Compulsory Licensing - Legal Issues
– A Critical Analysis

Project Assignment
PG Diploma in Patents Law

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## CONTENTS

<table>
<thead>
<tr>
<th>ACRONYMN</th>
<th>i.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CHAPTER 1</td>
<td>1-4</td>
</tr>
<tr>
<td>A. Introduction</td>
<td></td>
</tr>
<tr>
<td>B. Meaning and Rationale</td>
<td></td>
</tr>
<tr>
<td>2. CHAPTER 2</td>
<td>5</td>
</tr>
<tr>
<td>Research Methodology</td>
<td></td>
</tr>
<tr>
<td>3. CHAPTER 3</td>
<td>6-24</td>
</tr>
<tr>
<td>Compulsory Licensing System</td>
<td></td>
</tr>
<tr>
<td>A. Compulsory Licensing System Under Indian Patent Law</td>
<td></td>
</tr>
<tr>
<td>B. American Approach towards Compulsory Licensing System and its Cases</td>
<td></td>
</tr>
<tr>
<td>C. EU Perspective and its Cases</td>
<td></td>
</tr>
<tr>
<td>D. Conclusion</td>
<td></td>
</tr>
<tr>
<td>4. CHAPTER 4</td>
<td>25-28</td>
</tr>
<tr>
<td>Compulsory Licensing in the time of Health Emergencies</td>
<td></td>
</tr>
<tr>
<td>5. CHAPTER 5</td>
<td>29-30</td>
</tr>
<tr>
<td>Compulsory Licensing: Suggestions for Change</td>
<td></td>
</tr>
<tr>
<td>Bibliography</td>
<td>31</td>
</tr>
<tr>
<td>ACRONYMN</td>
<td>Description</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>TRIPS</td>
<td>Trade Related Aspects of Intellectual Property Matters</td>
</tr>
<tr>
<td>WTO</td>
<td>World Trade Organization</td>
</tr>
<tr>
<td>GATT</td>
<td>General Agreement on Tariffs and Trade</td>
</tr>
<tr>
<td>WIPO</td>
<td>World Intellectual Property Organization</td>
</tr>
</tbody>
</table>
CHAPTER 1

COMPULSORY LICENSING – LEGAL ISSUES

INTRODUCTION:

Competition policy and Intellectual Property Law intersect at the point of fostering innovation, efficiency, consumer welfare and economic growth; yet an inevitable chasm exists in the sphere of “monopoly rights”. The premise of IP laws is that rewarding human ingenuity, innovation and enterprise, by granting the right of “exclusive” use and exploitation to the innovator, augurs well for industrial and technical progress. Moreover, information, which is the quintessence of future research, is brought into public domain, thereby paving way for increased dynamic efficiency.

But occasions are not few, when IPRs are exercised in a manner which leads to attenuate the scope of competition. To exemplify, “Exclusivity” affords an opportunity to the right holder to manoeuvre the prices in a manner which enables her not only to recoup the R&D costs but also reap unprecedented profits. Moreover, IP owners often engage in “exclusionary conduct” towards innovators and potential competitors on markets which are secondary to and dependant upon an IPR protected industrial standard or de facto monopoly. This anti-competitive conduct has tended to take the form of “refusal to deal” or “refusal to license”. Such conduct whittles competition and results in fetters being placed on the free exercise of exclusive rights granted by IP laws.

One such fetter is that of “Compulsory licensing” which can be seen as a potent tool for mitigating the rigours of “abuse of dominant position by arbitrary refusal to deal or license”, thereby rectifying market failure.

This project deals with this tool of compulsory licensing. It defines the term as well as expatiates upon its rationale, whilst delving into the question as to how it mitigates, cures or recuperates the perils of anti-competitive activities. It offers an insight into the American and European position, with the aid of case law, in order to explain how this tool is put to practical application.
Compulsory Licensing – Meaning And Rationale

Compulsory licenses are "involuntary contracts between a willing buyer and an unwilling seller imposed or enforced by the state." Compulsory licenses are basically the abrogation of an IP right - an extra-ordinary legal instrument whereby the State allows itself or third party (typically the competitor) to have access to, produce, use or sell the IP protected product or process without the consent of the IP owner. Such mandatory and involuntary licenses as compelled by law may be granted with respect to patents, copyrighted works or other exclusive rights. In case of patents the Compulsory license provides a safeguard against lack of use of a patented invention or “misuse of the patent holder’s monopoly rights” in order to protect the public interest. The same principle may be applied in case of copyrights and other exclusive rights.

It is pertinent to mention that the power to enact laws on compulsory patent licensing arises from several international agreements such as the World Intellectual Property Organization (WIPO) Paris Convention for the Protection of Industrial Property, the relevant provisions of which were incorporated into the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

TRIPS provides a leeway to the Member States to smoothen the creases created by potential conflict between competition policy and IP law. Articles 8¹, 31² and 40³ deserve a special 注

1 ARTICLE 8 OF TRIPS

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

2 ARTICLE 31 OF TRIPS

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder
shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semiconductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

3 ARTICLE 40 OF TRIPS

CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.
mention. Members may “adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development.” Further, TRIPS handles compulsory licenses as an exception to the agreement’s minimum requirement that all Member States afford a patentee a right of exclusivity during the complete patent term. TRIPS portend a set of circumstances that establish a floor at which any Member State is allowed to issue compulsory license. The compulsory licenses that are allowed fall into two categories—where there is an overriding public interest or where the patent rights are being used in an anticompetitive manner.

In the realm of national laws, following are the examples that specify when Compulsory licenses can be issued:

- Refusal to enter into a voluntary licensing agreement on reasonable commercial terms (e.g. in the German and Chinese patent laws);
- Public interest (e.g. in the Swedish law);
- Public health and nutrition (e.g. provisions in the French law )
  National emergency or situation of extreme urgency;
- Anti-competitive practices on the part of patent holders
  Dependent patents;
- No or insufficient working of the invention in the national territory.

