INTELLECTUAL PROPERTY APPELLATE BOARD, CHENNAI

Guna Complex Annexe-I, 2nd Floor, 443 Anna Salai, Teynampet, Chennai 600 018.

Monday, the 4th day of March, 2013

OA/35/2012/PT/MUM

Hon'ble Smt. Justice PRABHA SRIDEVAN -- CHAIRMAN
Hon'ble Shri D.P.S.Parmar -- Tech. Member (Patents)

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… Appellant

Represented by: Shri P.S.Raman Senior counsel for
Shri Sanjay Kumar & Ms.Arpita Sawhney
for M/s.Perfexio Legal.

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,
Patent Office, Bhoudhik Sampada Bhavan,
S.M.Road, Antop Hill, Mumbai 400 037.

3. Natco Pharma Limited,
Natco House, Road No.2,
Banjara Hills,
Hyderabad 500 033, Andhra Pradesh.

… Respondents

Represented by: Shri C.V.Ramachandramurthy --- R1 & R2
Ms.Rajeswari
for M/s.Rajeswari & Associates -- R3

ORDER
(Order No.45 of 2013)

Hon'ble Smt. Prabha Sridevan, Chairman

"Compulsory licence" is not an unmentionable word. It is found in our Patents Act. Under a different name, it was there in the TRIPS (Trade-related Aspects of Intellectual Property Rights) too where it is called, "Other use without authorization of the right holder". It has been there even in the Paris Convention of 1883 "to prevent abuse which might result from the exercise of exclusive rights". The TRIPS Agreement did not give a carte blanche to the Members in the grant of compulsory licence but it hedged this 'other use with sufficient conditions and authorization of

this use would be considered only on a case to case basis of individualness'. This appeal challenges the compulsory licence ordered by the Controller-General.

2. Patent rights were created "not in the interest of the inventor, but in the interest of the national economy", says the Report on the Revision of Patents Law by Shri Justice N.Rajagopala Ayyangar (in short, 'Ayyangar Report'), quoting from Michel on Principal National Patent Systems. The report also quotes from Patents and Designs Amendment Bill which says that the monopoly is granted to the benefit of trade and industry to enlist the cooperation of the capitalist in this endeavour to bring in new invention. The Code of Federal Regulations of US says that "patent by its very nature is affected with the public interest". Therefore, we have to understand the perspective from which the Chapter of Compulsory Licence was introduced and is still there in the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005. The Ayyangar Report is the document we refer to when a question of importance arises. It says, "There is no uniformity in the economic problems which confront different countries at any time or even the same country at different periods of its history and account has therefore to be taken of the actual conditions in the matter of devising the precise adjustments which are needed to rectify the imbalance which the patent system is apt to produce if left uncontrolled".

3. In this case, several very important questions of pure law arise. The facts are relevant but we will deal with the facts very briefly. The drug for which the patent was granted is marketed by the appellant under the name, Nexavar, but the drug is Sorafenib Tosylate. It is said to be a palliative drug for patients suffering from Renal Cell Carcinoma (RCC) and Hepato-Cellular Carcinoma (HCC) at stage IV. US Patent was filed on 13.1.1999. PCT application was filed on 12.1.2000. The date of National Phase entry is 5.7.2001. The patent was granted on 3.3.2008 (Patent No.215758). The appellant obtained all the statutory approvals in India in January, 2008. Before applying for a compulsory licence, an applicant should approach the patentee for the grant of a licence. This is a *sine qua non* for exercise of the powers of the Controller in this regard. The third respondent addressed a letter on 6.12.2010. It was stated to be in compliance with this statutory requirement. The appellant filed C.S.No.1090 of 2011 on 5.5.2011 before the Hon'ble Delhi High Court against the third respondent herein for infringement of its patent. It had earlier filed C.S.No.523 of 2010 against CIPLA Limited for infringement. CIPLA's presence and the relevance thereof will be dealt with by us later. The 3rd respondent herein applied for compulsory licence on 28.7.2011 and it was granted. This appeal is against that order. Pending this appeal, the appellant had asked for stay which was not granted by us.

