# DISCUSSION PAPER

## SUBJECT: COMPULSORY LICENCING

### I. Invitation of Views:

1. The Intellectual Property regime of the Government of India underwent significant changes after India's accession to TRIPS in 1995. Amendments were made to the Patents Act and the Trade Marks Act. The Designs Act as well as the Geographical Indications Act were enacted. The focus on the IPR regime is now on consolidation as well as promoting a fair balance between IP protection and public interest. In this connection certain policy issues have been identified which will help in moving towards our development and technological goals while giving protection to intellectual property rights. These include the issue of compulsory licences, the promotion of utility models and the strengthening of geographical indications registered in India.

2. This paper deals with the subject of 'Compulsory Licensing of Patents'. Views and suggestions are specifically invited on Section XVII of the paper entitled 'Issues for Resolution' apart from any other issues of concern relating to compulsory licencing of patents. The objective is to develop a predictable environment for use of such measures. These views/ suggestions backed up by facts, figures and empirical evidence may be furnished by 30 September, 2010. The views expressed in this discussion paper should not be construed as the views of the Government. The Department hopes to generate informed discussion on the subject, so as to enable the Government to take an appropriate policy decision at the appropriate time.

## II. Origins of Compulsory Licencing.

3. Compulsory licensing is a system whereby the Government allows third parties (other than the patent holder) to produce and market a patented product or process without the consent of the patent owner. This mechanism enables timely intervention by the Government to achieve equilibrium between two objectives - rewarding inventions and in case of need, making them available to the public during the term of the patent. Through such an intervention mechanism, the Governments balances the rights of the patent holder with its obligations to ensure working of patents, availability of the products at a reasonable price, promotion and dissemination of technological invention and protection of public health and nutrition.

4. Compulsory Licensing (CL) has been an integral part of the patent regime since its inception. The introduction of patents in Venice in the fifteenth century was accompanied by a broad set of rules which included the state's right to issue a compulsory licence[1]. Article 5 A(2) of the Paris Convention of 1883 provides that "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work." During the World Wars, compulsory licencing was resorted to for the sharing of aviation technology and the manufacture of penicillin.

5. Relatively more recent instances of compulsory licencing are indicated below. As will be seen, both developed and developing countries have issued compulsory licences in the recent past.

## III. Recent Instances of Compulsory Licencing

### Internationally[2]

6. *United States of America*: Compulsory Licenses which have been/are being issued fall into six categories. These include a) Mandatory compulsory licences for patents whose term was extended by GATT implementation b) Cases involving government use under 28 USC 1498 c) Cases involving the Bay Dohl Act and d) cases involving merger reviews e) cases involving non merger remedies to anti

[1] Intellectual Property Rights – A Critical History: Christopher May and Susan Sell. Viva Books 2008

[2] This section is drawn from two sources. These are "Recent examples of Compulsory Licences on Patents : KEI Research Note 2007 by James Packard Love" and ' The Global Politics of Pharmaceutical Monopoly Power : Drug patents, access, innovation and application of the WTO Doha Declaration on TRIPS and Public Health by Ellen F. M 't Hoen AMB 2009"

competitive practices and f) cases subsequent to the Supreme Court opinion in eBay versus Merc Exchange.

7. *Canada*: Canada, which had a special compulsory licence regime for food and pharmaceuticals, issued 662 compulsory licences between 1923 and 1993. Of these, 613 were issued after 1969, when the law was amended to provide for import of generics under a CL. This allowed for low prices of pharmaceuticals while encouraging the growth of the local generic drug industry. In 1993, CLs for pharmaceuticals were effectively abolished.

8. *United Kingdom*: Compulsory licencing has been used by the National Health Service in the past. It imported drugs, patented in the UK from countries where no pharmaceutical patent had been granted, on the ground of 'Crown use'. Such provisions continue to exist in British Law.

9. *Italy*: In 2006, the Italian Competition Authority issued a CL on antitrust grounds for production of an active ingredient for an anti migraine drug. In 2007, it issued a CL for a drug to treat prostate enlargement and baldness on similar grounds.

10. *Developing and Least Developed Countries*: After the Doha Declaration on the TRIPS agreement and Public Health, about 52 countries have issued CLs. These include Brazil( 2007 for an anti AIDS drug); Thailand( 2006 and 2007 for anti AIDS drugs ), Malaysia ( 2003 for Anti AIDS drugs), South Africa ( Anti Aids Drug) Kenya ( voluntary licenses issued in 2004 after threat of CL), and most recently Ecuador ( April 2010 for an anti AIDS drug)

### In India

11. No CLs have been issued in India under the amended Patents Act. In September 2007, three applications under section 92A of the Patents Act, 1970 were received for grant of compulsory licence for the manufacture and export of patented drugs to countries which reportedly did not have manufacturing capacity nor had insufficient capacity. The process envisaged under the Act was initiated. However, the applicant subsequently withdrew his applications.