Thus, it is evident that compulsory licensing can potentially combat some of the most pernicious circumstances including anti-competitive practices. For our purpose such activities as having a dampening effect on competition are the main focus of attention. The following chapters throw some light on the position in US and EU; in order to understand how involuntary licensing “may” cure anti-competitive behaviour of IP owners and what are the conditions which define the ambit and scope of such licensing.

3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member's laws and regulations on the subject matter of this Section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either Member. The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.

4. A Member whose nationals or domiciliaries are subject to proceedings in another Member concerning alleged violation of that other Member's laws and regulations on the subject matter of this Section shall, upon request, be granted an opportunity for consultations by the other Member under the same conditions as those foreseen.
CHAPTER 2

RESEARCH METHODOLOGY

This Assignment is a critical analysis of a legal issues concerned with Compulsory Licensing. It aimed at projecting giving Compulsory License to the Pharmaceutical Companies in case of certain rules and emergencies. This Project deals with the legal issues dealt with the American Approach and European approaches and its cases which discusses that whether giving the Compulsory License to the Pharmaceutical Companies is worth it or not. Various cases are dealt in this project dealing with the various sections of Indian Patent Law as well as TRIPS. Legal aspects are discussed regarding whether issuing Compulsory License in case of emergencies is beneficial or not for the countries. The Research methodology adopted is of a descriptive - analytical method. The data has been collected from primary and secondary sources, which include internet sources, bulletin books, research publications, the judgment collected from the law journals. Knowledge gained by the participation in several seminars, meetings, listening to academic talks in several platforms involving policy makers, lawyers, scientists has also been used while analyzing.
CHAPTER 3

Compulsory licensing system

Compulsory licensing is certainly the backbone of patent laws. The question of constraints that would emerge after the implementation of TRIPS has been a subject of serious concern and was discussed in the TRIPS Council of the World Trade Organization during 2001. The issue was further hotly debated in the Doha Ministerial Conference held in November 2001.

The result was the Doha Declaration on TRIPS Agreement and Public Health, which clarifies that sufficient flexibilities and freedom to determine the grounds upon which compulsory licences can be granted are available to member countries. It is now up to member countries to exercise their right and make suitable provisions in their national legislations.

While enacting the Indian Patents (Second Amendment) Act 2002, this aspect did not receive due consideration even when the Indian delegation was a major player in the adoption of the Declaration on TRIPS Agreement and Public Health.

There are nine possibilities of structuring grant of compulsory licences arising from the TRIPS Agreement and the Paris Convention, and as clarified in the Doha Declaration on Public Health. These are:

- Voluntary licences.
- Authorisation for meeting government requirements.
- Compulsory licence due to abuse of patent rights by the patent-holder.
- Compulsory licence due to unsuccessful attempts by an enterprise to obtain a voluntary licence from the patent-holder.

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Indian Patent Act 2002:

The term of patent has been enlarged to twenty years for existing patents and patents granted on pending applications. If the applicant is not interested to secure a patent in India or the invention is not patentable according to the Indian law, he has to mandatorily file an application for the said invention and has to wait for the expiry of six weeks after filing the application and then only file the corresponding application abroad for the same invention.

The Patents (Amendment) Act, 2002 was passed by Parliament in May, 2002 and notified in June, 2003. The Act has been made effective from May, 2003 and has brought about lot of changes.
• Compulsory licence due to a national emergency.
• Compulsory licence due to circumstances of extreme urgency.
• Compulsory licence in cases of public non-commercial use.
• Compulsory licence to remedy anti-competitive practices.
• Second patent for an invention involving important technical advance of considerable economic significance over the existing patent.

The salient features of the Patents (Amendment) Act 2002 are as follows:

A. Modification of term invention:

The Sec. 2 (1)(j) of Patent (Amendment) Act 2002, defines the term “invention” as "a new product or process involving an inventive step and capable of industrial application" Where ”Inventive step” means a feature that makes the invention not obvious to person skilled in the art.

Earlier “invention” means any new and useful –

(i) Art, process, method or manner of manufacture;
(ii) Machine, apparatus or other article;
(iii) Substance produced by manufacture;

and includes any new and useful improvement of any of them, and an alleged invention.

B. Examination of application (Sec. 11(b)):

India has opted for a deferred examination system. This means the Controller will not initiate examination of the application. Examination of an application will now be taken up only upon request by applicant or in the Form 19 with fees of Rs.1000 for individual applicant or Rs. 3000 for legal entity other than an individual, at the appropriate office of the Patent office (Rule 24).

The request is to be made within forty-eight months from the application filing date. Where an application was filed prior to May 20, 2003 (i.e. before the commencement of the Patent (Amendment) Act 2002), a request for examination is required to be made within a period of twelve months from May 20, 2003 or forty-eight months from the filing date, whichever is later.
Upon failure to request examination, the application shall be treated as withdrawn by the applicant. The applicant or agents can also withdraw the application at any time (before the grant of the patent) after filing the application.

C. Publication/Notification of the Application (Sec. 11 (a)):

After the expiry of 18 months from the date of filing or the date of priority whichever is earlier, the Controller will notify the contents of the applications falling within the provision in the Gazette of India Part-III Sec.2 (Rule 25).

D. Term of Patent (Sec.53):

The term of patent has been enlarged to twenty years for existing patents and patents granted on pending applications. This term is calculated from the date of filing of the application.

Earlier the term of patent for method or process of manufacture of substance (e.g. food, medicines, drugs etc.) was five years from the date of the sealing of the patent, or seven years from the date of patent whichever period is shorter and in respect of any other invention, fourteen years from the date of the patent.

