COMPULSORY LICENSING AND GRANT OF PHARMACEUTICALS PATENTS IN INDIA: ISSUES AND CONCERNS

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INTRODUCTION

PATENTS in India are granted to encourage inventions and to secure that it is worked on a commercial scale. The Indian Patent Act ensures that a Patentee should not be able to enjoy a monopoly for the importation of the patented article. The Patent Act provides measures by way of Compulsory Licensing (CL) to ensure that the patents do not impede the protection of public health and nutrition and the patent rights are not abused by the patentee. The CL therefore serves to strike balance between two disparate objectives — rewarding patentees for their invention and making the patented products, particularly pharmaceutical products, available to large population in developing and under developed countries at cheaper and affordable cost.

As is known, CLs allow third parties to exploit a patented invention without the consent of the patentee. They there, deprive patentees of their most important right, *i.e.* the right to say 'no' to the exploitation of their invention by the third parties. CLs are usually granted through administrative procedures managed by a governmental body. CLs are granted by governments which, thereby, substitute their authority for the consent of the patent owner. They therefore are in the nature of administrative contracts.

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On March 9, 2012, India's first CL was granted by the Patent Office to Natco Pahrma Ltd. for producing generic version of Bayer Corporation's patented medicine Nexavar, used in the treatment of Liver and Kidney cancer. The Controller decided Bayer on all the three grounds in the Patents Act for the grant of CL (reasonably requirements of the public not being satisfied; non-availability to the public at a reasonably affordable price, and the patented invention not being worked in the territory of India). While the multinational giant was selling the drug at INR 2.80 lakh for a month's course, Natco promised to make available the same at a price about 3% (INR 8800) of what was charged by Bayer. Natco was directed to pay 6% of the net sales of the drug as royalty to Bayer. Among other important terms and condition of the non-assignable, non-exclusive license were directions to Natco to manufacture the patented drug only at their own manufacturing facility, selling the drug only within the Indian Territory and supplying the patented drug to at least 600 needy and deserving patients per year free of cost.

Aggrieved by the Controller's decision, Bayer immediately moved to the Intellectual Property Appellate Board (IPAB) alleging that the grant of CL was illegal and unsustainable. On March 4, 2013, IPAB upheld the country's first compulsory license to a pharmaceutical product. Specifically, the decision upheld a compulsory license issued to Natco Pharma Ltd., an Indian generic drug manufacturer, to sell Bayer's patented chemotherapy drug Nexavar (sorafenib tosylate). The Board rejected Bayer's appeal holding that if stay was granted, it would definitely jeopardize the interest of the public who need the drug at the later stage of the disease. It further held that the right of access to affordable medicine was as much a matter of right to dignity of the patients and to grant stay at this juncture would really affect them. Given the economic consequences of this compulsory license, Bayer is expected to further appeal this decision. It is important for companies procuring patents and doing business in India in all industries to understand the country's compulsory licensing laws.

A compulsory license is a statutorily created license that allows certain parties to use or manufacture a product encompassed by the claims of a patent without the permission of the patent owner (patentee) in exchange for a specified royalty. The Indian Patent Act contains very broad compulsory licensing provisions. The two provisions of the Act that allow for compulsory licenses are Sections 84 and 92.

GRANT OF COMPULSORY LICENSE DUE TO 'NON-WORKING/UNAFFORDABLE PRICES OF PATENTED ARTICLE'

Section 84

Under Section 84, the Controller of Patents can issue a compulsory license three years after the issuance of a patent if one of the following conditions is met:

1. The reasonable requirements of the public with respect to the patented invention have not been satisfied; or
2. The patented invention is not available to the public at a reasonable price; or
3. The patented invention is not worked in India.

Section 83 of the Patent implies that the working of the patent cannot be taken to include 'imports'. The patentee cannot hold the patent in India and import the product from another country, thereby compelling the Indian consumer to pay an excessive price.

Public Accommodation: The Act contains a list of circumstances in which the "reasonable requirements of the public" will be considered not met. These are:

1. The patentee does not grant a license on "reasonable terms" thereby causing: (a) a disadvantage to a trade or industry or the development or establishment of an industry in India; (b) demand for the patented product not to be sufficiently met or available on reasonable terms; (c) insufficient supply or development of a market in India for the exportation of the patented article; or (d) a disadvantage in the establishment or development of commercial activities in India.
2. The patentee imposes conditions with respect to the grant of license, sale or use of a patented product or process, the manufacture, use or sale of non-patented materials or the establishment or development of any trade or industry in India, which is prejudiced.
3. The patentee includes one or more of the following conditions in a license: (a) an exclusive grant-back clause for any improvements developed by the licensee on the patented product or process; (b) a clause prohibiting the licensee from challenging the validity of the licensed patent(s); or (c) a clause that is essentially a "coercive" package license (namely, requires the licensee to purchase

non-patented items from the patentee as a condition of the license).