## IV. Compulsory Licencing Provisions in TRIPS

12. Compulsory licencing under TRIPS is covered under two Articles. Article 30, allows limited exceptions to be provided to the rights conferred under patents provided they do not "unreasonably prejudice the legitimate interests of the patent owner, taking into

account the legitimate interests of third parties." This broadly covers the possibility of issuing CLs. However, Article 31 is more pointed. While providing for "Other Use without authorization of Right Holder", it qualifies the circumstances of this use through twelve conditions. The stipulations of local requirement and the public non commercial use/national emergency/extreme urgency clauses are not required to be applied whenever such licencing is aimed at addressing anti competitive practices. While TRIPS restricts the issue of CLs for semi conductor technologies to public non commercial use or to remedy anti competitive practices, it does not provide any other constraint on either the field of technology or the circumstances of issue. There is no restriction that such measures should be taken only to address public health concerns. The grounds on which a CL can be issued are not stipulated. The procedure to be followed for issuing CLs is also not specified, thus allowing for different procedures to be adopted for different circumstances. Thus, significant flexibility is provided to the member countries for the issue of a CL.

13. TRIPs also stipulate that 'the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization'. Remuneration is further discussed in Section XIV.

14. This paper explores the scope of compulsory licencing using the pharmaceutical industry as a basis. A similar approach can be adapted to any other sector where the issue of a compulsory licence is found necessary.

## V. National Pharmaceutical Policy

15. The National Pharmaceutical Policy 2002 recognizes the need to 'ensure abundant availability at reasonable prices of good quality essential pharmaceuticals of mass consumption'. The draft National Pharmaceutical Policy 2006 while acknowledging the explosive growth in this sector between 1990 and 2010, and the accompanying low cost of medicines notes, that concerns regarding the accessibility and affordability of medicines remain. It proposed a number of key objectives including a) ensuring availability of good quality medicines within the country at reasonable prices (b) improving accessibility of essential medicines for common man particularly the poorer sections of the population. To address these issues, the draft policy proposed a slew of measures. These included enacting a new law to exercise more effective price control /monitoring of the prices of drugs, creating a National List of Essential Medicines consisting of 354 drugs, strengthening the drug

regulatory system, limiting trade margins and negotiating prices for patented drugs. The draft policy has not yet been finalized. However, it made some pertinent observations on high prices and consequent low demand of cancer and aids drugs. These points, reproduced below, are relevant to the issue of the reasonable requirements of the public being met at reasonably affordable prices – part of the grounds for issue of CLs under the Indian Patents Act.

16. At any given point of time there are about 20 to 25 lakh people suffering from cancer in the country who are affected by various types of cancer. It is estimated that every year about 7 lakh people are detected with different types of cancer. Most of them are unable to afford the cost of expensive anti-cancer medicines. Going by a conservative estimate of average cost of anti-cancer medicines per patient as Rs 25,000 per annum, it would require medicines worth Rs 5,000 crore. As against this, the present turnover of this segment of medicines in India is estimated to be only Rs 150 crore. The big gap indicates the near non-accessibility of the medicines to a vast majority of the affected population mainly because of the high cost of these medicines.

17. India has the highest number of reported HIV/AIDS cases in the entire South Asian region. There are about 25 lakh people affected by HIV/AIDS in India, about 85% of the South Asian total. Presently, only those patients with a CD 4 below 200 per cu ml of blood are being treated. The number of patients being treated would be about 3 lakh. Further first generation drugs are being used which are gradually losing their effectiveness, requiring the use of second and third generation drugs. NACO purchases medicines and distributes them free of cost through its Centers and State Aids Control Societies. Lower prices for these medicines would allow greater coverage of affected patients.

