IN THE HIGH COURT OF JUDICATURE AT BOMBAY
ORDINARY ORIGINAL CIVIL JURISDICTION

WRIT PETITION NO.1323 OF 2013

Bayer Corporation
A Corporation Organized under the laws of
the State of Indiana, Unites States of America-100 Bayer Road,
Pittsburgh, PA 1505-9741,
United States of America. ...Petitioner.

vs.

1) Union of India through the Secretary
Department of Industrial Policy and Promotion
Ministry of Commerce and Industry,
Udyog Bhavan, New Delhi.

2) The Controller of Patents,
The Patent Office
Bhoudhik Sampada Bhavan,
S.M.Road, Antop Hill,
Mumbai-400037.

3) Natco Pharma Limited
Natco House,
Road No.2, Banjara Hills,
Hyderabad 500-033,
Andhara Pradesh. ...Respondents.

Shri. Ravi Kadam, Senior Advocate with Mr. Sanjay Kumar, Ms. Arpita Sawhney and Mr. Ramesh Gajria i/by M/s. Gajria & Co. for the Petitioner.
Ms.Rajani Iyer, Senior Advocarte with Mr. A. M. Sethna and Mr. G. Hariharan i/by Mr. A.A.Ansari for Respondent Nos. 1 and 2.
Mr. Anand Grover, Senior Advocate along with Dr. Birendra Saraf, Senior Advocate along with Ms. Rajheshwari H. i/by Nachiket Vilol Khaladkar for Respondent No.3.

Bombay High Court

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CORAM : MOHIT S. SHAH, C.J. AND
M.S. SANKLECHA, J.

PRONOUNCED ON : 15 JULY 2014.

C.A.V. JUDGMENT: (Per M.S. SANKLECHA, J.)

This petition under Article 226 of the Constitution of India challenges the order dated 4 March 2013 passed by the Intellectual Property Appellate Board (Tribunal). By the impugned order the Tribunal upheld the order dated 9 March 2012 passed by the Controller of Patents (Controller) granting Compulsory License to M/s. Natco Pharmaceuticals Limited (Natco) under Section 84 of the Patent Act 1970 (the Act). This compulsory licence was in respect of the petitioner's patented invented drug - Sorafenib Tosylate (compound of Carboxyaryl Substituted Diphenyl Ureas) sold under brand name Nexavar (patented drug).

2) This petition arises out of orders granting a compulsory license of the patented drug owned by the petitioner to Natco on application of the provisions of Chapter XVI and in particular Section 84 of the Act. The challenge of the petitioner is to the allowing of the application of Natco for compulsory licence and to the manner in which Chapter XVI of the Act and in particular Section 84 of the Act has been applied. We are informed at the Bar that it is for the first time after India became a signatory to Trade Related Aspects of Intellectual Property Rights (TRIPS) followed by the Doha Declaration in 2001 and the amendments to the said Act in 2003 and 2005 that the issue of compulsory licence has arisen for consideration before the

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authorities under the said Act and consequently also before this Court. The result of the examination of Chapter XVI of the Act and the manner of its application by the authorities under the Act would have far reaching impact as it would govern the issue of grant of compulsory license in respect of patented drugs.

I) **Factual background**

3) The bare facts necessary to consider the challenge in this petition are as follows:

a) The petitioner is a corporation incorporated under the laws of United State of America (USA). Consequent to its research and development (R & D) activities the petitioner invented and developed its patented drug to enable its administration to human beings. The patented drug is used in the treatment of patients suffering from Kidney cancer i.e. Renal Cell Carcinoma (RCC) and liver cancer i.e. Hepatocellular Carcinoma (HCC). The aforesaid patented drug acts more as a palliative i.e. relieves patients from pain and to an extent also slow down the spread of cancer by restricting the speed with which the cancer cells grow.

b) The aforesaid invention of the patented drug was done in USA. The patented drug is for treatment of Cancer of RCC and HCC. However, as the people suffering in America from the aforesaid cancer of RCC and HCC are rare/few i.e. less than 2,00,000 patients, the patented drug is classifiable as 'Orphan drug' in U.S.A. On classification of the patented drug as “Orphan drug”, in U.S.A. 50% of the amount

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spent by the petitioner on research and development of the patented drug is reimbursed to the petitioner by the Government of U.S.A.

c) On the successful invention of the patented drug in 1999, the petitioner applied for a patent in U.S.A. Thereafter, on 12 January 2000 the petitioner applied for an international patent under the Patient Co-operation Treaty (PCT) and on 5 July 2001 applied in India for grant of the patent to the patented drug in India. On 3 March 2008 the office of the Controller granted the petitioner's application dated 5 July 2001. This patent granted in India on 3 March 2008 corresponded to the patent granted to this patented drug in over 45 countries of the world.

d) As a consequence of being granted a patent, the petitioner had exclusive right to make/manufacture, use and sell the patented drug either by itself or through its licensee to the exclusion of all others for a period of 20 years from the date of its application. Thus, the petitioner had exclusive right to prevent third parties from making/manufacturing, using, selling or importing the patented drug in India without the petitioner's permission/license. This license/ permission is at most times voluntarily granted by a patent holder to any other party as a matter of its free will under a contract. However, Chapter XVI of the Act, inter alia, provides for grant of compulsory license to the applicant by the orders of the Controller from the patent holder. In terms of Section 84 of the Act after the expiration of 3 years from the grant of a patent, it is open to any person to apply to the Controller for grant of a Compulsory License from the original patent

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holder. Such an application for grant of Compulsory License would be granted by the Controller, if any, of the following circumstances with regard to the patented drug exist:-

i) Reasonable requirement of the public with regard to the patented invention is not being satisfied, or

ii) That the patented invention is not available to the public at the reasonably affordable price; or

iii) That the patented invention is not worked in the territory of India.

However a condition precedent for the grant of compulsory licence to any person making an application for it under Section 84 of the Act is the refusal and/or failure of the patent holder to grant the applicant a voluntary license. The aforesaid refusal by the patent holder to such an applicant must be in spite of applicant's efforts to obtain the same.

e) On 6 December 2010 Natco- a drug manufacturer in India approached the petitioner for grant of voluntary license for the purpose of manufacturing and selling the patented drug in India. In its communication dated 6 December 2010, the petitioner sought a voluntary license to manufacture and sell in India the patented drug under its brand name at a price of less than Rs.10,000/- per month of therapy as against the price of Rs.2,80,428/- per month of therapy charged by the petitioner. The above voluntary licence was sought on such reasonable terms and conditions to be offered by the petitioner as would make the patented drug available to the public by Natco at an

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affordable price. In the above application for voluntary licence Natco also stated the fact that the petitioner had not with regard to the patented drug met the reasonable requirement of public nor was it reasonably priced nor was it worked in the territory of India. By communication dated 27 December 2010, the petitioner rejected Natco's application for grant of voluntary license to manufacture and sell the patented drug. However, the petitioner in its above communication dated 27 December 2010 left the issue open by asking Natco to approach them within 14 days in case they have anything further to add.

f) Thereafter, on 29 July 2011 i.e. after the expiry of three years from 3 March 2008, Natco applied to the controller for grant of Compulsory License under Section 84(1) of the Act. In its application, Natco pointed out that in respect of the patented drug belonging to the petitioner all the three conditions for the grant of Compulsory License were fulfilled/satisfied. It was also pointed out in the application that they proposed to sell the patented drug under its brand name at Rs.8800/- per month of therapy. On a prima facie satisfaction of the applicant's case for grant of compulsory licence, the Controller directed the application to be served upon the petitioner and also had the application published in the official journal. This would enable not only the patent holder i.e. the petitioner but also any other person interested in the issue an opportunity to oppose the application. This was in terms of Section 87 of the Act.