E. Burden of proof (Sec. 104 A):

The burden of proof in a proceeding for process patent infringement has been reversed and imposed on Defendant.

F. Fees (First Schedule):

The fees for filing a new application for patents has been reduced from Rs. 1500 to Rs. 750 in the case of an individual applicant and from Rs. 5000 to Rs. 3000 in the case of legal entity.

G. Prohibition to apply abroad (Sec. 39):

No person shall file an application or patent for an invention without applying in India or without the written permission of the Central Govt. If the applicant is not interested to secure a patent in
India or the invention is not patentable according to the Indian law, he has to mandatorily file an application for the said invention and has to wait for the expiry of six weeks after filing the application and then only file the corresponding application abroad for the same invention.

H. Date of Patent (Sec. 45):

The date of every patent will be the date of filing the application for patent. According to The Patent Act 1970, the date of patent was the date of filing of complete specification. The date of patent is very important to determine the term of parent.

I. Rights of patentee (sec.48):

The rights can be considered as negative because the rights of patentee, in the case of product patent, prevent third parties without the consent of the patentee, from making, using, offering for sale, selling or importing into India and the rights in the case of process patent, prevent third parties without the consent of the patentee, from the act of using that process and offering for sale or selling in India or importing for those purposes the product obtained directly by that process, provided that the product obtained is not patentable under the Act.

J. The Powers of the Branch Office (Rule 4):

The branch offices of the Patent office have been vested with more powers. Under Sec. 68 the actions such as making a request of sealing of patents, registration of assignment (under Sec. 68) etc has to be made in the appropriate Branch offices of the Patent office and not at the Head Office as the case earlier.

K. Appellate Board (Sec. 2 (1a)):

Appeal Board appointed under the Trade and Merchandise Marks Act 1999 shall be the Appeal Board for purposes of Patents Act. This Appellate Board hears and decides appeals from the decision of the controller. The Head Quarter of the Appeal Board is to be in Chennai.

It is clear that the definition of term invention in Patent Act, 2002 has enlarged the scope of protection. The controller has also been vested with the power to consider the question of obviousness of the invention disclosed while conducting the examination of application for considering the grant of a patent for the invention. In this context it should be noted that in the
Patent Act, 1970 the Controller has no direct power to consider the question of obviousness. The power is only for the opponents while opposing the draft of patents under Sec. 25 of the Patent Act, 1970. The effect of this amendment is that it may not be possible to get a patent for trivial modifications.

L. Time for placing the application in order for acceptance (Sec. 21):

The time frame for putting an application in order for acceptance subsequent to its first examination has been shortened to 12 months (non-extendible) from the date of First Examination Report (FER). The first reply to the first examination report is required to be made within 4 months of the date of its issuance.

M. Unity of Invention (Sec. 10(5)):

The concept of 'unity of invention' has been broadened to include a group of inventions linked so as to form a single inventive concept. The claims in a specification should relate to a single invention or a group of invention linked so as to form a single inventive concept. Now, by this amendment it may be possible to claim more than one process in a single application if these processes fall under one group and are closely linked.

N. Electronic Communication (Rule 6):

The documents can also be filed by electronic transmission duly authenticated. In that event the document should be clear, properly addressed and mailed and its original has to be submitted within fifteen days from the date of receipt of communication. The drawings can also be filed electronically.

O. Statement and Undertaking (Rule 12(4)):

For filing the Statement and Undertaking on Form 3 a provision has been provided to seek extension beyond three months.

P. Declaration of inventor-ship (Rule 13 (6)):
The declaration of inventor ship on Form 5 should be filed along with the complete specification. An extension of one month beyond this period can be secured by filing a request on Form 4 with the fees Rs. 250/- pm if the applicant is an individual or Rs. 1000/- pm if the applicant is a legal entity.

Q. Abstract (Rule 13 (a) to (d)):

While filing the application accompanied with a complete specification, an abstract of the invention maximum 150 words have to be filed.

R. Application (Rule 20 (1)):

An application for patent corresponding to International application (PCT application) has to be filed on Form 1 A.

S. Licenses of right (Sec. 86 to 88):

The Provisions relating to "licenses of right" deleted.

T. Restoration of lapsed patent (Sec. 60):

The time for filing the request for restoration of the lapsed patent has been extended from one year to eighteen months.

**Voluntary licence**

The amended Indian Patents Act 1970 does not provide for a voluntary licensing system. This provision should be available in the Patents Act to meet the needs of those patentees who may not themselves like to promote their patented products in the market due to certain limitations. They are, however, interested in their patented products being sold in the country so that they are able to realise royalty and benefit from their product. The provision of a voluntary licence in the Patents Act would help meet this need.
To encourage this, the Act could also provide certain incentives for those patent-holders who may like to avail of this provision.

**Authorization for meeting government requirements**

Article 31 of the TRIPS Agreement clearly provides for the use of patented substances to meet government requirements through government undertakings or other private enterprises authorised by the government to produce and supply. There will be no need to consult the patent-holder while authorising use of the patented product to meet government requirements. Appropriate provision does exist in the amended Indian Patents Act 1970 in Section 100 thereof.

**Compulsory licence due to abuse of patent rights by the patent-holder**

Article 8 of the TRIPS Agreement and Article 5 A of the Paris Convention deal with the abuse of patent rights by the patentees. These Articles provide that suitable measures could be taken by the government to prevent abuse. Abuses arise when the patentee is charging a high price for his patented product, and the relevant product is not available in sufficient quantities to meet domestic demand either through imports or domestic production by the patentee. The grounds could be stipulated as any one of the following:

- That the reasonable requirements of the public with respect to the patented invention have not been satisfied.
- That the patented invention is not available at a reasonably affordable price.
- That the patented invention is not being worked in different regions of the country to meet demand.

