction of the Controller. The applicant would have to submit evidence by way of documents as well as affidavits to prove the facts outlined in para 52 and 53.

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?

The Government may like to follow the WHO remuneration guidelines on patented medical technologies to adhere to international practices since it has to address the issue of adequate compensation being made to the patent holder after the grant of compulsory, available at http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf

Principles:

a) royalty – not to make good any loss: It should be noted whenever royalty is fixed under compulsory license provisions, such royalty is not to make good the losses that the patentee would suffer; it is only a small amount to be given to the patentee in recognition of the fact that he had made the invention. This is completely opposed to the category of general licenses, wherein the rate of royalty is to allow the patentee to earn and make profit from his invention.

b) Govt. has absolute right to fix royalty- no negotiation with patentee: Another aspect is that the royalty has to be fixed by the Controller/Government; not to be demanded by the

Patentee. The provision has no room for allowing the patentee to demand a royalty, and there is no room for any negotiation thereafter.

With this background it is but natural that the royalty rate for Category I and Category II cannot remain the same. In fact, it would vary from product to product. There of course might be an upper limit and lower limit which is fixed by the Government.

As a thumb rule, the royalty all over the world does not exceed 5% to 8%. The minimum royalty is 0% to 4% of the price indicated on the invoice to the company. It would not be proper to take a uniform stand in all categories of inventions, pharma and non-pharma. It should be dealt with on a case to case basis. However, a broad range can be fixed and be made known that royalty will not exceed 5% or as may be determined by the government.

Examples:

Country	Drug	Patentee	Disease	Year	royalty
Thailand	Kaletra	Abbott	AIDS/HIV	2007	0.5%
Thailand	Plavix	sanofi	Heart disorders	2007	0.5%
South Africa	ritonavir, lamivudine, ritonavir+lamivudine and nevirapine	GSK. Boehringher	AIDS/HIV	2001	Upto 5%

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?

With the background that the patentee is not to be compensated fully or in such a manner so as to make good any losses, the royalty has to be fixed at a minimum so that his rights are recognized whilst at the same time the payment of royalty is not burdensome for the licensee to even work the invention. In fact, if a royalty of 10% is fixed, the generic company may find it unviable to manufacture the product and sell in the market in a cost effective manner; it may actually scale up the price of the product in the market.

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?

Operational constraints can be resolved if the TRIPS Counsels issue fresh guidelines or if the provisions are interpreted by the Court.

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?

If a patentee does not disclose the complete invention in the specification, the patent should be refused for insufficiency under Section 10(4) read with other provisions of the Act. In such cases the Controller should not grant the patent and if granted, it should be revoked. If such patent has been granted, the same can be revoked under section 25 (2) or section 64 (h).

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?

Processing of CL application should not take ordinarily more than 3 months.

As has been explained before, those circumstances of national emergency enshrined u/s 92 require expediency. Valuable time would be lost in case of an endemic or other similar outbreak. It would thus be wise if the government suo moto issues a compulsory license and affix some royalty to be paid to the patent holder and exempt such cases from the requirements mentioned u/s 92(2) which may cause undue delay in giving the needy timely access to medicine during such an outbreak. Article 31 of TRIPS also provides enough discretion in this regard under circumstances of national emergency which one should make use of. As far as the other instances of issuing compulsory licenses are concerned i.e. 84, 100 etc., India should continue to follow the usual procedures as required by TRIPS and which is already being done so in the said sections. However, it would only help to expedite the matters of procedures under these sections also and streamline them to finish within 3 months.

Yes, the Controller should be obligated to examine and take a final view on CL applications within specific period such as 6 months. In case of Category I applications it may be expeditious, i.e. within 2-3 months or even earlier.

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?

This is a very good suggestion from national pride angle. At the same time, it imposes a restriction on the commercialization of patents by public funded research institutions. It is also necessary to examine the impact of the proposed condition on the bill before the Parliament about public funded research. Further, what will be the impact if developed countries too

imposed such a condition? Will this not have an impact on assessment of IP valuation of a company's assets?

This may not be possible to execute via contracts. One a research/technology is assigned, the ownership changes hands and any 'such' stipulations restricting the new owner become void. Thus, it will not be possible to enforce such contracts if challenged. If however the contract is only a license given by the public funded research institution which entitles another entity to use such research on the condition that the contract would be revoked if they allow foreign entities to use the same then the same may be valid as the ownership would still be retained in this case.