g) On 18 November 2011, the petitioner filed its opposition

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to the grant of Compulsory License to Natco before the Controller. Thereafter, a personal hearing was granted in respect of the application for Compulsory License filed on 29 July 2011 by Natco. On 9 March 2012, the Controller by his order allowed the application dated 29 July 2011 of Natco. By order dated 9 March 2012 of the Controller while granting compulsory licence to Natco to manufacture and sell the patented drug also directed it to pay to the petitioner royalty at 6% of its net sales of the patented drug under its brand name which was allowed to be sold at price of Rs.8800/- for 120 tablets for a month of treatment. Besides, the grant of Compulsory License to Natco was non-exclusive, non-assignable and for the balance term of the patent.

h) Being aggrieved by the above order dated 9 March 2012 of the Controller, the petitioner preferred an appeal to the Tribunal and also sought a stay of the order dated 9 March 2012 till the disposal of its appeal. The Tribunal by its order dated 14 September 2012 rejected the petitioner's application for stay of the order dated 9 March 2012 passed by the Controller. However, whilst rejecting the application for stay, the Tribunal directed that the appeal be listed for hearing at an early date.

i) On 4 March 2013 the Tribunal after hearing the parties, by the impugned order upheld the order dated 9 March 2012 of the Controller granting the Compulsory licence to Natco while increasing the royalty payable by Natco to the petitioner from 6 to 7% of the sales of the patented drug under its brand name. However, the Tribunal did not agree with the view of the Controller as reflected in order dated 9

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March 2012 that working in India in terms of Section 84(1)(c) of the Act would only be satisfied if the patented drug is manufactured in India. The Tribunal in its order dated 4 March 2013 took a view that the requirement of working of the patented drug in India could also be satisfied by importing the patented drug on the patent holder satisfying the authorities under the Act that the manufacture of the patented drug was not possible in India. Therefore, it held that manufacture in India was not necessary in every case for satisfaction of Section 84(1)(c) of the Act. It held that the working in India would have to be decided on a case to case basis and there can be no general rule that when the products are imported into India and not manufactured, it follows that patented drugs is not being worked in the territory of India.

j) The aforesaid impugned order dated 4 March 2013 of the Tribunal into which has merged the order dated 9 March 2012 of the Controller is being challenged before us by the petitioner under Article 226 of the Constitution of India.

II) **Relevant Legal Provisions** :

4) Before dealing with the submissions of the parties, it may be useful to reproduce the relevant provisions of Chapter XVI of the Act which would arise for our consideration while dealing with the submissions. The relevant provisions are as under :-

CHAPTER XVI

WORKING OF PATENTS,COMPULSORY LICENCES AND REVOCATION

Section 82 :-Definition of "patented articles" and "patentee"

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In this Chapter, unless the context otherwise requires,—

(a) "patented article" includes any article made by a patented process; and

(b) "patentee" includes an exclusive licensee.

Section 83- General principles applicable to working of patented inventions:- Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely;—

a. that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
b. that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
c. that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
d. that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
e. that patents granted do not in any way prohibit Central Government in taking measures to protect public health;
f. that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
g. that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

Section 84- Compulsory licences:- (1) At any time after the expiration

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of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence 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) to (5).....

(6) In considering the application field 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 anticompetitive 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.

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(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

(c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing; or

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable; or

(e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by—

(i) the patentee or persons claiming under him; or

(ii) persons directly or indirectly purchasing from him; or

(iii)other persons against whom the patentee is not taking or has not taken proceedings for infringement.

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Section 85 .....

Section 86 - Power of Controller to adjourn applications for compulsory licences, etc., in certain cases:-

(1) Where an application under section 84 or section 85, as the case may be, is made on the grounds that the patented invention has not been worked in the territory of India or on the ground mentioned in clause (d) of sub-section (7) of section 84 and the Controller is satisfied that the time which has elapsed since the sealing of the patent has for any reason been insufficient to enable the invention to be worked on a commercial scale to an adequate extent or to enable the invention to be so worked to the fullest extent that is reasonably practicable, he may, by order, adjourn the further hearing of the application for such period not exceeding twelve months in the aggregate as appears to him to be sufficient for the invention to be so worked:

Provided that in any case where the patentee establishes that the reason why a patented invention could not be worked as aforesaid before the date of the application was due to any State or Central Act or any rule or regulation made thereunder or any order of the Government imposed otherwise than by way of a condition for the working of the invention in the territory of India or for the disposal of the patented articles or of the articles made by the process or by the use of the patented plant, machinery, or apparatus, then, the period of adjournment ordered under this sub-section shall be reckoned from the date on which the period during which the working of the invention was prevented by such Act, rule or regulation or order of Government as computed from the date of the application, expires.

2) No adjournment under sub-section (1) shall be ordered unless th Controller is satisfied that the patentee has taken with promptitude adequate or reasonable steps to start the working of the invention in the territory of India on a commercial scale and to an adequate extent.

Section 87 .....

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Section 88 .....

Section 89 -General purposes for granting compulsory licences:-

The powers of the Controller upon an application made under section 84 shall be exercised with a view to securing the following general purposes, that is to say,-

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

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

Section 90 - Terms and conditions of compulsory licences_

(1) In settling the terms and conditions of a licence under section 84, the Controller shall endeavor to secure—

(i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;

(ii) that the patented invention is worked to the fullest extent by the person to whom the licence is granted and with reasonable profit to him;

(iii) that the patented articles are made available to the public at reasonably affordable prices;

(iv) that the licence granted is a non-exclusive licence;

(v) that the right of the licensee is non-assignable;

(vi) that the licence is for the balance term of the patent unless a shorter term is consistent with public interest;

(vii)to (ix) .....

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Section 93 :- Order for licence to operate as a deed between parties concerned- any order for the grant of licence under this chapter shall operate as it it where or deed granting a licence executed by the patentee and all other necessary parties embodying the terms and conditions, if any, settled by the Controller.

III) **Submissions on behalf of the Petitioner** :

5) Mr. Ravi Kadam learned Senior Counsel appearing for the petitioner in support of the petition submits as under:-

a) The grant of Compulsory License to Natco under Section 84 of the Act by the Controller and upheld by the Tribunal are completely without jurisdiction. The condition precedent to entertain any application for Compulsory License under Section 84(1) of the Act, is that the applicant before the Controller should have made efforts to obtain voluntary license from the patent holder under Section 84(6)(iv) of the Act on reasonable terms and conditions. In this case, the applicant has not made efforts to obtain a voluntary license before applying for Compulsory License under Section 84(1) of the Act. The communication dated 6 December 2010 does not indicate any efforts made by M/s. Natco to obtain a voluntary license but appears in the form of notice, if not a threat, to grant voluntary license. Therefore, on the aforesaid short ground alone the impugned order be set aside for failure to satisfy the condition precedent for grant of Compulsory License.

b) No occasion arose to grant compulsory licence on the ground that the petitioner had not met the reasonable requirement of the public in respect of the patented drug. Thus the finding that the

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petitioner fell within the ambit of Section 84(1)(a) of the Act for grant of compulsory licence is arbitrary. The reasonable requirement of public with respect of the patented drug was being satisfied by the petitioner. This was on a two fold basis. Firstly the patented drug is administered to cancer patients at the last stage of their illness. Therefore, the requirement of the public is much smaller then the universe of patients in India suffering from kidney and liver cancer. Secondly, the quantity of patented drug available has to be the consolidated quantity of the patented drug made available not only by the petitioner but also by Cipla and Natco (both as infringers) to determine whether reasonable requirement of the public with regard to the patented drug has been satisfied or not.

c) The patented drug is being offered to the general public at reasonably affordable price. The authorities under the Act have ignored the fact that the determination of the reasonable affordable price has to be examined not only from the perspective of the user of the patented drug but also from the patent holder's cost of inventing and developing the patented invention. The petitioners had spent huge amount on research and development of the patented drug. The evidence led by the petitioner on the above aspect also adverts to the fact that while fixing the price of the drug the expenses incurred in respect of failed drug has to be factored in. Moreover, Cipla is offering the patented drug at Rs.30,000/- per month of treatment. This shows that the patented drug is available at a reasonable price. Further the test of reasonable price has to be determined keeping in mind the class of the public to whom the patented drug is made available. For this the