The validity of the above grounds would be examined and terms and conditions for grant of compulsory licence for any of the reasons stated would be settled by the Controller of Patents in consultation with the patent-holder. There is also no need for the intended enterprise to approach the patent-holder first to apprise him of the abuse. The stipulation in the Indian Patents Act in this respect needs to be suitably modified.

**Compulsory licence due to unsuccessful attempts at obtaining a voluntary licence**
Article 31 (a) of the TRIPS Agreement stipulates that authorisation of use of the subject matter of a patent shall be considered on the individual merits of each case.

Article 31 (b)\(^5\) provides for a compulsory licence due to unsuccessful attempts by an enterprise to obtain a voluntary licence on reasonable commercial terms and conditions from the patent-holder. The requirement is that the patent-holder should be directly approached first by the interested enterprise, offering commercial terms and conditions. If this effort is unsuccessful within a reasonable period of time, then the enterprise can approach the Controller of Patents for grant of compulsory licence. The Controller shall grant the licence on such terms as he deems reasonable.

This is an important provision for an effective role for domestic enterprises and must be incorporated into the national Patents Act. The application of compulsory licence under this possibility is virtually at par with licences of right, as was stipulated in the non-amended Patents Act 1970.

The TRIPS Agreement in Article 31 (b) also deals with situations of national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use. These contingencies arise under different circumstances and should be dealt with under independent sections of the Patents Act as suggested hitherto:

**Compulsory licence due to national emergency**

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\(^5\) **ARTICLE 31(a) and (b) OF THE TRIPS:**

**Article 31**

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

Article 31(b) TRIPS sets reasonable period of time to negotiate a licence with the right holder on the basis of reasonable commercial terms, but these conditions can be waived in the event of a national emergency.
When a government notifies a situation of national emergency, compulsory licence can be granted by the Controller of Patents. The formulation of provision in the Patents Act could be as follows:

“In the situation of notification of a national emergency by the government, the Controller of Patents may issue authorisation of right at any time during the national emergency for working of any patent in the country on application by any enterprise interested to use the patent on such terms and conditions as the Controller of Patents may deem reasonable.”

**Compulsory licence due to circumstances of extreme urgency (health emergency, environment emergency, etc)**

Under circumstances of extreme urgency, contingencies may arise because of health crises or serious environmental conditions. The government may notify the urgency, and thereafter the Controller of Patents can grant compulsory licences to the interested enterprises. The formulation of provision in the Patents Act could be as follows:

“In circumstances of extreme urgency as notified by the health authorities which may arise as the case may be, including prevention or control of HIV/AIDS, malaria, tuberculosis or any other epidemic among human beings or animals, and control of crisis arising from pollution of air or water or soil as notified by the concerned authorities in the government, the Controller of Patents shall issue authorisation of rights on relevant patented products to any enterprise interested on such terms and conditions as he may deem reasonable. The urgency may be for the country as a whole or for any region of the country.”

**Compulsory licence in cases of public non-commercial use**

Circumstances of public non-commercial use are totally different from other contingencies. The formulation in the Patents Act could be as follows:

“At any time after the expiration of three years from the date of sealing of a patent any enterprise may make an application to the Controller of Patents for grant of compulsory licence for using the patented substance to produce finished formulations for distribution/sale on a public non-commercial basis, that is, on a no-profit no-loss basis; “that the concerned enterprise shall furnish
a certificate to the Controller of Patents at the end of each year that the product has been used for public non-commercial purposes;

“that the term of the licence will be as may be requested by the concerned enterprise. The royalty payable to the patentee shall be decided by the Controller of Patents in consultation with the patentee.”

Compulsory licence to remedy anti-competitive practices

Article 31 (k) of TRIPS offers a procedure for remedying anti-competitive practices. Where the situation of resorting to anti-competitive practice by the patentee has been determined after judicial or administrative process, and that the need to remedy the practice has been notified by the government in the official gazette, the Controller of Patents will issue a compulsory licence to remedy the situation. The terms and conditions of the compulsory licence will be decided by the Controller of Patents.

Second patent for an invention involving important technical advance

Article 31 (l) provides that if an important technical advance of considerable economic significance over the first patent has been justified by an interested enterprise to the satisfaction of the Controller of Patents, a compulsory licence may be granted to that enterprise in consultation with the first patent-holder on such terms and conditions as may be settled by the Controller of Patents.

If all the above possibilities are suitably provided in the national patent law, it would be possible to strengthen the competitive environment regarding availability of patented drugs and pharmaceuticals in the country. In the Indian Patents (Second Amendment) Act 2002, certain possibilities that are available have not been incorporated nor adequately provided. The framing of appropriate provisions on this subject has been suggested above.

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ARTICLE 31(K) AND (l) of THE trips:

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:
Working of patented inventions

The Indian Patents Act 1970, in Chapter XVI, specifically deals with the ‘Working of Patents, Compulsory Licences and Revocation’. Section 83 of this chapter deals with the general principles applicable to the working of patented inventions and is as follows:

General principles applicable to working of patented inventions: Without prejudice to other provisions contained in this Act, in exercising the powers conferred by the chapter, regard shall be had to the following general considerations, namely:

• 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.
• That they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.
• 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.
• That patents granted do not impede protection of public health and nutrition and should act as an instrument to promote the public interest especially in sectors of vital importance for India’s socio-economic and technological development.
• That patents granted do not in any way prohibit the central government from taking measures to protect public health.
• 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 inter-nation transfer of technology.
• Those patents are granted to make the benefits of the patented invention available at reasonably affordable prices to the public.

The section quoted above is virtually the patent policy the Indian government aims to accomplish through other sections of this chapter. However, an in-depth examination of formulations of other
sections of this chapter leaves some ambiguities that ought to be rectified through further amendments to the Patents Act 1970.