4. Learned senior counsel Mr.P.S.Raman appearing for the appellant submitted that the compulsory licence order was vitiated by several errors;

(i) Under Section 87(1) where the Controller should have arrived at prima facie satisfaction that a case has been made out, notice was not given to the appellant herein which is a grave miscarriage of justice;

(ii) The compulsory licence application is not supported by any evidence;

(iii) The appellant had sought for adjournment to enable the invention to be worked to the fullest extent and this was not granted which is against the law;

(iv) While deciding whether the reasonable requirement of the public has been satisfied, the Controller ought to have taken into reckoning the presence of other player, CIPLA (not before us) and the supply made by CIPLA and by totally ignoring its presence, injustice has been caused;

(v) The Controller ought to have ascertained what is the reasonable price and thereafter, decided the issue of granting compulsory licence; and

(vi) The controller was in error in concluding that the manufacture in India was necessary to meet the "working" requirement under Section 84(1)(c) of the Act.

The learned senior counsel also referred to the conduct of the third respondent in not mentioning the presence of CIPLA in its application which was a relevant fact and in contending that it had obtained a process-patent for manufacturing the invented product, which it had not. According to the learned senior counsel, these two factors disentitle the 3rd respondent from obtaining compulsory licence. The Controller was in error in not taking note of Patient Assistance Programme (PAP) which is a relevant factor for deciding whether the reasonable requirement of the public had been met. It was submitted that this provision was a discretionary power granted to the Controller under certain circumstances laid down in the Act and not a penal provision. Finally, the learned senior counsel submitted that even assuming without accepting that compulsory licence ought to have been granted, the manner in which the terms and conditions were fixed was totally arbitrary.

5. The Counsel on both sides made their submissions orally and in writing. The learned Counsel for the respondents 1 & 2 adopted the submissions of the learned counsel for the 3rd respondent and submitted that the order was in accordance with the law.

6. First we will take up the issue of opportunity at the prima facie stage.

7. According to Ms.Rajeswari, the learned counsel for the 3rd respondent, the Controller is under no obligation to give any hearing before arriving at a prima facie satisfaction and in this regard, referred to the decision in **Competition Commission of India v. Steel Authority of India & Anr.** [2010 CompLR61 (Supreme Court)] where it was held that the issue of notice to a party at the initial stage where there has been no determination of rights cannot be implied.

8. Section 87(1) of the Act deals with the procedure adopted by the Controller, while dealing the applications under Sections 84 and 85. Section 87(1) deals with the Controller arriving at satisfaction that prima facie case has been made out and directs the applicant to serve copies on the patentee and other persons appearing to be interested. Section 87(2) requires the patentee to give to the Controller a notice of opposition within the time prescribed. Section 87(3) refers to the grounds on which the compulsory licence application is opposed. Section 87(4) deals with the opportunity to be given to the applicant and the opponent before deciding the case. Rule 129 of the Patents Rules, 2003 deals with the exercise of discretionary power by the Controller and requires the Controller to give to an applicant or a party a hearing before exercising any discretionary power that may affect the applicant or the party adversely. Having taken part in the proceedings thereafter, this ground may not be available to the appellant. However, since it is a pure question of law, we will answer it.

9. At the stage of Section 87(1), the Controller has two options. Even on the face of it, he may decide that the compulsory licence cannot be granted. This may be for various obvious reasons like, the application having been made before the lapse of the three years mandated by law. The Controller has another option. On the face of it, he may decide that this is a matter where the parties have to be heard before a decision is arrived at. It does not mean that the Controller has decided one way or the other. It means only that on going through the application and considering

the facts alleged, he is of the opinion that the other side should be heard. Therefore, he directs the applicant to serve copies on the other side. It is clear from S.87(1) that prima facie satisfaction precedes the direction to issue notice to the patentee or other persons. Therefore, it is futile to contend that for arriving at prima facie satisfaction, the other side should be heard. The hearing of the other side arises only after notice of opposition is filed and Section 87(4) stage is reached. After hearing both the parties, the Controller again has two options. He may reject the application for licence or he may grant the licence. At the stage of 87(1) no such determination of rights is contemplated and all that is contemplated at that stage is whether this application deserves to be granted a hearing. Therefore, this ground is rejected.