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concept of differential pricing has also been invoked under which the petitioner had introduced a Patients Assistance Programme (PAP) which would enable poorer patients to obtain the patented drug at cheaper prices as against the richer class of patients who would obtain the patented drug at the normal price which would be reasonable from the perspective of the richer class of patients. This differential pricing enabled the economically weaker patients to pay for three days medicines and obtain 27 days of medicines free of costs from the petitioner. The above aspect of differential pricing has not been considered by the authorities under the Act thus leading to an arbitrary conclusion that the patented drug was not available to the parties at reasonable affordable price.

d) The authorities under the said Act before concluding that the patented drug was not available to the public at a reasonably affordable price, should have first determined the reasonably affordable price in respect of the patented drug. This would be evident from a co-joint reading of Section 84(1)(b) read with Section 90(1)(iii) of the Act. The aforesaid exercise of fixing the reasonable price not having been done it is impossible to conclude that the patented drug is not available to the public at reasonably affordable price. The price at which Natco has offered the patented drug has been accepted without any independent investigation as reasonably affordable price. It is therefore, submitted that the petitioner does not fall within the mischief of Section 85(1)(b) of the Act.

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e) The petitioner has worked the patented drug in the territory of India inasmuch as the same has been imported by them for the supply to patients in the country. The fact that the working of the patented drug in India can be done also by import and not necessarily by manufacture of goods in India is an undisputed position as it is so held by the Tribunal. However, there is no requirement of Section 84(1)(c) of the Act that working in the territory of India would mean working in India to the fullest extent. It is submitted that even initial working of the patented drug would be sufficient to make Section 84(1)(c) of the Act inapplicable.

f) The application of Natco for grant of compulsory licence ought to have been adjourned under Section 86 of the Act. This adjournment would have enabled the petitioner some time to make available its patented drug on a commercial scale to an adequate extent. By not granting an adjournment the entire object of the Act viz. encouraging the inventor to invent and exploit his invention is being thwarted after the inventor has made his invention (processes involved) available for exploitation by all after a period of 20 years; and

g) The terms and conditions on which the Compulsory licence has been granted to Natco has completely ignored the mandate of Section 90(1)(i) of the Act. This requires the authority to take into account the costs incurred by the petitioner to invent the patented drug while fixing of royalty for the petitioner. It is submitted that in the absence of the above exercise, the mandatory requirement of the Act has not been followed leading to the impugned order being bad.

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In view of the aforesaid submissions, it is prayed that the impugned orders dated 4 March 2013 of the Tribunal into which has merged the order dated 9 March 2012 of the Controller be quashed and set aside.

IV) Submissions on behalf of Respondents

6) As against the above, Mr. Anand Grover learned Senior Counsel appearing on behalf of the respondent No.3 in support of the impugned order submits as under.

a) This being a petition under Article 226 of the Constitution of India seeking a writ of certiorari to quash the impugned order dated 4 March 2013 of the Tribunal into which has merged the order dated 9 March 2012 of the Controller and not an statutory appeal, the scope of interference is limited. It is submitted that the Court would exercise of its extra ordinary jurisdiction only if the impugned order is without jurisdiction and/or suffers from errors apparent on the face of the record and/or the conclusion reached by the authorities under the Act is based on no evidence on record and/or is perverse. It is submitted that the impugned order does not fall within the parameters laid down herein above to warrant the invocation of this Court's extra ordinary jurisdiction.

b) It is submitted that the sine quo non for exercise of jurisdiction under Section 84(1) of the Act is for the applicant having made efforts to obtain voluntary licence from the patent holder i.e. the petitioner is held to be satisfied on the basis of the evidence on record,

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as held by concurrent findings of fact by two authorities on the basis of evidence on record. It is submitted that both the authorities i.e. Controller as well as Tribunal on the basis of the evidence available before it concluded that on 10 December 2010 the petitioner had made efforts to obtain voluntary licence from the petitioner calling upon the petitioner to fix the terms and conditions for grant of voluntary licence. However, the petitioner by its reply dated 27 December 2010 rejected the efforts made by Natco to obtain voluntary licence from the petitioner. Thus leaving Natco no option but to approach the Controller for grant of compulsory licence under Section 84(1) of the Act. Both the authorities under the Act have held that the condition precedent for applying to the Controller for compulsory licence under Section 84(1) of the Act was satisfied. Thus, no interference with the impugned order on the above ground is called for.

c) The requirement of Section 84(1)(a) of the Act of making a patented drug available to meet reasonable requirements to the public has not been satisfied as held by both the Controller as well as Tribunal in their respective orders. The patented drug is admittedly administered to persons suffering from either Kidney or liver cancer at the final stages of their illness. It was submitted that even if one accepts the submission of the petitioner of the number of patients requiring the patented drug is less and that infringing goods made available by Cipla and Natco are to be added to the patented drug made available by the petitioner to determine the availability of the drug in India, it would make no difference. This is for the reason that the Controller has proceeded on the above submissions of the petitioner and yet on

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examination concluded that the patented drug does not meet the reasonable requirement of the public.

d) The patented drug was not available to the general pubic at reasonably affordable price under Section 84(1)(c) of the Act as held by the Controller and the Tribunal. It was pointed out that the price at which the the petitioner made the patented drug available was about Rs.2,80,000/- per month of therapy. The patented drug even when made available by the infringer is at Rs.30,000/- per month of treatment. This again was at a price which is not affordable at all in the Indian context. It was emphasized that in terms of Chapter XVI of the Act the obligation was of the patent holder i.e. petitioner to make the patented drug available at a reasonably affordable price to the public. The requirement is of reasonably affordable price to the members of the public. It was emphasized that the price at which the patented drug is available under the PAP programme is not available to the public. The PAP price is conditional price. This is for the reason that the patented drug is available at a conditional price at the discretion of the doctors and the petitioner. Moreover, the PAP even according to the petitioner is a charitable programme and therefore, not a price of the patented drug. Therefore, patented drug was not being made available at reasonably affordable price by the petitioner warranting the grant of compulsory licence to Natco i.e. respondent No.3.

e) The patented drug has not been worked in the territory of India as required under Section 84(1)(c) of the Act and as concluded by the Controller and also the Tribunal in the impugned order. For the

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purpose of this petition, Natco accepts the view of the Tribunal that working of patented drug in India does not mean it has only to be manufactured in India. The satisfaction of work in India would have to be determined on case to case basis always keeping in view the parameters/tests laid down in Section 83 of the Act. In this case the petitioner has led no evidence to show the reasons for not manufacturing the patented drug in India or that the patented drug was being worked in India by import and further that import was justified. Moreover, worked in India would only mean worked on a commercial scale and not to token working of the patented drug. Therefore, no fault can be found with the impugned order.

f) The non granting of adjournment to the patent holder in terms of Section 86 of the Act cannot in the present facts be found fault with. The Controller while considering the application for compulsory licence found that the patent holder had not taken any steps to work its invention in India on a commercial scale in all the time it had after it granted the patent for India in 2008. Further, the petitioner has not shown any attempt on its part to work the patent in India on commercial scale. Moreover, Section 86(2) of the Act clearly provides that no adjournment of application for compulsory licence would be granted unless the Controller has been satisfied that the patent holder has taken steps to work an invention in the territory of India on a commercial scale with promptness. In the present facts the petitioner has failed to act with promptitude so as to work the patented drug in India on commercial scale. Accordingly, no fault can be found with the order refusing to adjourn the application for grant of compulsory

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licence to Natco.

g) The terms and conditions on which the Compulsory License has been granted to Natco is in compliance with the requirement of Section 90 of the Act. Therefore, no fault can be found, particularly, as the Tribunal has enhanced the royalty from 6% to 7% of the sales turn over of Natco.