There is another important issue that needs to be re-examined. This is with regard to Section 92, dealing with grant of compulsory licensing during circumstances of national emergency and circumstances of extreme urgency. Section 117 A\(^7\) provides for an appeal to be filed, even for compulsory licences under Section 92, with the Appellate Board. This stipulation needs reconsideration.

**Royalty payments**

Article 31 (h)\(^8\) of TRIPS provides that “the right-holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation”. This stipulation is not specific about the rate of royalty that should be paid. The non-amended Patents Act 1970 provided a ceiling of 4% on royalty payments.

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\(^7\) Section 83,92,117A of the patent act 1970

Section 83 of the Patent Act 1970

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 reasonable practicable without undue delay, and

b. that they are not granted merely to enable patentees to enjoy a monopoly for the important patented article

**Article 117A of the patent act**

117. Restoration of name of persons removed from the register of patent agents

(1) An application for the restoration of the name of any person removed from the register of patent agents under sub-section (2) of section 130 shall be made in Form 24 within two months from the date of such removal.

(2) If the name of a person is restored to the register of patent agents, his name shall be continued therein for a period of one year from the date on which his last annual fee became due.

(3) The restoration of name to the register of patent agents shall be notified by the Controller in the Official Gazette and communicated to the person concerned.

**Article 92 of the Patent Act 1970**

Registration of title or interest in a patent

After the receipt of an application under sub-section (1) or sub-section (2) of section 69, the Controller shall register the title of the person concerned or his interest in a patent, as the case may be, and an entry in the following form shall be made in the register,

\(^8\) **ARTICLE 31(H) OF THE TRIPS:**

(b) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
This provision has been deleted and substituted by a provision in Section 90 of the amended Act which does not stipulate any ceiling on payment of royalty.

Because of the long term of protection of 20 years for patents, whether product or process, royalty payment has to be very carefully determined to avoid a long-term burden on the prices of patented drugs.

Thailand’s Ministry of Health, on November 29, 2006, issued a compulsory licence for imports and local production for five years on a patented AIDS drug, Efavirenz, originally developed by Dupont Pharma and now marketed by Bristol Myers-Squibb. Merck has marketing rights in a number of countries including Thailand and China. The royalty allowed by the Thai government is 0.5% of sales in Thailand. The generic version will be sold in Thailand by the Government Pharmaceutical Organisation at half Merck’s price.

Earlier, Malaysia and Indonesia also issued similar compulsory licences.

**COMPULSORY LICENSING SYSTEM**

1. **Compulsory licensing under the Indian Patent Law**

The Indian Patent Law has provided for adequate powers to the Controller of Patents to issue compulsory licenses to deal with the following extreme and/or urgent situations.

A) **Section 84**—To prevent the abuse of patent as a monopoly and to make way for commercial exploitation of invention by an interested person.

B) **Sections 92 (1) and 92 (3)**—Circumstances of national emergency or extreme urgency.

C) **Section 92 A**—For exports of pharmaceutical products to foreign countries with public health problems.

(A) **Section 84**—The law provides for compulsory license under section 84 of the Indian Patent
Act, to prevent the abuse of patent as a monopoly and to make way for commercial exploitation of invention by an interested person. Under this section, any person can make an application for grant of compulsory licence for a patent after three years, from the date of grant of that patent, on any of the following grounds:

(a) The reasonable requirements of the public with respect to the patented invention have not been satisfied;

(b) The patented invention is not available to the public at a reasonably affordable price.

(c) The patented invention is not worked in the territory of India.

Moreover, Section 89 specifies and explains the general purposes of granting compulsory license under Section 84 as:

(i) That the 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;

(ii) 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.

Further, the subsection 6 of Section 84 elaborates that the Controller shall take into account the following factors while considering the application under section 84.

(1) The nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patent or licensee to make full use of the invention;

(2) The ability of the applicant to work the invention to the public advantage;

(3) The capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

(4) As to whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable
period as the Controller may deem fit. Notably, Section 90 of the Act also empowers the controllers to settle the terms and conditions for compulsory licences.

(B) Sections 92 (1) and 92 (3)—Both these sections enable the Central Government and the Controller, respectively, to deal with circumstances of national emergency or circumstance of extreme urgency related to public health crises by granting relevant compulsory licences.

(C) Section 92 A—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.

2. The American Approach towards Compulsory Licensing

As a general matter, the US antitrust laws do not impose on individual firms, even monopolies, a duty to do business with anyone or otherwise to make other facilities available. The position can be succinctly summarized with the aid of the following case

a. Hartford-Empire Co. v United States

The court asserted that “a patent owner is not in a position of a quasi-trustee for the public or under any obligation to see that the public acquires the free right to use the invention. He has no obligation either to use it or grant its use to others”.

However, there have been some decisions over the years – sometimes termed “essential facility cases” – imposing duty to deal or decreeing compulsory licenses. In fact in US the principle of granting involuntary compulsory licenses is inextricably interwoven with the concept of “essential facility” which developed in relation to access to physical infrastructure. “Essential facility” is a “facility or infrastructure which is necessary for reaching customers and/ or enabling competitors to carry on their business.” The essence of this concept is captured appositely in the Terminal Railroad Association case.
b. United States v Terminal Railroad Association

A group of railroads which jointly owned the only railroad switching yard across the Mississippi River at the important city of St. Louis prevented competing railroad services from offering transportation to and through that destination. The Supreme Court required the railroads group to give access to non-members; and concomitantly held that such conduct constituted both an illegal restraint of trade and an attempt to monopolize.