## VI. Views of the Parliamentary Standing Committee

18. The Department Related Parliamentary Standing Committee on Health and Family Welfare presented its forty fifth reports on 'Issues Relating to the Availability of Generic, Generic Branded and Branded medicines, their formulations and therapeutic efficacy and effectiveness' to the Parliament on 4th August 2010. Its report expressed its concern on the following issues :

a. The high prices of the newly patented medicines which were not being regulated by the NPPA and the need for bringing in more drugs under the ambit of the NPPA

b. Even in the case of the 74 drugs which were being regulated by the NPPA, the increasing incidence of unorthodox practices adopted by drug companies wherein regulated drugs were substituted with new ingredients in popular brands to avoid regulation.

c. The super profits being generated by some drug companies who price their products significantly above cost and the need to explore possibilities of capping profit margins for all medicines including those not covered by the DPCO.

d. The takeover of Indian drug companies by some foreign companies and the need to generate policy options to ' ensure that major Indian pharma companies remain in Indian hands '

19. The Prime Minister, Dr Manmohan Singh in his remarks at the Fortune Global Forum in New Delhi in October 2007 stated " We have affirmed our commitment to the protection of intellectual property rights. But, the global economy, the global community cannot afford the complete privatization of research, of knowledge generation, especially in fields like medicine. We need to evolve mechanisms that protect intellectual property and at the same time, address the needs of the poor".

## VII. The Pharmaceutical Sector

20. Over the past fifteen years, the pharmaceutical sector has witnessed significant growth. India is now recognized as the one of the leading global players in the manufacture of pharmaceuticals. India now ranks third in terms of volume of production (9.3% of the global share) and 14th in terms of value (1.5% of global share). India is now supplying affordable and high quality medicines to a number of DCs and LDCs and has become the pharmacy of choice to the developing world. Its costs are also amongst the lowest in the world. Annexed I details the sales, and export turnovers of the Indian Pharmaceutical industry between 1994-95 and 2008-09. This analysis raises some concerns. The gross sales turnover increased from Rs 14,200 crore in 1994-95 to Rs 75,500 crore in 2008-09. This has been accompanied by a more than proportionate growth in exports. Pharma exports have risen from Rs 2512 crore in 94-95 to Rs 39,538 crore in 2008-09. During 2008-09, the export growth rate was 29% against the industry growth rate of only 8 %. Table I below details the exports, imports, sales and domestic consumption between 2003-04 and 2008-09.

**Table 1**

*Rs crore*

| Indicator | 2003-04 | 2004-05 | 2005-06 | 2006-07 | 2007-08 | 2008-09 |
|---|---|---|---|---|---|---|
| Exports Value | 15213.2 | 17857.8 | 22115.7 | 26895.2 | 30759.6 | 39537.7 |
| Imports Value | 2958 | 3169.3 | 4550.9 | 5851.6 | 6712.9 | 8617.6 |
| Sales Value | 40800 | 42500 | 49500 | 61000 | 70000 | 75500 |
| Market Size (Value) | 43758 | 45669.3 | 54050.9 | 66851.6 | 76712.9 | 84117.6 |
| Domestic Consumption (Value) | 28544.8 | 27811.5 | 31935.1 | 39956.5 | 45953.3 | 44579.9 |
| Domestic Consumption Growth | | -3% | 15% | 25% | 15% | -3% |

*Source: CMIE data Base*

21. Though imports have been growing, the emphasis on exports has resulted in a significantly lower growth of domestic consumption when compared to exports during most years during this period. During 2008-09, domestic consumption in value terms fell from Rs 45,953 crore to Rs 44,579 crore.

22. This is despite the fact that India itself has a large unmet domestic demand for critical medicines. 65% of the Indian population still lacks access to essential medicines[3] . Share of drugs in OPD expenses were estimated at 63 per cent by NSSO 60th Round (January 2004). NSSO in their Report on 61st Round indicated this expenditure having increased to 82 per cent.[4] As per National Health Accounts, medicines accounted for 38-62 per cent of inpatient expenditure in rural and urban areas.[5] With total household expenditure on health estimated at Rs 92,838 crore in 2004-05, at 60 per cent level, expenditure on medicines is estimated to cross Rs 50,000 crore.

23. This data appears to reinforce the issues raised by the Parliamentary Committee on the need to increase the availability and accessibility of drugs to the poor in the country

24. Given this background, the need for affordable and high quality medicines is critical for the sustainable growth of the Indian economy. In this context, three developments in the pharmaceutical sector in India have heightened the concerns being expressed. These are the enactment of the amendments to the Indian patents Act in 2005, the recent restructuring of ownership in the sector and the strategic alliances being forged by some large Indian players in this sector.

25. The enactment of the Patent Amendment act in 2005 allowed for the grant of product patents in the pharmaceutical

[3] World Medicine Situation WHO 2004 quoting 1999 figures

[4] Indrani Gupta- Out of Pocket Expenses and poverty Estimates- A paper submitted to the Expert Group on Methodology of Poverty Estimates, 2009

[5] Ministry of Health and Family welfare, National Health Accounts, 2004-05-, page 31

sector. The first pharmaceutical product patent under the amended act was granted in 2006. While the bulk of essential drugs are still under the process patent regime, new formulations will steadily be issued product patents resulting in focusing of monopoly power among the patent holders.