7) Ms. Rajani Iyer, Senior Counsel appearing for the Union of India while supporting the impugned orders dated 9 March 2012 and 4 March 2013 of the Controller and the Tribunal after taking us through the history of the patent legislation in India by large adopted the submissions made on behalf of Natco. The additional submissions made by her with a slightly different emphasis was in respect of the patented drug being worked in the territory of India under Section 84(1)(c) of the Act. According to her, the primary meaning which has to be given to the word worked in India is manufacture in India on a commercial scale. This according to her is evident from the factors to be considered as stated in Section 83 of the Act which inter alia provides for transfer of technology to the mutual advantage of the producers and users of the technology and also to ensure that the patent holder should not monopolize the patent only for importation of the patented article. Similarly, Article 27 of the TRIPS agreement has to be read in the light of Article 2 of TRIPS Agreement which states that the provisions of Paris Convention 1883 shall be complied with while implementing the TRIPS agreement by the member States. Article 5(A)(2) of the Paris Convention gives freedom to each member to take such measures for

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grant of Compulsory License in order to prevent abuse of the patent rights. However, as held by the Tribunal each case is to be examined on case to case basis and it is open for the patent holder to establish before the authorities under the Act that given the peculiar facts of the case the patented drug was worked in the territory of India by import. The submission of the petitioner that the word "worked in the territory of India" does not mean to be manufactured in India on the basis of the erstwhile Section90(a) (Prior to 2002 amendment) of the Act. This, it was submitted is not correct as the erstwhile Section 90(a) of the Act was dealing with the concept of reasonable requirement of the public being met and in that context provided that the same shall be deemed to have not been satisfied if the patent holder fails to manufacture in India to an adequate extent. The aforesaid requirement was not a part of the condition for examining whether the patented invention is worked in the territory of India. In view of the above, it was submitted that the patented durg has not been worked in India. The petitioner has failed to make out a case before the Tribunal that the peculiar facts of the petitioner's case required that the patented drug be worked in India by import. Consequently the orders of the authorities calls for no interference.

V) **History of the Patent Law**:-

8) Before considering the rival submissions, we take a brief overview of the origin, history and object of the law on Patents.

a) Patent Law is a species of intellectual property law. A right to intellectual property is an invisible/intangible right to a product of a

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man's brain/ mind such as a new invented product i.e. property of the mind as against a right for material things/tangibles i.e. goods such as a right to the invented goods. An Intellectual Property is at times described as 'knowledge goods'. An Intellectual Property right could be broadly divided into two categories viz. Industrial property and Copyrights. Industrial property would include patents, trade marks, industrial designs while Copyright would include literary and artistic works. A patent is an intellectual property right granted to an invention. The object of the patent law is to encourage scientific research, new technology and industrial progress. The grant of a patent necessarily means a new invention of commercial utility. Patent law encourages research and invention by guaranteeing to the holder of the patent an exclusive right to prevent all others from manufacturing, using and/or selling invented goods i.e. patented product for a particular number of years to the exclusion of all others. In consideration for the above rights, an inventor has to make available/disclose his knowledge of the invention. This disclosure would allow the other members of the society to exploit the same after the prescribed number of years. Thus, an inherent objective in the grant of patent is the obligation of the patent holder to utilize the invention to meet the needs of the society. The invented product is not to kept in the attic but is to be available to Society for use and also to form the basis for further research and development. All of which would lead to betterment of human existence on planet earth while contributing to improvement of technological advancement. It is in the above context that Sir Isaac Newton had said " I have been able to see further than others is because I stood on the shoulders of giants". We all owe a great debt of gratitude

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to all inventors beginning with the inventor of the wheel for the quality of life enjoyed by us today. This quality of life has been possible only because the inventions have been made available for use/exploitation to the benefit of the society. Therefore to prevent abuse of the patent by the patent holder, it was as far back as 1883 that an International Treaty viz. Paris Convention for the Protection of Industrial Property provided that where the patented invention is not being worked sufficiently then the member country can provide for legislative measures to ensure due working/ exploitation of the patent. Significantly, Patent and Design Act 1911 which governed the Law of Patents in India also provided for grant of compulsory licence so as to prevent abuse of the patent by the patent holder. Thus, the requirement/obligation of the patent holder to utilize his invention for the benefit of the society was always a part of the consideration for grant of a patent. This grant of patent gave patent holder exclusive rights for a certain period of time in respect of his patented invention.

b) After independence in 1949, a Committee was constituted under Justice Dr. Bakshi Tek Chand to undertake a review of Patent Law in India. Thereafter in 1957, the Central Government appointed Justice N. Rajagopalan Ayyanger Committee to examine the Patent law in the country and make recommendations. On the basis of the recommendations of the Justice Ayyangar Committee, the Act was passed and brought into force w.e.f. 20 August 1972, inter alia providing for process patent, besides inter alia continuing to provide for compulsory licensing as in the earlier Act viz. Patent and Drugs Act 1911.

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c) In 1995 India became a signatory to the WTO (World Trade Organization) Trade Related Intellectual Property Rights (TRIP) in Marrakesh Morocco. The preamble to TRIPS inter alia recognizes the objectives of national systems for the protection of Intellectual Property including developmental and technological objectives. Part-I, TRIPS dealing with General provisions and Basic Principles at Article 7 states that the objective of TRIPS is for protection and promotion of Intellectual Property, transfer of technology to the advantage of producers and user in a manner conducive to social and economic welfare. Article 8 of Part I of TRIPS while setting out the principles of TRIPS inter alia allows its members to take appropriate measures to prevent abuse of Intellectual Property Rights by Patent holders while ensuring that international transfer of technology is not unreasonably restrained and/or affected.

d) Part II of TRIPS deals with Standards Concerning the Availability, Scope and use of Intellectual Property Rights. Section 5 thereof deals with Patent. Article 27 which is part of Section 5 of TRIPS inter alia provides that there would be no discrimination between imported or locally produced patents. However, the aforesaid Article 27 is qualified by exceptions in Articles 30 and 31 of the TRIPS. Article 30 provides that members may provide exceptions to the rights conferred on patent holders so as to not prejudicially affect the rights of patent holders taking into account interest of third parties. Article 31 of TRIPS allows member countries to provide for use of patent by the Government or third parties without authorization of patent holder. However, where such use by others is allowed it shall be non assignable,

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non exclusive and the patent holder should be paid adequate remuneration taking into account the economic value of the authorization.

e) The aforesaid TRIPS Agreement was followed by Doha Declaration on 14 November 2001 on the TRIPS Agreement. The Doha Declaration after recognizing the public health problems affecting many developing countries inter alia in Clause 4 of Doha Declaration provided that TRIPS does not and should not prevent members from taking measures to protect public health and promote access to medicines for all. Further Clause 5 of Doha Declaration provided that flexibilities to member countries would include the right to grant compulsory licence and the grounds upon which it is to be granted. We have set out/discussed the provisions of TRIPS and the Doha Declaration 2001 in some detail as India is a signatory to it. Therefore,while considering and interpreting the Municipal law, the same would have to be necessarily construed in consonance with International Treaties/Agreements to which India is a party.

VI) Scheme of Compulsory Licence under the Act:

9) Consequent to TRIPS, the Act was amended in 1999, 2002 and 2005 to make it TRIPS compliant. In fact,Chapter XVI of the Act dealing with "Working of Patent, Compulsory Licenses and Revocation" was substituted in its entirety by the 2002 amendment which come into effect on 20 February 2003. Further, changes/amendments were made in 2005. The framework of Chapter XVI of the Act is briefly as under :-

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a) The scheme of Chapter XVI of the Act with regard to Compulsory Licence is that it applies to a patented product and also a patented process. In terms of Section 84 of the Act an application for Compulsory Licence can be made by any person to the Controller on satisfaction of the following two per-requirements/conditions:-

a) An application for compulsory licence can be made only after expiration of three years from the date of the grant of patent to the patent holder; and

b) The applicant should have made an effort to obtain a voluntary licence of the patented invention from the patent holder on reasonable terms and conditions.