4. The patentee does not work the patented invention in India to the fullest extent possible or on a commercial scale to an adequate extent.
5. The working of the patented invention on a commercial scale in India is being prevented or hindered as a result of the importation of the patented invention by: (a) the patentee or a person authorized by him; (b) persons purchasing from the patentee, either directly or indirectly; or (c) the infringement of the patent by a third party against whom the patentee is not taking or has not taken any action to eliminate said infringement.

Reasonable Price: With respect to the patented invention not being available to the public at a reasonable price, a compulsory license will be granted if a patented invention is not being made available to the public at an affordable price. For example, Bayer was selling Nexavar® for about Rupees 280,000 (around US $5,160) per month compared to Natco selling the drug for about Rupees 8,800 (around US $162) per month.

Worked in India: With respect to a patented invention being worked in India, a compulsory license will be granted if the patented invention is not worked in India. An invention is considered to be "commercially worked" in India if the patented invention is: (a) manufactured in India; (b) imported into India; (c) licensed and forms a part of a product that is sold in India; or (d) commercialized in India in any other manner.

Interested Person: Any person interested may file an application for a compulsory license in the Indian Patent Office three years after the grant date of a patent. A "person interested" is interpreted broadly under the Act and includes a licensee of patent for which a compulsory license is sought. The application must include the nature of the interest of the party filing for the license, the facts supporting the application and license conditions (royalty rates, etc.) the applicant is willing to accept.

Controller Review: The Controller will review the application and if satisfied that a *prima facie case* has been made will direct the applicant met the requirements to grant the license, will send a copy of the application to the patentee or any other person having an interest in the patent. The application for the compulsory license will be published in the official journal of patents.

Within two (2) months of publication in the official journal, the patentee (or any other person) may file a notice of opposition opposing the

application. The notice of opposition must state the grounds of the opposition, the terms and conditions of a license that would be acceptable to the opponent and any evidence necessary to support the opposition. A copy of the notice of opposition is provided to the applicant for the compulsory license. A hearing is conducted during which both parties will have the right to be heard. After each party is heard, the Controller will make his/her decision on the compulsory license.

If after the Controller's review of the application he/she is not satisfied that a *prima facie case* has been made, he/she will notify the applicant. The applicant may then request a hearing within one month from the date of such notification. If the applicant does not request a hearing, the application for a compulsory license will be refused. If the applicant files a request for a hearing, a hearing will be conducted and after hearing, the Controller will make a decision on whether or not to allow or refuse the compulsory license. If the Controller decides to allow the compulsory license, the patentee or other person having an interest in the patent will be notified and the procedure described above will be followed.

After deciding to grant a compulsory license, the Controller will determine the terms and conditions of the license. For example, in the case involving Nexavar®, a non-exclusive, non-assignable license was given Natco. In addition, the Controller initially awarded Bayer a royalty of 6% for sales of Nexavar® by Natco. The IPAB increased this royalty to 7%.

Section 92

Under Section 92 of the Act, compulsory licenses can be granted on notification by Central Government:

1. In a case of a national emergency (including a public health crisis), extreme urgency or in the event of public non-commercial use; [Section 92(1)]; or
2. For export [Section 92A(1)].

Emergency: With respect to compulsory licenses granted as a result of national emergency, extreme urgency or as a result of public non-commercial use, such licenses are published by Central Government in the official gazette. Once these licenses are published, the Controller will grant a compulsory license to any interested person who applies for such a license. The granting of compulsory licenses under Section 92(1) cannot be

challenged by the patentee either through an opposition proceeding or in court. However, the Controller is required to notify the patentee of the granting of the compulsory license under this section.

GRANT OF COMPULSORY LICENSE FOR THE EXPORT OF PHARMACEUTICAL PRODUCTS

Article 31 (f) of the TRIPS Agreement undermined the need for the availability of medicines to the countrises having less or no manufacturing capacity through importation from other countries. WTO adopted a mechanism to resolve this problem by implementing para 6 of the Doha Declaration on the TRIPS Agreement and Public Health on August 30, 2003. Obligation under Article 31 (f) of the TRIPS Agreement was thus waived off in case of export of pharmaceutical products to the countries having least or no manufacturing capacity provided the eligible members has made a notification to the Council for TRIPS.