26. Six reported cases where foreign companies have taken over Indian companies are provided in Table 2 below.

**Table 2**

| *Year* | *Indian Co taken over* | *Foreign Company which took over* | *Country of origin* | *Take over amount US$ mill* |
|---|---|---|---|---|
| Aug 2006 | Matrix Lab | Mylan Inc | USA | 736 |
| April 2008 | Dabur Pharma | Fresenius Kabi | Singapore | 219 |
| June 2008 | Ranbaxy Laboratories | Daiichi Sankyo | Japan | 4600 |
| July 2008 | Shanta Biotech | Sanofi Aventis | France | 783 |
| Dec 2009 | Orchid Chemicals | Hospira | US | 400 |
| May 2010 | Piramal Health Care | Abbot Laboratories | US | 3720 |

*Source: Press Reports.*

27. Most of these companies are export oriented. There is a concern that their takeover by multinationals will further orient them away from the Indian market, thus reducing domestic availability of the drugs being produced by them. This may weaken competition leading to headroom for increase in domestic drug prices. Data Base from the Centre for monitoring Indian Economy indicates that while the rate of growth of sales of the pharmaceutical companies declined during 2001-2009 (14.2 per cent annual) compared to their growth during 1988-2000 (19.5 per cent annual), their ratio of profit after tax to total income increased to 9.7 per cent (average of 2001-2009) from 4.9 per cent (average of 1988-2000). This may point to the

worsening in both the availability and affordability of pharmaceutical products.[6]

28. Additionally, the strategic alliances being forged by other foreign companies with Indian drug manufacturers for licencing and supply also alter the pharmaceutical landscape. These include alliances between GSK with Dr Reddys; Pfizer with three companies - Aurobindo, Strides Arcolab and Claris Life Sciences; Abbot with Cadilla Health Care and Astra Zeneca with Torrent . Further foreign companies are taking over domestic drug companies in other countries also. For e.g. Sanofi Aventis took over Medley in Brazil and Zantiva in the Czech Republic, GSK took over BMS in Egypt and Pakistan. It can thus be said, that there is a move towards consolidation in developing country markets

## VIII. Concerns relating to drug prices and availability

29. The top 10 pharmaceutical companies by 2008-09 sales are listed below in Table 3. Their aggregate sales ( including exports) represent nearly 39 % of the total industry sales

**Table 3**

*Rs crore*

| | |
|---|---|
| Cipla | 4807.67 |
| Ranbaxy Laboratories: | 4755.76 |
| Dr. Reddy's Laboratories- | 4394.90 |
| Lupin | 2934.25 |
| Sun Pharmaceutical Inds. | 2830.86 |
| Aurobindo Pharma | 2730.75 |
| Cadila Healthcare | 1765.40 |
| Glaxosmithkline Pharmaceuticals | 1668.08 |
| Piramal Healthcare | 1565.42 |
| Wockhardt- | 1448.87 |

*Source : CMIE Data Base*

30. After the recent takeover, three of these ten companies are multinationals. In 1998-99, (see Annex 2) only one of the top ten companies ranked by sales was a multinational company. There are increasing concerns that if such a takeover trend continues, an oligopolistic market may develop which may result in a few companies dictating prices of drugs critical for addressing public health concerns including fighting front line diseases like HIV/AIDS, Hepatitis C. Such a contingency while reinforcing the newly acquired monopoly patent power of the foreign companies may also weaken the government's ability to address such challenges through the issue of

[6] CMIE Prowess Data Base

compulsory licences. If large Indian generic companies with the capability to manufacture drugs based upon a CL ( where they issued to them) are themselves taken over, then the regime of cheap and effective drugs may be threatened for four reasons:

a. The large Indian pharmaceutical companies, which have been taken over by foreign companies, may no longer be willing to apply for a Compulsory Licence even if eligible. Their deterrent threat is thus emasculated.

b. When government notifies a public emergency and recognizes the need for issue of a CL for a particular drug, adequately capable drug manufactures may not be available to come forward to apply for CL and work it at a reasonable cost.

c. There is a concern that foreign companies may utilize the marketing channels of the Indian companies they take over to sell higher cost patented drugs or branded generics rather than the cheaper generics that were being sold earlier. This may push up drug prices in general.

d. Some of the Indian companies taken over were recipients of substantial grants as well as tax concessions. Others were transferred or allowed to work patents owned by the CSIR at concessional prices. Thus a significant portion of their market value arose because of state support and they were catering to niche markets for relevant drugs. With their transfer to foreign control, they may no longer be interested in doing so.