It is only on the satisfaction of the above two requirements that the Controller can consider the application for compulsory licence. This application for compulsory licence must allege that all or any one of the following three conditions mentioned in Section-84(1) of the Act are not satisfied.

i) reasonable requirement of the public for the patented invention is not being met; or

ii) the patented invention is not available to the public at reasonably affordable price or

iii) that the patented invention is not worked in the territory of India.

The condition (i) above would be deemed to have been met if the conditions set out in Section 84(7) of the Act are met. Section 84(7) of

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the Act inter alia lays down that where the supply of patented invention is not to an adequate extent and where the patent holder has refused to grant a voluntary licence to the applicant it would be deemed that the reasonable requirement of the public for the patented invention has not been met. So far as condition (iii) above viz. working in territory of India is concerned the same is to be decided having regard to the provisions of Section 83 of the Act. Section-83 of the Act provides general principles which one must have regard to while determining whether the patented invention is being worked in India. The factors to be regarded inter alia are whether the patented invention is being worked in India on a Commercial scale , the transfer of technological advances is taking place for mutual advantage of the producer and users of the technology knowledge. Besides the grant of patent should not enable the patent holder to enjoy a monopoly for import and the patent holder should not abuse his rights so as to adversely affect the transfer of international technology.

(b) In terms of Section 87 of the Act whenever an application is made for compulsory licence, the applicant has to satisfy the Controller that prima facie conditions exist for a grant of compulsory licence in respect of the patented invention. It is only on the prima facie satisfaction of the Controller that the application will be served upon the patent holder as well as published in the official journal. On publication in the official journal, the patent holder (independently served) or any other person desiring to oppose the application could file their notices of opposition to the grant of compulsory licence. The Controller would thereafter hear the applicant and the opposition i.e.

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patent holder or any other person desiring to oppose application before passing the final order. In terms of Section 86 of the Act the Controller could adjourn an application for Compulsory Licence where the patent holder is able to satisfy the Controller that the patented invention is not being worked in the territory of India only because of insufficient time to enable the invention being worked on a commercial scale in India. However, the adjournment on the above ground by the Controller shall be for a period not exceeding 12 months and the adjournment will be granted only on satisfaction of the Controller that the patent holder has taken prompt steps to initiate the working of the patent in the territory of India on a commercial scale.

c) The Controller would after considering the evidence and hearing the parties before it either grant or refuse to grant the Compulsory Licence by a reasoned order. However, in case the Controller does grant a Compulsory Licence the terms and conditions of the grant would be in terms Section 90 of the Act which inter alia provides:-

i) that royalty and other remuneration to be paid to the patent holder should be reasonable, having regard to the nature of the invention, the expenditure incurred by the patent holder in making and developing patent;

ii) that the patented invention is worked to the fullest extent by the person to whom the compulsory licence is granted with reasonable profit to him;

iii) that the patented articles are made available to the public at reasonably affordable price; and

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iv) the licence granted to the applicant would be non exclusive licence and non assignable.

d) The grant or refusal to grant the compulsory licence is appellable to the Tribunal under Section 117-A of the Act. Thereafter, the order of the Tribunal is open to review before the Court under Article 226 of the Constitution of India.

VII) **Discussion** :-

Keeping the above broad parameters of the provisions of Chapter XVI of the Patent Act, we shall now consider the submissions made by the parties before us.

A) **Did the applicant (Natco) make efforts to obtain voluntary licence from the Patent holder (Bayer)?**

11) It is an undisputed position between the parties that out of the two conditions precedent to consider an application for Compulsory Licence one of the conditions viz. 3 years should have elapsed from the grant of the patent before an application can be made is satisfied. However, the petitioner urges that the other condition precedent to entertain the application viz. making of efforts to obtain voluntary licence from the patent holder on reasonable term and conditions as mandated by Section 84(6)of the Act has not been satisfied i.e. the applicant has not made efforts. On this ground alone, it is submitted that the impugned order needs to be set aside. It is pointed out that the letter dated 6 December 2010 was more in the nature of a notice rather then an effort to obtain a voluntary licence from the petitioner. In

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any case it is submitted by the petitioner that in its reply dated 27 December 2010 it had informed Natco that, in any case, if Natco had anything further to state they could do so within 14 days from the receipt of the petitioner's aforesaid letter. Thus, if Natco's approach to the petitioner for grant of voluntary licence was bonafide it would have again approached the petitioner for a voluntary licence. At this stage we did enquire of the petitioner's Counsel whether petitioner was willing to consider a grant of voluntary licence to Natco and the categorical answer was No. It is undisputed that the letter dated 27 December 2010 of the petitioner to Natco very categorically states that it does not consider it appropriate to grant voluntary licence to Natco.

12) We have examined the correspondence between the Natco and the petitioner. It is on the basis of examination of evidence i.e. exchange of letters between the parties in the context of Section 84(6) of the Act that both the authorities concluded that effort was made by Natco to obtain for voluntary licence. This concurrent finding of fact was based on appreciation of evidence before the authorities. We also find that the petitioner's response dated 27 December 2010 to Natco's request for a Voluntary licence very clearly records its refusal to grant voluntary licence to the applicant. The so called window in the petitioner's response for Natco to approach is illusory as it is open only if the Natco had anything to add to the application already made. Therefore, we find no reason to interfere with the findings of the authorities under the Act. We hold that the second condition precedent for consideration of application for compulsory licence namely an effort to obtain a voluntary licence has been satisfied by Natco. Therefore the

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consideration of the application by Natco for grant of Compulsory Licence to the Controller cannot be faulted nor the impugned order can be faulted on the above ground..

B) **Has the reasonable requirements of the public been satisfied?**

13) The petitioner next contends that grant of compulsory licence was not warranted as the reasonable requirement of the public for the patented drug has in fact been satisfied. We deal with various facets in support of the above submissions made by the petitioner as under:-

(a) It is submitted that the burden/onus is on Natco to establish that the reasonable requirement of the public is not satisfied with regard to the patented drug. This the petitioner submits Natco failed to do.

We find that in the scheme of the Act it for the applicant while filing an application for Compulsory Licence in terms of Section 87 of the Act to make out a prima facie case that one or all the grounds stated in Section 84(1) of the Act are prima facie attracted/applicable in respect of a patent for which the Compulsory Licence is sought. It is only on prima facie satisfaction of the Controller that the patent holder is called upon to file its opposition to the grant of its patent to the applicant i.e. Natco by invoking compulsory licence. At that time it is for the patent holder in its opposition to aver and thereafter lead evidence to show that the reasonable requirement of the public with regard to the patented drug has been satisfied. The best evidence with regard to the extent the patent holder is making

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available the patented drug is within the knowledge of the patent holder i.e. petitioner. This information the petitioner has to furnish in support of its opposition only after the Controller is prima facie satisfied that the applicant has made out a prima facie case in support of its application. Thus the initial burden is admittedly on the applicant i.e. Natco to make out a prima facie to the satisfaction of the Controller and only after that the petitioner is required to establish with facts in its possession that the reasonable requirement of the public is not satisfied. Therefore, we do not find any substance in this objection.

(b) The reasonable requirement of the public has to be considered by the authorities in the context of number of patients requiring the patented drug. It is submitted by the petitioner that it is not in every case that a person suffering from HCC or RCC Cancer is required to be administered the patented drug. The occasion to administer the patented drug arises only during the last stages of a patient's illness and even in that case the Doctor may opt for a line of treatment requiring measures other then the intake of the patented drug. The aforesaid exercise it is submitted has not been carried out by any of the two authorities under the Act and therefore, without first determining the exact quantum of the patented drug required by the public it is not possible to conclude that reasonable requirement of the public is not met by the patented drug.