The Indian Patent Act was thus amended on January 1, 2005 and Section 92 (A) was incorporated for grant of CL for export of pharmaceutical products in certain exceptional circumstances. The CL under the said section can only be granted if the importing country has also granted CL or has, by notification or otherwise, allowed importation of the patented pharmaceutical product from India. This condition is not applicable for least developed countries (LCD) having no patent regime. The LCDs is only required to notify the Council of WTO about their willingness to import the Pharma product subject to para 6 of the Doha Declaration.

Export: With respect to compulsory licenses granted for export, such licenses may be granted for the manufacture and export of patented **pharmaceutical products** to any country having insufficient or no manufacturing capacity in the pharmaceutical area relevant to the patented pharmaceutical product in order to address "public health problems". Compulsory licenses will only be granted under Section 92A(1) if the country experiencing the "public health problems" has already granted a compulsory license for the patented pharmaceutical product at issue or if the Government of that country has provided notice in the country's Official Gazette, with respect to the pharmaceutical patented product to be imported from India. In these instances, the Controller will grant a compulsory license to an applicant on certain terms and conditions (which will be published) and only for manufacture and export of the patented pharmaceutical product to the country in question. The Controller will also determine the compensation to be paid to the patentee.

LICENSE REVISION AND TERMINATION

Twelve months after the licensee has worked the invention on a commercial scale, the licensee of a compulsory license may make an application to revise the terms and conditions of the license on the ground that the terms and conditions settled upon have proven to be more onerous than originally expected and as a consequence thereof, the licensee is unable to work the invention except at a loss. The application must include facts and evidence to support the application as well as the remedy or relief sought by the license holder. The license holder may request a hearing. The Controller will review the application and after the hearing, will grant or deny the application. If the application is granted, the Controller will revise the terms and conditions of the compulsory license. However, such an application for revision of a compulsory license shall not be entertained more than once. Given that Bayer received a 1% increase in the royalty rate by IPAB, it will be interesting to see if after one year Natco will attempt to have the royalty rate reduced back to 6%.

A compulsory license can be terminated if the circumstances under which the license was granted no longer exist and are not likely to recur. The patentee (or another party in interest) may filed an application in the Indian Patent Office with supporting evidence requesting that the compulsory license be terminated. The compulsory license holder will be provided with a copy of the application and has a period of one month from the date of receipt of the application to object to the application. If the license holder objects to the application, he/she must notify the patentee (or other interested party) and the Controller of his/her objection. After receipt of such an objection, the Controller will hold a hearing and decide the application based on the facts and evidence submitted by the parties. If the Controller decides to terminate the compulsory license, he shall issue an order providing the terms and conditions of such termination and serve copies of the order on both the licensee and compulsory license holder.

COMPULSORY LICENSES IN INDIA

As mentioned above, the IPAB upheld the compulsory license to Nexavar on March 4, 2013, which was originally granted by the Controller in March 2012. Since 2012, compulsory licenses have been granted or are in process of being granted for several pharmaceutical products as shown by below:

Drug	Company	Indication	When Issued
Nexavar®	Bayer	Hepatocellular carcinoma	March 2012 – Decision upheld March 2013 (Article 84)
Herceptin®	Genentech	Breast cancer	In process by the Department of Industry Property and Promotion (DIPP) (Article 92)
Ixempra®	BMS	Breast cancer	In process by the DIP (Article 92)
Sprycel®	BMS	Leukemia	In process by the DIPP (Article 92)

COMPULSORY LICENSES ISSUED IN OTHER COUNTRIES

India is not the only country that has issued compulsory licenses for patented pharmaceutical products. While the compulsory license laws vary country-by-country, as shown in the below table, compulsory licenses have been issued by several countries for a number of different pharmaceutical products, as under:

Country	Drugs
Brazil	Efavirenz
Cameroon	Lamivudine, Nevirapine
Canada	Oseltamivir
Ecuador	Lopinavir/Ritonavir
Ghana	Generic HIV and AIDS medicines
Indonesia	Lamivudine, Nevirapine
Israel	Hepatitis B vaccine
Italy	Imipenem/cilastatine, Sumatripan succinate
Malaysia	Didlanosine, Zidovudine
Mozambique	Lamivudine, Stavudine, Nevirapine
Thailand	Lopinavir/Ritonavir, Clopidrogel, Erlotinib, Letrozole, Docetaxel
Zambia	Lamivudine, Stavudine, Nevirapine

The issue of compulsory licenses in India is something that every company should be concerned about when procuring patents and conducting business in India. While most of the recent attention has centered on compulsory licenses for patented pharmaceutical products, it is important to remember that India's Patent Act provides for broad compulsory license provisions that are not limited to just pharmaceutical products but encompass products from any technology.