c. Lorain Journal case

Likewise in Lorain Journal case, the Supreme Court considered whether the defendant, the only local newspaper circulating news and advertisements in northern Ohio, violated the Sherman Act by refusing to accept advertising from businesses that placed advertisements with a small radio station. The Court approved an order requiring the newspaper to accept advertisements as it was considered an “indispensable medium” of advertising. Therefore, through the course of such decisions was born the “essential facilities” doctrine and the accompanying remedy of compulsory access. This doctrine is certainly not an independent cause of action but a strand of the monopolization claim. It has been articulated as a subset of the so-called “refusal to deal” cases which place limitations on a monopolist’s ability to exclude actual or potential rivals from competing with it. Hence, “Where facilities cannot practicably be duplicated by would-be competitors, those in possession of them must allow them to be shared on fair terms. It is illegal restraint of trade to foreclose the scarce facility.”

d. Intergraph Case

In the realm of IP monopoly, the federal circuit in Intergraph case, trimmed the ambit of “essential facilities” doctrine by holding that only when the facility owner and the user compete in a downstream market that requires access to the facility, will the doctrine apply. In this case, the plaintiff Intergraph argued that Intel had an affirmative obligation to continue supplying it with chips, technology and interoperability information because Intel products were the de facto industry standard and thus essential facility to do business in the industry. Intel dominated the market with well over 80 percent share of microprocessor chip sales, thus Intergraph asserted that the refusal to deal was monopolizing conduct in violation of Sherman Act. However, the court
held that Intel and Intergraph were not competitors and since they did not compete in downstream market, a compulsory license could not be granted.

e. Eastman Kodak Co. v. Image Tech. Inc.

Another important case is that of Eastman Kodak Co. v. Image Tech. Inc. The Supreme Court emphasized that power gained through some natural or legal advantage such as patent, copyright or business acumen can give rise to liability if “a seller exploits his dominant position in one market to expand his empire into the next”. In this case, the plaintiff won its monopolization claim that Kodak’s practice of refusing to sell patented parts to independent service providers was an unreasonable restraint of trade that violated Sherman Act section 2. A perusal of the above decisions makes it amply clear that in US, apart from mere “ownership” of an IPR, some additional exclusionary conduct is essential for the grant of compulsory and involuntary license.

3. The EU Perspective

The competition policy under Article 82 of the EU Treaty has been used to restrict the abusive commercial conduct of individual owners of IPRs, particularly where the IPR protects a market standard or a de facto monopoly. This form of regulation has extended to excessive pricing, but has been more frequently focused on the IPR holder’s conduct towards innovators who are ‘downstream’ of an IPR protected industrial standard including “refusals to deal” and “refusals to license”. Article 82 in the system of EC competition law regulates undertakings which have been found to occupy positions of dominant market power, such as monopolies or near monopolies. It not merely prohibits exploitative pricing or limitations of output, but also concerns itself with the use of market power to damage effective competition in markets by preventing access to markets or driving out existing competition. It has been interpreted to prohibit anti-competitive or ‘exclusionary’ abuses such as refusal to supply without justification. In essence, this provision of EU Treaty has been the conduit pipe for implementing “compulsory licensing”, which can be understood by perforating through a series of important cases.

a. The first such case is AB Volvo v Erik Veng

Volvo held the design right in the UK over front wings for cars. Veng imported panels into UK from Italy and Denmark where they had been manufactured without Volvo’s consent. Volvo
alleged infringement of its UK registered designs. Veng’s defense was that Volvo’s refusal to grant license was an abuse of dominant position when Veng was willing to pay a reasonable royalty for license. The question before ECJ was whether refusal to grant license by Volvo was an “abuse of dominant position”? The ECJ said:

“An obligation imposed upon the proprietor of protected design to grant to third parties, even in return for a reasonable royalty, a license for the supply of products incorporating the design would lead to the proprietor thereof being deprived of the substance of his exclusive right, and that a refusal to grant such a license cannot itself constitute an abuse of a dominant position.”

Outlining the circumstances, under which refusal to license may be deemed to constitute “abuse of dominance”, the court said that Article 82 may be attracted if an undertaking holding a dominant position involves in abusive conduct such as – “arbitrary refusal to supply spare parts to the independent repairers, the fixing of prices for spare parts at an unfair level, or a decision no longer to produce spare parts for a particular model even though many cars of that model are still in circulation…”

Therefore, the significance of this case lies in determining the boundaries of “compulsory licensing”. It is pertinent that merely a refusal to grant license may not be anti-competitive in nature. Such refusal should be “arbitrary”, so as to compel involuntary compulsory licensing, in order to mitigate the rigours of abusive conduct.

b. Magill

In the landmark case of Magill, broader and more flexible approach was adopted - Magill, a Dublin company, was the compiler of a comprehensive weekly television guide combining the listings of three television companies broadcasting in the UK and Ireland. Since these listings were protected by copyright, Magill inevitably required a license, the grant of which was refused by these companies. The ECJ affirmed the grant of compulsory license by the Commission, on grounds of Article 82, and held that copyright itself did not justify a refusal to license in the ‘exceptional circumstances’, where there was a consumer demand for the new product, where the TV companies had a de facto monopoly over the listings by virtue of their scheduling of TV programs, where a license of the listings was an indispensable input for the
comprehensive TV guide and where they were not themselves supplying the product to the consumers.

c. A more recent case is that of IMS Health v. NDC Health

IMS was the largest supplier of sales data and other information on pharmaceutical services to pharmacies in Germany using a ‘brick like’ structure, which divided Germany into 1860 areas or ‘bricks’, corresponding to a particular geographical area. This structure became the ‘market standard’ for delivery of such pharmaceutical information and was protected by copyright. NDC developed a similar structure, deriving from IMS and the German court prohibited NDC from using any structure derived from IMS. On a referral from the German court, the ECJ emphatically reiterated that all the criteria of the “exceptional circumstances,” as stated in Magill, must be fulfilled in order for a compulsory license to be granted. In the absence of such exceptional circumstances, the IP owner has the exclusive right of reproduction, and a refusal to grant license even by a dominant undertaking, cannot, of itself, constitute an abuse of Article 82.