We find that this exercise can never be carried out on a mathematical basis. It has to be on a broad basis and this broad exercise has been done on the basis of the evidence produced by the parties. In fact, authorities under the Act have considered the rival statistics of the

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patients before it and on that basis determined the reasonable requirement of the public. In any view, the parties before the authorities had relied upon Globocan 2008 figures for the incidence of patients suffering from cancer in India and sought to put different interpretation on it. In any case the authorities have examined the issue whether the patented drug is meeting the reasonable requirement of the public on the basis of the interpretation of the Globocon figures put by the petitioner. Therefore, we see no basis for the above grievance on the part of the petitioner even as we hold that question of reasonable requirement of the public is to be determined on the basis of evidence led by the parties before the authorities.

c) The petitioner before us sought to contend that the number of patients requiring the patented drug in India arrived at by the authorities is not correct. We find no substance in this submission. The Controller has examined the issue of reasonable requirement of the public for the patented drug being satisfied on the basis of figures given by the petitioner in affidavits of its Country Medical Director one Dr. Manish Garg dated 8 February 2012. The above affidavit of Dr. Garg states that about 4004 RCC patients would require the patented drug while total number of HCC patients who would require the patented drug would be another 4838 thus making it an aggregate of 8842 patients. As against the above requirement the petitioner has sold only 593 number of boxes i.e. supplied patented drug to about 200 patients in 2011. The Controller in his order has found that if one adds the patented drug supplied by Cipla i.e. 4686 packets the total availability would be only for 5279 packets which even according to the figures of

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petitioner would not any where meet the annual requirements of the patients. Thus, the reasonable requirement of the public with regard to the patented drug has not been satisfied. For the purposes of the above exercise we have, just as the Controller, proceeded on the basis that even if patented drug supplied by the infringers namely Cipla is taken into account. reasonable requirement of public is not being met/satisfied. Thus the reasonable requirement of the public under Section 84(1)(a) of the Act is not satisfied even if one accepts the figures of the petitioner.

B-I) **Whether the supplies by infringers of the patented drug is to be considered/taken into account to determine the satisfaction of the reasonable requirement test?**

d) It was contended by the petitioner that while determining the satisfaction of the reasonable requirement of the public for the patented drug, the supplies made by the infringers i.e. Cipla has to be taken into account.

In the present facts this exercise may not be necessary as the test of meeting the reasonable requirement of the public is not satisfied even after taking into account the supplies of Cipla as done in (c) above. However, as submissions were advanced on this issue and it would have a bearing on other applications for compulsory licence, we are considering the same as a pure legal issue. The authorities have held that the supplies by infringers of the patented drug cannot be taken into account as the supply of the patented drug by the infringer is uncertain. This is because the petitioner has filed infringement of patent proceeding against the infringer and at any time the Court could injunct

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the infringer from making/selling the patented drug. The petitioner has strongly contested the finding and placed reliance upon the decision of the High Court of of Justice Chancery Division dated 7 November 1910 in the matter of Fiat Motors Limited for revocation of seven patents of Mercides Daimler Motor Company Limited 1910(27) RPC 762 wherein the Court held that the quantity of patented goods supplied by the infringers could be considered while deciding an application for revocation of the patent on the ground that patented article is mainly manufactured outside of U.K. The Court was of the view that the quantity made available by the infringer can be taken into consideration to determine whether the goods are mainly manufactured in U.K. The above decision, in our view, would not apply for the simple reason that from the record it does not appear that any proceedings were initiated by the patent holder therein against the infringer unlike in this case where the petitioner has filed infringement suit against the infringer viz. Cipla. It is the petitioner's contention before us that the suit filed before the Delhi High Court against Cipla the alleged infringer for injunction should be ignored as no injunction has yet been granted. This is of no avail to the petitioner as it could be granted at any time as the suit continues to be pending. Therefore infringer's quantity of goods cannot be taken into account only because it could stop on any day. It is only where the patent holder accepts the infringer's participation in the market and in fact grants him defacto licence could the infringer's supplies be taken into account.

e) Moreover, the obligation to meet the reasonable requirement of the public is of the patent holder alone either by itself

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or through its licensees. This is so as the application for compulsory licence seeks a licence under Section 84 of the Act from the patent holder. Section 84(6) of the Act, requires the Controller while considering the application for compulsory licence to consider the measures taken by the patent holder to make full use of the patented invention. One more fact as held by the Tribunal which cannot be lost sight of is that the petitioner in its Form 27 filed with the Controller on yearly basis has not included Cipla's sale of the infringed patented drug as participating in meeting the reasonable requirement of public. The petitioner places reliance upon CIPA Guide to the Patents Act 6th Edition by the Chartered Institute a Patent Attorneys at page 572 which opines to the effect that an infringer's goods could also be taken into account to consider the availability of the goods for the purpose of satisfaction of the reasonable requirements of the public. However, the CIPA Guide to the Patents Act deals with the patent law as in existence in England. Moreover, it appears to be a view which is not supported by any reasoning. Therefore, being a mere ipsi dixit of the Institute, we do not find any reason to accept the opinion in CIPA Guide to Patents as it is bereft of any justification.

B-II) <u>The meaning to be given to the words "adequate extent"</u>

(f) Before we conclude on the issue of meeting the reasonable requirement of the public, it must be pointed out that Section 84(7) of the Act provides a deeming fiction which deems that reasonable requirement of the public is not satisfied, if the demand for patented article is not met to an adequate extent. The Parliament has deliberately used the word "adequate extent". The aspect of adequate extent would

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vary from article to article. So far as luxury articles are concerned the meeting of adequate extent test would be completely different from the meeting of adequate extent test so far as medicines are concerned. In respect of medicines the adequate extent test has to be 100% i.e. to the fullest extent. Medicine has to be made available to every patient and this cannot be deprived/scarified at the altar of rights of patent holder. In fact this is the mandate of Parliament by providing for Compulsory Licensing. This would also be in accord with Doha Declaration 2001 which inter alia reiterates flexibility to member countries so as to ensure access to medicines for all. Undisputedly the requirement of all the patients are not being met by the patented drug.

In view of all the above reasons, we find no merit in the petitioner's submission that it has met the reasonable requirement of the public in respect of the patented drug under Section 84(1)(a) of the Act.

C) <u>Was the patented drug available to the general; public at reasonably affordable price?</u>

14) The petitioner next contended that as the patented drug was available to the general public at reasonably affordable price the impugned order to the contrary is not sustainable. It is submitted by the petitioner that in view of the availability of the patented drug at reasonably affordable price to the public, no occasion to invoke Section 84(1)(b) of the Act has arisen in the present facts. The various aspects in support of the above submission highlighted by the petitioner are examined as under:-

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(a) The petitioner submits that before deciding whether the patented drug was available to the public at reasonably affordable price it was necessary for the authorities to first determine what is the reasonably affordable price in respect of the patented drug. This would be evident from reading of Section 84(1)(b) with Section 90(1)(iii) of the Act. It is mandated by Section 90(1)(iii) of the Act that the Controller should ensure that the patented drug is available at reasonably affordable price. We are of the view that the Act itself does not bestow any powers of investigations with regard to the reasonably affordable price and therefore, the authorities do not have the where withal/personnel to carry out the above exercise. Thus, the same has to be arrived at on the basis of the evidence led by the parties before it of their respective prices. The obligation of the authorities under the Act is with regard to grant, control and revocation of patent and not price determination of the patented invention. It is for this reason that Section 90(1) (iii) of the Act on which reliance is being placed does not direct the Controller to fix the reasonably affordable price but only directs the Controller to endeavor to ensure/secure the patented article is available at reasonably affordable prices. As rightly pointed out by Ms. Iyer, Counsel for Union of India, the Controller while exercising his jurisdiction under Section 84 of the Act for grant of compulsory licence is essentially adjudicating a lis between the patent holder and the applicant for the compulsory licence. In this lis, any other person who is opposed to the grant of Compulsory Licence could also file its notice of opposition to the Controller. It is axiomatic that while deciding a lis it is not open to an adjudicator to become a participant in the lis. Therefore, the evidence led by the parties and impeached by the other side would

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form the basis of determining reasonably affordable prices. This reasonably affordable price has to be determined on the basis of the relative price being offered by the patent holder and the applicant after hearing other interested parties opposing the application. Therefore, in the present case the price at which the petitioner is selling the patented drug is at about Rs.2,84,000/- per month of therapy and the applicant was offering the same at Rs.8,800/- per month of therapy. In such a case the reasonably affordable price has to necessarily be the price of the applicant as it by itself establishes that the price of the petitioner is not a reasonably affordable price.