This is a good condition that may be imposed because public funding is involved. However, it must also be borne in mind that if the patent reverts to the public funded research organizations, the patent might actually lay in the hands of the people who cannot commercialize it since the power to commercialize vests only with the industry.

ANNEXURE I:

Sno.	Website	Taken over by Pharma MNC				Strategic Alliance				Proposed Acquisitions
		Company Name	Origin	Stake	Year	Company name	Origin	Product	Year	
1	www.alembic-india.com									
2	www.alkemlabs.com					Taro	Israel	antibiotics	2006	
3	www.aurobindo.com									
4	astralpharma.com					Sagent Pharma	USA	Injectable Antibiotic	2007	
5	www.bluecrosslabs.com									
6	www.cipla.com									GSK or TEVA
7	www.cadilapharma.com					Novavax	USA	VLP vaccines, cance	2009	
8	www.drreddys.com					GSK	UK	Selected products	2009	Pfizer
9	www.elderindia.com									
10	www.lillyindia.co.in									
11	www.emcure.co.in					Bristol-Myers Squibb	US	ARVs	2006	
12	www.glenmarkpharma.com					Swiss subsidiary of G	US	asthama	2004	
13	www.granulesindia.com					Heritage	US	Selected drugs	2007	
14	www.heterodrugs.com					Roche (during bird flu	Switzerlan	Tamiflu	2005	
15	www.indswiftlabs.com									
16	www.intaspharma.com									
17	www.jubl.com					JV with Eli Lilly	US	drug development se	2009	
18	www.lupinworld.com					Forest Labs	US	AeroChamber plus	2008	
19	www.meyer.co.in									
20	www.matrixlabsindia.com	Mylan	US	71.5	2007					
21	www.morepen.com					MorepenMax (JV with	US		2002	
22	www.orchidpharma.com	Hospira	US		2010					
23	www.piramalhealthcare.com	Abbott	US		2010					
24	www.grotius.com					Dalton Pharma	CANADA	Contract Chemistry S	2009	
25	www.plethico.com					Molekule GbmH		Herbal and Nutraceu	2008	
26	www.ranbaxy.com	Diachii Sankyo	Japan	64% (in year	2008					
27	www.sunpharma.com									
28	www.suryspharma.com									
29	www.suven.com					VPSCRO China		clinical services	2008	
30	www.tabletsindia.com									
31	www.torrentpharma.com									
32	www.twilightlitaka.com									
33	www.usvindia.com					http://www.usvindia.com/htmls/markets/alliances.html				
34	www.unichemlabs.com					Korean GnSouth Korea		Urokinase	2000	
35	www.vetnex.com/	Pfizer	US		2009					
36	www.venusremedies.com									
37	www.wockhardtin.com - Veterinary arm	Vetoquinol	US		2009					
38	www.syduscadila.com					Gulin Phan China		Falcigo	1995	
39	www.paraspharma.com									Sanofi Aventis or Abbott or Pfizer

INDIAN BIOTECH COMPANY TAKEOVERS

Sno.	Website	Taken over by Pharma MNC				Strategic Alliance				Proposed Acquisitions
		Company Name	Origin	Stake	Year	Company name	Origin	Product	Year	
1	www.rellife.com/									
2	www.indimmune.com/									
3	www.bharatserums.com/									
4	www.indusbio.co.in/									
5	www.concordbiotech.com/									
6	www.bharatbiotech.com					Novavax	USA	pandemic influenza v	2006	
8	www.clarisllifesciences.com					Pfizer	USA	Anti infective injecta	2009	
9	www.panacea-biotec.com					PharmAthene		Biodefence and emer	2008	
11	www.biocon.com					Amylin	USA	Novel peptides for di	2009	
12	www.rpglifesciences.com									
13	www.seruminstitute.com					Lipoxen		anticancer drugs and	2005	
14	www.shantabiotech.com	Sanofi Aventis	France		80% 2009					
15	www.biologicale.com									
16	Tibo Tec	Jhonson &Jhonson	USA							

INDIAN HERBAL COMPANIES TAKEOVERS

Sno.	Website	Taken over by Pharma MNC				Strategic Alliance				Proposed Acquisitions
		Company Name	Origin	Stake	Year	Company name	Origin	Product	Year	
1	www.baidyanath.com									
2	www.dabur.com - Pharma arm	Fresinius Kabi AG	German	73%	2009					
4	www.zandusayurveda.com/									

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