The court reasserted that the three cumulative criteria must be met for a refusal to be regarded as abusive:

• The undertaking which requested the license must intend to offer new products or services not offered by the owner of copyright and for which there is a potential consumer demand.

• The refusal cannot be objectively justified

• The refusal must be such as to exclude competition on a secondary market. In this case it was for the national court to determine whether the brick structure constituted an indispensable factor in the downstream supply of regional pharmaceutical sales data.

The above cases reflect, to an extent that the American doctrine of “essential facility” has been the conduit to enforce “compulsory licensing”, albeit in a different form.
4. Conclusion

Both in US and EU the principle of “compulsory licensing” has been used to countervail the dampening effect of anti-competitive behaviour. However, this approach has not transcended beyond the various pre-requisites such as – competition in secondary market and indispensability and the jurisprudence in the EU and in the U.S. both suggest that under exceedingly limited circumstances, compulsory licensing can be an appropriate remedy in antitrust cases. Though applied cautiously and within a limited ambit, compulsory licensing has served the purpose rectifying the market failure, which is the quintessence of competition policy. The narrow and well defined application has at the same time ensured that an efficacious and delicate balance is maintained between innovation and competition.
CHAPTER 4
Compulsory licensing in the time of health emergencies

In a compulsory license, a government can force a patent holder who has an exclusive right to grant a licence to be used by the state. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreed by member countries under World Trade Organisation (WTO) also allow the grant of compulsory licenses. TRIPS allows those third world countries which often lack the technology to be able to manufacture the drugs, in case of emergencies and pandemic outbreaks. In such situations, compulsory licensing is seen as a balancing act between exclusive rights and public health concerns. Apparently, TRIPS handles compulsory licenses as an exception to the agreement’s minimum requirement that all WTO Member States afford a patentee a right of exclusivity during the complete patent term. The Doha declaration recognized the need for compulsory licensing in emergency situations. Following this, Canada implemented it in 2005. On 17 May 2006 the European Union also legalised compulsory licensing provision. Doha declaration allows compulsory licences to be issued in developed countries for the manufacture of patented drugs, provided they are exported to those on the least-developed countries and other countries having per-capita incomes of less than US$745 a year as per UN list. So public interest one of the major considerations for allowing compulsory licencing. With a great public health emergency underway, it is almost certain that the compulsory licensing provision will come into play as the World Trade Organization allows various countries to buy from low-cost suppliers or generics firms.

1. Oseltamirv & zanamivir: India’s generic edge

Several countries have already developed capabilities and capacities to produce oseltamivir and zanamivir. Indian generic companies say that they could also swiftly boost the output of antiviral drugs to tackle swine flu in case of demand. Hyderabad-based Hetero Drugs, for instance, claims to be the world’s largest licensed producer of the generic version of Swiss drugmaker Roche Holding’s Tamiflu (oseltamivir).
“We’ve created a capacity to produce 80 million doses a month,” Hetero director of marketing Srinivas Reddy said. Hetero supplied 200 million doses of the drug in the last three years to India and other countries. Hetero is negotiating with many nations around the world for supplies, Mr Reddy said. Same for Cipla, which has been recently allowed by an Indian High Court for selling its own version Roche’s Tamiflu in India. “We have received some inquiries from Mexico, Israel, New Zealand and Latin America, but nothing has been finalized in terms of exports,” stated joint managing director Amar Lulla. Cipla has the capability to supply 1.5 million doses of oseltamivir in four to six weeks, Lulla said. Cipla’s cheaper version of Tamiflu costs about Rs 50 ($1) a capsule for export markets, slightly more than Hetero’s 10 doses for about Rs 300 ($6.0). Ramesh Adige, president of Ranbaxy Laboratories, the third supplier in India, said his company was also prepared to begin supplying a generic version of the drug if needed. Already India government is planning to buy nine million doses of oseltamivir (Tamiflu) within a week, to boost its reserve. The government has already received price bids from Cipla, Ranbaxy Hetero and the local unit of Switzerland-based Roche Holding AG, Vineet Chawdhry, joint secretary in the ministry of health and family welfare said. Clearly, with needing countries and growing demands, Indian generic makers stand to gain, once the compulsory licensing provision come into play.

2. Bayer, GSK, Pfizer and other MNCs agree to bypass drug patents in Ecuador

No legal right is superior to the requirements of public health, say pharma MNCs. Multinational pharmaceutical companies operating in Ecuador has agreed to bypass patents of some 2000 medicines sold in the country. Foreign pharmaceutical companies accepted the decision of Ecuador’s President Rafael Correa to enable the country “to bypass patents on 2,000 drugs in order to produce them locally or buy cheaper versions elsewhere,” 14 multinational companies including European and American giants such as Pfizer, Bayer and GSK conveyed through the local pharmaceutical industry association that the would bypass patent rights of their medicines for the benefit of public health in Ecuador. “We accept the democratic decision … to legally implement this extraordinary measure,” the 14 companies reportedly stated. “No legal right is superior to the requirements of public health, especially in such serious circumstances,”.