(b) One more fact which cannot to be lost sight of, is the stand of the petitioner before the Controller that it is not open to the Controller to call for balance sheet and other figures of the patent holder on an application for compulsory licence. This even when it is urged by the applicant that the patented drug is not being offered at a reasonably affordable price by the petitioner. Thus, in the present facts it would be impossible for the authorities, in the absence of figures being made available by the patent holder to independently determine the reasonably affordable price of the patented drug.

c) It was next submitted by the petitioner that price of the patented drug was to be arrived at taking into account not only the research and development costs for the patented drug but also the costs incurred in respect of research and development on failed drugs. In support of the above, petitioner relied upon two affidavits of Mr. Dintar dated 9 February 2012 and 9 July 2013 who works with the petitioner

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as head of its Global Drugs Discovery Operations. The above affidavits state that the petitioner had in 2010 invested about Rs.114 billion in its research and development activities. It is also submitted that costs incurred on failed product which is to be recovered from its customer is also to be taken into account to arrive at reasonably affordable price. Thus, it was submitted that the price at which it is selling the patented drug in India, is a reasonably affordable price. It was emphasized that the reasonably affordable price would not mean the lowest price but would include a reasonable consideration/return for the patent holder also. Moreover, it is sought to be emphasized that the price charged by the petitioner for the patented drug is uniform all over the world including India (subject to factors like exchange rate, tax etc.).

As against the above, Natco had led evidence before the Controller of one Mr. James Love who filed an affidavit pointing out figures evidencing that the total amount spent on research and development from 1994 up to 2004 were recovered by the petitioner in one year itself. The petitioner has not produced its audited accounts to establish the amounts spent on research and development. In fact, before the Controller, the petitioner had protested at the calling for the Balance Sheet etc. In any case, the patented drug is classified as a orphan drug in U.S.A. As an orphan drug, the petitioner is entitled to be reimbursed either by tax credit or otherwise to the extent of 50% of its costs incurred on research and development of the patented drug. However, the petitioner has not made available either before the Controller or before the Tribunal or before us the quantum of reimbursement received. The above figures would establish the total

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costs incurred by the petitioner on research and development of the patented drug. This could have formed the basis to decide the reasonable price at which the petitioner could make the drug available to the public in India. The petitioner has not chosen to produce the above best evidence before the authorities. An adverse inference, must necessarily be drawn against the petitioner. Further, in terms of Section 90(1) of the Act on which the petitioner is placing reliance only requires the expenditure incurred for research and development on the patented drug to be included for the purposes of considering the terms and conditions of the Compulsory License. These figures are known to the petitioner and yet not produced by it. Therefore, no fault can be found with the impugned order holding that the patented drug is not available to the public at a reasonably affordable price.

d) The petitioner also contended that it has introduced a Patient Assistance Programe (PAP) in respect of the patented drug. The PAP is a compromise between the commercial interest of the petitioner and the public health interest. According to the petitioner, w.e.f. April 2012, when a patient buys three dosages of the patented drug i.e. 12 tablets then the remaining tablets for the month i.e. 108 tablets for 27 days are given free to the patients covered under the PAP. However, we find substance in the submission of Mr. Gorver, learned Counsel appearing for Natco that the medicine supplied under PAP is not medicine available at the reasonably affordable price to the public. It is a special price given only to particular patients. The patient covered by PAP would be given assistance by the petitioner on the recommendation of the doctor and at the discretion of the petitioner. The patented drug

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is not in the ordinary course available to any member of the public at the PAP price. The PAP price is conditional price depending upon the patient satisfying certain preexisting criteria and completely at the discretion of the petitioner and the doctor attending the patient. The requirement under Section 84(1)(b) of the Act is that the patented drug should be available to the public at a reasonably affordable price i.e. to any member of the public tendering the price. This is admittedly not so in respect of the PAP price. It is an exception created subject to satisfaction of certain conditions. The exceptional price is not the price at which the patented drug is made available to the public. In any view of the matter, the petitioner itself has in its opposition to the grant of Compulsory License categorically stated that the medicine distributed under PAP was a charity. In case of charity, it is not open even to any of the beneficiaries, leave alone any member of the public, to demand and insist on the charitable PAP price being extended to him. The decision whether or not to extend the charity would be sole prerogative of the donor i.e. the petitioner.

(e) The petitioner contended that the authority should have accepted the dual pricing system adopted by them for the purpose of determining the reasonably affordable price. No fault can be found with the concept of dual pricing. In fact, the concept of dual pricing would appear to fit in Section 84(1)(a) of the Act which covers a situation where the reasonable requirement of a public with respect to the patented invention is not satisfied. This situation would arise not only on account of sufficient patented drug not being available in adequate quantity but it can also arise on account of the price of the patented

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drug being so high that a large section of the public is not able to access the patented drug. An indication of this is found in Section 84 (7)(ii) of the Act which while dealing with factors under which the reasonable requirement of the public shall be deemed not to have been satisfied states that if patented article is not made available to an adequate extent or on reasonable terms. (emphasis supplied) This phrase 'reasonable terms' does not speak about the price of the patented drug available to the public but would refer to the cases covered by PAP. In such cases, where a poor patient is unable to access the medicine because of the price, then the same is made available to the poor patient concerned on reasonable terms i.e. adoption of PAP price. In such a case, the reasonable requirement of the public with regard to the patented drug has been satisfied. The concept of dual pricing such as PAP would be available while applying Section 84(1)(a) of the Act and not while applying Section 84 (1)(b) of the Act. There can be no quarrel with adopting the differential price terms so that the economically weaker patients in our country are able to access the medicine at a lower price, where the costs of medicine itself is prohibitive.

In view of the above, we find no reason to interfere with the impugned order to the extent it holds that the patented drug is not available to the public at reasonably affordable price. Thus attracting Section 84(1)(b) of the Act to the present facts.

d) Has the Patented Drug been worked in the territory of India?

15) It was next contended that the patented drug had been worked in the territory of India. Consequently, the grant of compulsory

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licence on the above account was not sustainable. In support it is urged as follows:-

a) The petitioner submits that the patented drug had been worked in the territory of India by importation of the same. In particular, attention was invited to Article 27 of the TRIPS which inter alia provides that there would be no discrimination in respect of patented product whether legally manufactured or imported. It is the case of the petitioner that the requirement of patented drug has been worked in India by virtue of import and this is also apparent from Form 27 prescribed under the said Act and the Patent Rules. Patent holder has to file a statement in Form 27 with the Controller regarding the working of the patent in India. In the aforesaid form the patent holder while giving details of patented drug in India, has to make declaration of working in India of the patented product under under two classifications namely manufacture in India and secondly imported from other countries. The petitioner submits that there is no requirement in the Act that for the purpose of patented drug being worked in the territory of India, it should necessarily be manufactured in India as provided prior to 2002. This according to the petitioner is evident from erstwhile Section 90 of the Act prior to 2002 using the word 'manufactured in India' as a part of Chapter XVI of the Act. This itself is a further indication that the imported supply of goods within the territory would amount to working of patent in India. It was submitted that the Tribunal in the impugned order dated 4 March 2013 has specifically held that the working in India could be done even by import.