## IX. Options available

31. In the event of any or all these concerns crystallizing, four possible responses are available with the Government of India. One is an immediate response and three are short term policy responses. These are:

a. If the circumstances so require; for example a public emergency like a pandemic , or whenever the demand for a critical drug is not being met, then a compulsory licence can be issued promptly to a qualified company to produce such a drug or the government use provision invoked.

b. The first short term option is invoking the Competition Act 2002 to scrutinize whether the price or availability of a drug is a consequence of an anti competitive agreement or a combination which has an adverse effect on competition; or the abuse of dominant position by a company and initiating suitable action .

c. The second short term option is to review the policy on foreign investment for pharmaceutical companies. Presently, investment up to 100% in the pharmaceutical sector is on the automatic route. This could be shifted to the government route so that proposals for mergers and acquisitions in this important sector could be scrutinized by the FIPB. This could be a way of monitoring whether new technology is being brought in by a foreign company while taking over an Indian company.

d. The third short term option is to expand the ambit of the National Pharmaceutical Pricing Authority and vest it with the power to regulate the prices of a larger number of drugs than the present 74.

32. The first option is a focused and sharp response – which can be invoked when a single critical drug is either unavailable per se or unavailable at reasonably affordable prices. The other three options deal with broader issues and will not be discussed here. This paper exclusively discusses the first option- the issue of compulsory licences.

## X. Provisions under TRIPS

33. Article 4 of 'The Declaration on the TRIPS Agreement and Public Health' adopted in Doha in November 2001 affirms that the TRIPS agreement does not and should not prevent member countries from taking measures to protect public health. Accordingly, it allows for interpretation and implementation of the TRIPS agreement in a manner supportive of the WTO's members right to protect public health and in particular, promote access of medicines to all. Article 6(b) of the Doha Declaration recognizes that the flexibilities of the TRIPS agreement include the right of each Member to grant compulsory licenses and the freedom to determine the grounds under which such licenses are granted. Article 6(c) recognizes the right of each Member to determine what constitutes a national emergency or other circumstances of extreme urgency.

34. These flexibilities have been incorporated in the Patents Act 1970 as amended in 2005 which is fully consistent with TRIPS. Chapter XVI of this Act entitled 'Working of Patents, Compulsory Licenses and Revocation' deals with the issue of Compulsory Licences (CLs). Sections 84, 85, 91, 92, and 92A enumerate the various circumstances under which CLs may be issued. Chapter XVII contains provisions for use of inventions for the purposes of government and the acquisition of inventions by the Central Government. Chapter VIII of the Patent Rules 2003 as amended in 2006 provides for the modalities of issue and maintenance of Compulsory Licences. Rule 97 discusses the action to be taken when a prima facie case has not been made out. Rule 98 enables a notice of opposition to the CL to be made out while Rule 100 provides for amendment to the terms of the CL.

35. Section 84(1) of the Act provides that at any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence. The earliest pharmaceutical product patents were granted in January 2006 under the amended Act. More than five years have elapsed since then. It is necessary that an objective framework for the issue and maintenance of compulsory licences be developed using the mandate provided by the law as the basis for the same.

36. This Discussion Paper highlights the issues which need to be addressed while formulating such a framework and discusses various options available

## X. Legal Provisions.

37. Section 83, at the beginning of Chapter XVI unusually lists the "General principles applicable to working of patented inventions". These 'Directive Principles of Patent Policy' incorporate the philosophy of the patent frame work under Indian law. This Section is also the bedrock on which the edifice of compulsory licencing is built in the subsequent sections. It states as under:

*Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely,—*

*(a) That patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and*

*to the fullest extent that is reasonably practicable without undue delay;*

*(b) That they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;*

*(c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;*

*(d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;*

*(e) That patents granted do not in any way prohibit Central Government in taking measures to protect public health;*

*(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and*

*(g) That patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.*

38. This Section draws significantly from TRIPS. Section 83( c) is a replication of Article 7 of TRIPS – its Objectives. Section 83(d) draws from Article 8(1) of TRIPs – its Principles. Section 83(f) draws on Article 8(2) of TRIPS - the second part of the Principles.