Certain provisions agreed under World Trade Organization, countries can issue ‘compulsory licenses’ to disregard patent rights, allowing local manufacturing companies the ability to produce generic versions of drugs. WTO rules, however, mandates that the Compulsory Licensing provision should be used only after negotiating with the patent owners and paying them
adequate compensation. In that case – when countries use the Compulsory Lisensing provision in emergency health needs under WTO – Ecuador has to pay royalties to the holders of international pharmaceutical patents, basing the payments on the sale price of locally produced medicines. Several countries across the world Brazil, Thailand, Zimbabwe, Malaysia, Indonesia, and Thailand have invoked the Compulsory License procedure to import cheap generic medicines, especially American AIDS drugs. NGOs and other human rights watchdogs have praised these countries noting that patients who develop resistance to older anti-retrovirals need second-line drugs that can be prohibitively expensive. High costs, insufficient production and a lack of research have contributed to the fact that millions of people do not enjoy equitable access to medicines in developing countries such as Ecuador, said Andres Ycaza, president of Ecuador’s Intellectual Property Institute.

3. MINT CASE

Local units of multinational drug makers — who make billions of dollars of revenues from drugs protected by patents — say they are increasingly worried over a vigorous push by Indian peers to revoke such protection through what are called compulsory licences, and questioned such efforts in the absence of a national emergency. Local drug makers, who make most of their revenues from sales of non-patented or generic drugs, are exploring the use of a controversial public health provision in global trade laws called compulsory licence that allows the World Trade Organization’s member-nations to override patents and permit cheaper versions of patented drugs. This provision can be invoked if a drug maker is willing to make and supply copies of patented drugs in a medical emergency or to export to least developed countries, which are yet to be covered by the TRIPS, or the Trade-Related aspects of Intellectual Property Rights, regime and entitles the patent holder to an “adequate remuneration”. Mint reported on 29 January that Hyderabad-based Natco Pharma Ltd’s request for compulsory licences on two patented cancer drugs could emerge as a larger trend. Natco Pharma is seeking licences for Sutent, a renal cancer drug of Pfizer Inc. and Swiss F. Hoffmann-La Roche Ltd’s lung cancer medication, Tarceva, which costs Rs1.5 lakh for a month’s treatment—nearly four times the Indian per capita annual income. Sutent, awaiting a patent grant in India, is likely to be priced at $4,000 (Rs1.57 lakh) for a six-week treatment.

Expressing concern that patent provisions could be misused to make products available illegally in the Indian market, Pfizer Ltd’s managing director Kewal Handa said in an email response,
“This would be a clear disregard of Indian patent laws.” He added that if continued, this would take the country back “to the pre-product patent era.” He expects the judiciary and the Indian government to “uphold the spirit of innovation.” The top executive at Novartis India Ltd said the move was unjustified in the absence of a national emergency for which compulsory licensing is designed. “Generic drug makers talk of evergreening of patents but this is (cutting short) patents. What signals are we giving to the global drug makers?” asked Ranjit Shahani, managing director of the Novartis unit. Makers of patented drugs are often accused of trying to extend the life of patents beyond 20 years, a tactic commonly called patent evergreening. Roche Scientific Co. (India) Pvt. Ltd’s managing director Girish Telang declined comment. Cipla Ltd, one of country’s largest drug makers, is fighting Roche over the latter’s patent in India for Tarceva in the Delhi high court, though the Indian firm is not asking for a compulsory licence on it. Foreign drug makers also point out that they run patient access programmes to deliver their patented drugs to those who can’t afford it, though patient groups argue the reach of such initiatives is limited. Pfizer, for instance, has recently put together a Sutent Patient Access Programme that will partly or fully subsidize treatment options for patients in India and expects to extend it to Nepal. Novartis’ Glivec International Patient Assistance Programme helps some 7,000 patients of myeloid leukaemia, the company says on its website. Novartis is fighting in court and at an appeals tribunal the rejection of a patent for the cancer drug by Indian authorities.

4. Compulsory licensing of Tamiflu & Relenza on the cards

Made-in-India low-cost generics to gain most in case of copulsory licensing of Tamiflu and Relenza. As swine flu (H1N1 Influenza A) threatens to assume epidemic proportions, there is a possibility of compulsory licensing being introduced for Tamiflu and Relenza. Producers of low-cost generic versions of Tamiflu and Relenza including Cipla, Hetero, Ranbaxy, Natco would be the greatest beneficiaries, once compulsory licensing of the patented drugs Tamiflu and Relenza come into force. Compulsory licensing of Roche’s Tamiflu (oseltamivir) and GSK’s Relenza (zanamivir) may well be a possibility as more and more nations across the world start stockpiling these medicines – the only available treatments against the deadly flu virus – which threatens to assume epidemic proportions.

Industry analysts say that the compulsory licencing provision can be invoked anytime now since the world is currently facing a grave emergency of swine flu epidemic which can be a threat to the entire humanity.
CHAPTER 5

COMPULSORY LICENSING: SUGGESTIONS FOR CHANGE:

The Paris Convention, TRIPS Agreement and Doha Declaration on TRIPS and Public Health stipulate provisions on compulsory licensing for implementation by member countries of the World Trade Organisation in their national patent systems (to read a backgrounder on compulsory licensing based on these documents. There is hardly any developing country, including India, that has made full use of stipulations in these three above-mentioned documents. The article deals with the various possibilities for ensuring the working of patents under certain contingencies through compulsory licences granted by the concerned government authorities to meet the demands of the relevant products, particularly in the area of healthcare. India, in particular, has ignored certain important provisions in the amending process of its national Patents Act 1970

Article 27 of the TRIPS Agreement absolves patent-holders from the obligation of working their patents as ‘patent rights are enjoyable whether products are imported or locally produced’. However, working of patent through domestic enterprises must be ensured through the system of grant of compulsory licences.

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9 ARTICLE 27 OF THE TRIPS:

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.
Presently, there are over 20,000 pharmaceutical manufacturers registered in India; hundreds of enterprises are producing the same product and competing amongst themselves to meet the country’s requirements. This phenomenon cannot be equated with the working of patent through imports by the patent-holder. Extensive involvement of domestic enterprises in the production and availability of patented products is absolutely necessary in India.
Bibliography