However, the Union of India before us contends that for

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the purposes of working in India, patented drug has to be manufactured in India.

b) So far as reliance upon Article 27 of TRIPS by the petitioner is concerned, we find that it ignores the exceptions thereto provided in Articles 30 and 31 of TRIPS. So far as erstwhile Section 90 of the Act is concerned it dealt with the situations under which the reasonable requirement of the public is deemed not to be satisfied i.e. similar to Section 84(7) of the Act now existing. We find that the words 'manufacture in India' under the erstwhile Section 90 of the Act have been omitted and have not been introduced in Section 84(7) of the Act, while dealing with the issue of the reasonable requirement of the pubic being deemed not to be satisfied. Further, prior to 2002, the erstwhile Section 90 of the Act read as under:-

> *"**90:-** When reasonable requirement of the public deemed not satisfied-*
> *for the purposes of Section 84 ..... shall be deemed not to have been satisfied-*
> *(a) if, by reason of the default of the patentee to manufacture in India to an adequate extent and supply on reasonable terms, the patented article or a part of the patented article which is necessary for its effective working or .....*

Therefore even earlier, the requirement was failure to manufacture in India to an adequate extent. Be that as it may, whether the invention is being worked in territory of India has to be looked at through the prism of Section 83 of the Act which contains the legislative guidelines to govern the meaning of the words 'worked in the territory of India'. The guidelines viz. Section 83 of the Act in particular states that the patent is not granted so as to enable the patent holder to enjoy

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a monopoly with respect to the importation of the patented article. Thus it would presuppose that some efforts to manufacture in India should also be made by the patent holder. This is further supported by the other considerations set out in Section 83 of the Act to be applied in construing 'worked in territory of India'. Section 83(c) of the Act provides that there must be transfer of technological knowledge to the mutual advantage of the producers and users of the patented article. In this case, the user of the knowledge of the technology is the patient in India i.e. cancer patients. Section 83(f) of the Act provides that patent holder should not abuse his patent so as to inter alia adversely affect international trade. As against the above, Form 27 as prescribed also gives an indication that importation could also be a part of working in India. Therefore, as rightly held by the Tribunal, it would need to be decided on case-to-case basis. It would, therefore, follow that when a patent holder is faced with an application for Compulsory License, it is for the patent holder to show that the patented invention/ drug is worked in the territory of India by manufacture or otherwise. Manufacture in all cases may not be necessary to establish working in India as held by the Tribunal. However, the patent holder would nevertheless have to satisfy the authorities under the Act as to why the patented invention was not being manufactured in India keeping in view Section 83 of the Act. This could be for diverse reasons but it would be for the patent holder to establish those reasons which makes it impossible/ prohibitive for it to manufacture the patented drug in India. However, where a patent holder satisfies the authorities, the reason why the patented invention could not be manufactured in India then the patented invention can be considered as having been worked in the

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territory in India even by import. This satisfaction of the authorities is necessary particularly when the petitioner admittedly has manufacturing facilities in India. In the circumstances, the contention of Union of India that 'worked in India' must in all cases mean only manufactured in India is not acceptable.

E) <u>Whether the application for compulsory licence ought to have been adjourned by the Controller</u>?

16) It was contended that in any view of the matter the Controller ought to have adjourned the consideration of the application for compulsory licence filed by Natco. This would have given petitioner time to work the patented drug on commercial scale in India. We find no merit in the aforesaid submission. This is for the reason that Section 86 of the Act which provides for adjourning application for compulsory licence has to essentially satisfy two conditions which are as follows:-

a) The time which has lapsed since the patent was granted and when an application for compulsory licence was made was insufficient to enable the patent holder to work the patented drug in India on a commercial scale; and

b) Patent holder should have taken steps towards working the patented drug in India on a commercial scale with promptitude.

In the present case the petitioner was granted the patent in India in 2008. The petitioner also has manufacturing facilities available in India. The petitioner has led no evidence before the authorities to

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indicate what steps they have taken and with what promptitude the same have been taken for the purposes of working the patent in India after 2008. The patent holder i.e. petitioner has led no evidence before the authorities in support of its submission that application for compulsory licence should be adjourned in view of the petitioner satisfying the requirement of Section 86 of the Act. In the circumstances, we find no fault with the order of the Controller refusing to adjourn the application for compulsory licence.

F) **Terms & Conditions for grant of compulsory licence**

17) It was lastly submitted that grant of compulsory licence to Natco has been done without proper application of Section 90 of the Act which provides for the terms and conditions under which a compulsory licence is to be granted. In terms of Article 31 of the TRIPS agreement it is provided that the patent holder shall be provided adequate remuneration while granting compulsory licence. Similar provision has been incorporated in Section 90 of the Act which inter alia provides that while settling the terms and conditions of the compulsory licence the Controller has to ensure that the royalty and other remuneration, if any, paid to the patent holder should be such as would reasonably cover the expenses incurred by the patent holder in making and/or developing and/or maintaining patented invention. The Controller in the impugned order dated 9 March 2012 provided that royalty be paid at 6% of the net sales made by Natco. This royalty was fixed keeping in view the fact that the petitioner had led no evidence to show the expenses incurred by it to invent the patented drug. Besides, globally it has been recorded by the Controller in his order dated 9March 2012 that the United Nation Development Programme specifically

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recommended that the normal rate of royalty should be 4% which has been further adjusted to 6% of the net sale by the Controller. As against the above that the Tribunal has increased the royalty from 6 to 7%. of net sales by Natco. The petitioner has not been able to show in what manner the royalty fixed at 7% is inadequate particularly as the petitioner has led no evidence of the cost incurred by it to develop the patented drug. In view of the above we see no reason to interfere with the royalty being fixed at 7% of the net sale of Natco in respect of the patented drug.

18) During the course of its submission the petitioner submitted that the impugned order of the Tribunal was not sustainable in law as it was based on Ayyangar Committee report on the ground that above report essentially deals with process patent scenario and not product patent regime. The Act has been passed on the basis of the Ayyangar Committee report to replace the Patent and Design Act 1911. In any case, the decision has been rendered on the basis of the provisions of the Act, particularly Chapter XVI of Act. Mere reference to the Ayyanger Committee report in the order does not make it based on that report. Therefore, there is no substance in the above objection.

19) It was also submitted that the Tribunal in its impugned order has held that proceedings under Section 84 of the Act are in public interest. If proceedings are in public interest it was submitted that the Tribunal and the authorities under the Act should have independently examined and determined the reasonable requirement of the public as also the reasonably affordable price as contemplated in Section 84(1)(a) and 84(1)(b) of the Act. The aforesaid objection has been dealt with by us separately while considering the provisions of

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Section 84(1)(a) and 84(1)(b) of the Act. The observations of the Tribunal that the proceedings under Section 84 of the Act are in public interest is in view of the fact that the entire basis of grant of compulsory licence is based on the objective that patented article is made available to the society in adequate numbers and at a reasonable price. These are matters of public interest. The law of patent is a compromise between interest of the inventor and the public. In this case, we are concerned with patented drug i.e. medicines to heal patients suffering from Cancer. Public interest is and should always be fundamental in deciding a lis between the parties while granting a compulsory licence for medicines/drugs. Therefore, the above objection is also without any merit.

20) For all the above reasons, we see no reason to interfere with the orders dated 9 March 2012and 4 March 2013 of the Controller and the Tribunal respectively granting compulsory licence under Section 84 of the Act to Natco.

21) Accordingly, the petition is dismissed. There shall be no order as to costs.

CHIEF JUSTICE

(M.S. SANKLECHA, J.)

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