APPENDIX

1.84. *COMPULSORY LICENCES*

1. At any time after the expiration of *three years* from the date of the sealing of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:-
   (a) that 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.
2. An application under this section may be made by any person notwithstanding that he is already the holder of a licence under the patent and no person shall be estopped from alleging that the reasonable requirements of the public with respect to the patented invention are not satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price by reason of any admission made by him, whether in such a licence or otherwise or by reason of his having accepted such a licence.
3. Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.
4. The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may grant a licence upon such terms as he may deem fit.
5. Where the Controller directs the patentee to grant a licence he may, as incidental thereto, exercise the powers set out in section 88.
6. In considering the application filed under this section, the Controller shall take into account,-
   (i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

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

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

(iv) as to whether the applicant has made efforts to obtain a licence 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: Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.

Explanation —For the purposes of clause (iv), "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months.

7. For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied-

(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,-

(i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or

(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii) a market for export of the patented article manufactured in India is not being supplied or developed; or

(iv) the establishment or development of commercial activities in India is prejudiced; or

(b) if, by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or

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.

2. The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.

3. The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under any other provision of this Act.

Explanation — For the purposes of this section, "pharmaceutical products" means 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.

THE DOHA DECLARATION

(a) Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognise that these flexibilities include: ...

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

Available at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

3.92. *SPECIAL PROVISION FOR COMPULSORY LICENCES ON NOTIFICATIONS BY CENTRAL GOVERNMENT*

1. If the Central Government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licences should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette, and thereupon the following provisions shall have effect, that is to say,–

   (i) the Controller shall, on application made at any time after the notification by any person interested, grant to the applicant a licence under the patent *on such terms and conditions* as he thinks fit;

   (ii) in settling the terms and conditions of a licence granted under this section, the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentee deriving a reasonable advantage from their patent rights.

2. The provisions of Sections 83, 87, 88, 89 and 90 shall apply in relation to the grant of licences under this section as they apply in relation to the grant of licences under section 84.

3. Notwithstanding anything contained in sub-section (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub-section (1) that it is necessary in-

   (i) a circumstance of national emergency; or

   (ii) a circumstance of extreme urgency; or

   (iii) a case of public non-commercial use, which may arise or is required, as the case may be, including public health crises, relating to Acquired Immune Deficiency Syndrome, human immunodeficiency virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in Section 87 in relation to that application for grant of licence under this section:

   Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of Section 87.

6.226. *POWER OF HIGH COURTS TO ISSUE CERTAIN WRITS*

1. Notwithstanding anything in Article 32 every High Court shall have powers, throughout the territories in relation to which it exercise jurisdiction, to issue to any person or authority, including in appropriate cases, any Government, within those territories directions, orders or writs, including writs in the nature of *habeas corpus*, mandamus, prohibitions, quo warranto and certiorari, or any of them, for the enforcement of any of the rights conferred by Part III and for any other purpose.

2. The power conferred by clause (1) to issue directions, orders or writs to any Government, authority or person may also be exercised by any High Court exercising jurisdiction in relation to the territories within which the cause of action, wholly or in part, arises for the exercise of such power, notwithstanding that the seat of such Government or authority or the residence of such person is not within those territories.

3. Where any party against whom an interim order, whether by way of injunction or stay or in any other manner, is made on, or in any proceedings relating to, a petition under clause (1), without.

   (a) furnishing to such party copies of such petition and all documents in support of the plea for such interim order; and

   (b) giving such party an opportunity of being heard, makes an application to the High Court for the vacation of such order and furnishes a copy of such application to the party in whose favour such order has been made or the counsel of such party, the High Court shall dispose of the application within a period of two weeks from the date on which it is received or from the date on which the copy of such application is so furnished, whichever is later, or where the High Court is closed on the last day of that period, before the expiry of the next day afterwards on which the High Court is open; and if the application is not so disposed of, the interim order shall, on the expiry of that period, or, as the case may be, the expiry of the aid next day, stand vacated.

4. The power conferred on a High Court by this article shall not be in derogation of the power conferred on the Supreme Court by clause (2) of Article 32.

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