39. Section 89 further specifies the objectives of a compulsory licence. It states that "The powers of the Controller upon an application made under section 84 shall be exercised with a view to securing the following general purposes, that is to say,—

*(a) that patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable*;

*(b) that the interests of any person for the time being working or developing an invention in the territory of India under the protection of a patent are not unfairly prejudiced.*

40. Compulsory licensing is enabled under four sections of the Patents Act. These are Section 84 ( general CLs to be issued by the Controller on application ) , Section 91( issue of CL by the Controller for a related patent on application ) , Section 92( issue of CL by the Controller based upon a notification by the Central Government of circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use) and Section 92 A( issue of CL by the Controller on application for manufacture and export of patented pharmaceutical product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems). In addition, Chapter XVII provides for use of inventions for the purpose of government and acquisition of inventions by Central Government.

41. Under Section 92, the Controller can issue a CL on application only after the Central Government issues a special notification. Under 92A, he is required to act only after either issue of a CL by the importing country or on the basis of a suitable notification issued by that country. For the purposes of this Discussion Paper, such licences are called Category I Compulsory Licences. In the remaining two of the four sections outlined above, the Controller is independently empowered to issue a compulsory licence on application and on the satisfaction of the conditions mentioned in the respective sections. For the purpose of this discussion paper, they are called Category II Compulsory Licences. Internationally, most compulsory licences issued in the past so far relate to manufacture or import of pharmaceuticals products and have been issued based on recognition by the Government of either an emergency or the requirement of public use. These are the Category I CLs referred to above and it is to these that we turn first.

## XI. Category I CLs

42. Under Section 92, the Central government can notify the need for issue of a CL on the following grounds

a. Circumstances of national emergency;

b. Circumstances of extreme urgency;
c. In case of public non-commercial use.

43. These grounds are identical to those mentioned in Article 31(b) of TRIPs which allows members to issue CLs. Section 92(3) clarifies en passant that such circumstances could include public health crises, relating to Acquired Immune Deficiency Syndrome, Human Immune Deficiency Virus, tuberculosis, malaria or other epidemics. This is consistent with Para 5(c) of the Doha Declaration on TRIPS and Public Health which states that public health crises including those related to HIV/AIDS, tuberculosis, malaria and other epidemics can represent a national emergency or other circumstances of extreme urgency. The Patent Act however, does not in any way stipulate that the circumstances justifying issue of a CL are exclusively public health crises. The three circumstances mentioned in Para 42 above could occur in other sectors also.

44. Given the extremely diverse nature of these three grounds, one view is that it may not be feasible or even desirable to focus the scope of their application in a definitional sense. Another view is that it is necessary to clarify that these grounds can be used for promoting access to medicines like cancer and diabetes. Para 4 of the " Doha Declaration on the TRIPS agreement and Public Health" specifically clarifies that the TRIPS agreement does not and should not prevent Members from taking measures to protect public health. It further affirms the Members rights to protect public health and in particular to promote access to medicines for all. Thus chronic diseases can also be addressed though such provisions.

45. While granting a Category I licence, the Controller should endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights. In contrast, while granting Category II licences, the Controller is required to ensure that the patented articles are made available to the public at reasonably affordable prices while ensuring that the patented invention is worked to the fullest extent and with reasonable profit to him. Thus, the Controller appears to have a higher burden in the case of issue of Category I licences in the matter of the price at which the patented article is made available to the public.

46. Under Section 92A, a compulsory licence shall be issued for export of patented pharmaceutical products to a country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by

such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

47. This provision mandates that the Controller shall issue a CL when its stipulations are met. Such a CL is restricted to pharmaceutical products which are defined separately under the explanation to the section as "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use".

48. This Section mirrors the August 30 decision of the TRIPS Council. Article 31(f) of TRIPS provides that production under a compulsory licence must be 'predominantly for the supply of the domestic market'. This restriction limited the quantity of exportable products, and inhibited the advantage of economies of scale being leveraged in the manufacture of such products. Acting on the mandate provided by paragraph 6 of the Doha Declaration, the TRIPS Council resolved on 30 August 2003 to waive the requirements of Article 31(f) till the proposed amendment (Article 30 bis) comes into force. The amendment puts in place a mechanism providing for a CL based export approval by the TRIPS Council on a drug by drug, case by case and country by country basis. Both the exporting and the importing countries are required to notify the TRIPS Council in advance.

49. The three applications received by the Indian patent office in September 2007 referred to in Para 11 above were for grant of CLs under this section. Since the corresponding CLs/notifications from the importing country could not be made available[7], the applications were withdrawn. A similar trend is seen internationally in invoking the August 30 decision. Only in one case has this decision been invoked over the last eight years[8]. The additional burden of compliance with respect to the stipulations of the TRIPS Council in such cases appears to be a deterrent.

## XII. Central Government Use

50. Chapter XVII of the Patents Act provides for the Central Government using an invention for the purpose of government

[7] Interview with representative of Natco Pharma.

[8] The Global Politics of Pharmaceutical Monopoly Power : Drug patents, access, innovation and application of the WTO Doha declaration on TRIPS and Public Health by Ellen F. M 't Hoen AMB 2009

on payment of royalty. Section 100(1) specifies that the Central Government or any person authorised by it in writing may use the invention for the purpose of government. Section 99 defines the term purpose of government to mean "made, used, exercised or vended for the purposes of the Central Government, a State Government or a government undertaking." Such a definition caters to the needs of the Central Government, the State government as well as both Central and State government undertakings. Since such making, using, exercising or vending is for the purposes of government and not by the government, Central Government can authorize third parties to manufacture products patented by others to fulfill government purpose. Thus the first part of Chapter XVII effectively allows for compulsory licensing of patents. This provision can also invoked at any time after the application for a patent has been file, thus making it stronger.

51. Section 100(6) clarifies that the right to make, use, exercise and vend an invention for the purposes of government under sub-section (1) shall include the right to sell on non-commercial basis, the goods which have been made in exercise of that right. The use of the words' sale on non commercial basis' contrasted to the words 'use on non commercial basis' in 92(3) appears to empower the government under this provision to manufacture or cause to manufacture patented products and sell them without profit. For example, in the case of pharmaceuticals, patients can be charged cost price for drugs provided to them through such an arrangement. Since general Government expenditure on health is only 25%[9] of total health expenditure, it may be necessary to use all available channels for such distribution, including the private sector.

52. Section 102 provides for outright acquisition of a patent by the Central Government by notification, if it is satisfied that it is necessary to do so for a public purpose, subject to payment of compensation. Compensation may be determined by the High Court under Section 102.

53. This avenue could possibly be used for the production of cost effective and orphaned drugs by public sector pharmaceutical companies. If necessary, new public sector companies could be promoted for producing essential medicines that are not being produced by private companies at an affordable cost.

[9] Central Bureau of Health Intelligence : National Health Profile of India 2009- accessed from MoH&FW web site

## XIII. Category II CLs

54. The essential element in Category II licences is the ability of the applicant to prove that a) the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India. While conditions required to satisfy the first set of circumstances are amplified in Section 84(7), there is no guidance available in the Act for determining the existence of the second and third set of circumstances. However under Section 90, the Controller is required to secure on an endeavor basis compliance with a number of conditions.

55. Under Section 84(6) (ii) and (iii), the Controller is required to satisfy himself about the ability of the applicant to work the invention to the public advantage as well as the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

## XIV. Payment of Royalty

### WHO-UNDP Guidelines for Non Voluntary Use of Patent[10]

56. These guidelines published in 2005 outline four different methods for payment of remuneration consistent with TRIPS. These are briefly described below.

57. The simplest is the method recommended in the 2001 UNDP HDR report which proposes a royalty rate of 4 percent of the price of the generic product. This can be increased or reduced by 2 percent depending upon other factors.

58. The Japanese Patent Office published guidelines in 1998 for setting royalties on government owned patents. These guidelines allow for a base royalty of 4 percent which can be increased or decreased within a band of 0 to 6 percent. In case the product licensed spans a number of patents, there is a provision to bias this percentage downwards for each patent depending upon its individual contribution to the composite patent.

59. The Canadian government in 2005 adopted royalty guidelines for compulsory licencing of patents for export to countries which lack the capacity to manufacture such medicines. These guidelines use a base rate of 4 percent of the generic sales price. This

[10] Remuneration guidelines for no voluntary use of a patent ; James Love ; UNDP WHO; Technical Cooperation for Essential Drugs and Traditional Medicine

royalty rate is then biased downwards based upon the rank of the importing country in the UN Human Development Index. The lowest ranked country in the index will pay 0.02 percent, while the highest ranked country will pay 4percent.

60. The Tiered Royalty Method (TRM) is computed using as a base the price of the patented product in the high income country. The royalty rate of 4 percent applied on this rate is then biased downwards by the ratio of per capita incomes of the respective countries. For countries with a high burden of disease, the relative income per person with the disease could be used as the biasing factor.

61. In the case of Government use of a patent, the proviso to Section 100(3) of the Patents Act stipulates that in case of Central Government use of an invention the patentee shall be paid not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent. However, any dispute on the amount paid can be referred to the High Court under Section 103.

62. Another view is that the amount paid must be including a reasonable solatium to the patentee, with the aim of not radically discomfiting him both economically and otherwise. It is thus argued that the amount paid should be significantly above the maximum royalty of 4% indicated in the TRM method. Under this view, an aggregate payment of about 10% of the generic sale price of the drug in the country where the CL is used is appropriate.

### In Practice:

63. In April 2010, Ecuador used the tiered royalty method (TRM) to allow for royalty payments of 5% of the US price biased downwards by the ratio of per capita incomes for the CL issued by it for the manufacture of Ritonavir. Thailand in 2006 allowed a royalty fee of 0.5 percent of the sale value of the product in that country. Indonesia in 2004, allowed a royalty of 0.5% of the net selling value in that country.

## XV. Local working of the Patent

64. Article 84(4) of the Patents Act authorizes the Controller to grant a compulsory license if amongst other things, he is satisfied that the patented invention is not worked in the territory of India. He can also grant a compulsory licence if he is satisfied that the reasonable requirements of the public with respect to the patented invention have not been met. Under Section 84(7) (e), one of the

criteria for deciding the latter is ' if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article' . There are thus two independent grounds :

a. The invention is not worked in the territory of India at all.

b. The reasonable requirements of the public are not being met as the working of the patent in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by interested persons.

65. The issue which then arises is what the term 'working in the territory of India' means. Whether this implies that the product must be manufactured in the territory of India, or it can be taken to mean making available for local sale. Expectedly, there are opposing views in the matter.

66. Article 27(1) of TRIPS partially reads "... patents shall be available and patent rights enjoyable without discrimination as to ...whether products are imported or locally produced". This Article appears to mandate that so long as the patented product is available in the market at an affordable cost, the use of the patent cannot be differentiated on the basis of its sourcing – whether it was manufactured within the country or imported from without. However, it has been argued [11] that the exceptions provided in Articles 30 and 31 of TRIPS override the general stipulations in Article 27.It is further argued that Articles 7 and 8 of TRIPS which recognize the need to promote transfer of technology support provisions for local sourcing . Therefore local working stipulations are valid and enforceable.

67. Local Working requirements with a corresponding remedy of issue of a compulsory licence for non compliance find place in the laws of a number of countries – both developed and developing. Such provisions can be traced to the origin of the patent system[12]. A number of countries have local working conditions in their patent laws. Brazil's Intellectual Property Law authorizes the government to issue a compulsory licence if the patent owner does not manufacture the product in the territory of Brazil within three years of the grant of the patent. This provision was challenged by the US in a WTO dispute hearing in 2000.

[11] Patent Rights and Local Working under the WTO TRIPS Agreement- An analysis of the US-Brazil Patent dispute : Paul Champ and Amir Attaran

[12] Ibid

68. Though the US subsequently withdrew its complaint, it reserved its rights to recommence the WTO complaint. However, it is noteworthy that during a Congressional hearing in Nov 2005, the US DHSS Secretary testified that he had effectively required the patent owners of Tamiflu to set up manufacturing facilities in the US so that the US would have access to Tamiflu if confronted with an avian flu pandemic[13] .

69. The entire Chapter XVI on ' Working of Patents, Compulsory Licences and Revocation' with sections 82 to 98 was substituted for the old Chapter XVI containing sections 82 to 94 by way of amendments to the Patent Act (Act 38 of 2002) with effect from 20/5/2003. Section 90(3) provides that Central Government may, in public interest, direct the Controller at any time to authorize any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad. Section 86 provides that the Controller may adjourn hearing of applications on this ground by up to 12 months if he is satisfied that adequate time was not available to the patentee to work the patent in the territory of India. Read together, these two sections appear to assert that the local working requirement implies manufacture within the territory of India.

## XVI. Other Considerations

70. One concern has been whether issue of compulsory licences in a country will inhibit the growth of technology. In a recent study on whether compulsory licensing encourages inventions by nationals in nascent industries, an NBER Working Paper indicates that compulsory licensing has a strong and persistent positive effect on domestic invention.[14] Even without any effects on innovation, compulsory licensing may create significant positive welfare effects on consumers in developing countries as a mechanism to maintain product variety.

## 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*

[13] Patents, Compulsory Licences and Access to Medicines- Some recent experiences – Martin Khor Third World Network.

[14] NBER Working Paper (15598)- Compulsory licensing- Evidence from The Trading with The Enemy Act, by Petra Moser and Alessandra Voena, December 2009

*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?*

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?*

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?*

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?*

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?*

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?*

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?*

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?*

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?*

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?*

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?*

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?*

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?*

**_____eod**