10. The next ground raised by the appellant is that the letter dated December 6, 2010 issued by the third respondent which is allegedly in compliance of Section 84(6)(iv) is not a genuine attempt. The compulsory licence applicant must make an effort to obtain the licence from the patentee on reasonable terms and conditions. According to Mr.P.S.Raman this letter was more in the nature of a notice or threat and was not really a request for the grant of licence on terms and conditions. According to the learned senior counsel, had the 3rd respondent been serious about his application for grant of licence, it would have made a real effort. Learned senior counsel submitted that the appellant's reply left the door open for negotiation. The 3rd respondent had not availed of this. Therefore, no reasonable efforts have been made by the third respondent prior to the compulsory licence application.

11. According to the learned counsel appearing for the 3rd respondent, the letter addressed by the 3rd respondent to the appellant was sufficient compliance. The refusal by the appellant was clear and therefore, there was no purpose in making any further efforts to obtain voluntary licence.

12. Learned Controller had in this regard, held that the 3rd respondent could not have taken any further efforts for the grant of voluntary licence and that therefore, the requirements of Section 84(6)(iv) were satisfied. The appellant had stated in the reply, "In view of what has stated above, our client does not consider it appropriate, to grant voluntary licence to manufacture and market the product." The section requires the Controller to take into account 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 the reasonable period as the Controller may fix. In the letter dated 6.12.2010, the 3rd respondent had approached the appellant and written that 'we understand that the cost of therapy per month for the said drug as sold by you works out to about Rs.2,80,000/- and …… most of the patients are from the low and middle income groups that can seldom afford such expensive drug'. The letter stated that the access to the treatment of cancer is denied 'particularly due to the high pricing of the product'. The 3rd respondent wrote that they would be in a position to make the product available to the public in India at a cost of less than Rs.10,000/- for one month and that at such price, even the Government Agencies would come forward to offer financial assistance to the patients and in this context, they applied for licence for the manufacture and marketing of Nexavar so that protection of public health is not impeded due to the present high price. They finally requested for the "grant of a voluntary licence to us to manufacture and market the product on such reasonable terms and conditions which would not prevent us from making the drug available to the public at the affordable price as projected above". We must also record here that this request for voluntary licence was made without prejudice to their right to attack the patent.

13. To this, the appellant/respondent by letter dated 27.12.2010 denied everything stated in

paragraph-1 and stated that the 3rd respondent must appreciate the backdrop of the huge sums invested by the appellant in Research and Development before working out the cost of the patented product. The appellant thereafter gave rough figures of their investment. They denied that they had failed to meet the fundamentals of the Patents Act and they said that "the demand for drug covered by our client pattern is being met to an adequate extent ……". They denied that Nexavar was not available to the patients in India at affordable price. They denied that the invention covered by the patent is not being worked effectively. They said that as long as their patent is in force, the entry of generic version is legally prevented and they denied that the reasonable requirement of patients suffering from renal cancer is not met. As far as the cost suggested by the 3rd respondent is concerned, the appellant stated that the third respondent may offer to manufacture the product at a cost less than Rs.10,000/- since they had not spent any resources in R & D. Therefore, according to the appellant, it was in full compliance of the requirements of the Patent law with regard to the reasonable requirement, availability at a reasonably affordable cost, working of the patented invention in India. It is stated in the reply that, "Your company is not able to make out a case for the grant of voluntary licence to manufacture and market the product Nexavar. Therefore, our client does not consider it appropriate to grant voluntary licence to manufacture and market the product Nexavar to NATCO'. There was a tail piece to the effect that as per the Act, the 3rd respondent may take action within 14 days from the date of receipt of this letter.

14. We find from a reading of the two documents, viz., the letter and the response that the 3rd respondent who is the compulsory licence applicant had stated what according to it was a reasonable cost. The letter stated that Rs.2,80,000/- was not accessible to a large number of patients for whom the drug is meant and that they were willing to make available the drug at less than Rs.10,000/- per month if the appellant would grant licence. The appellant calls this letter more in the nature of a threat than a real request. We find that the third respondent had stated that the price at which it would offer the drug was less than Rs.10,000/-. On these terms, NATCO applied for voluntary license.

15. It is true that the letter spells out three conditions for the grant of licence in paragraph-6 and states that because of the prohibitory high cost, these three conditions are not satisfied, but yet, the offer had been made. The appellant on its part had understood the tenor of the letter. According to the appellant it had satisfied all the requirements of law. If there was a veiled threat, it was met equally by a veiled answer.

16. If the appellant thought that less than Rs.10,000/- was not a bargaining point, all that it should have stated was that there was some room for negotiation. But, the response did not indicate that, instead it clearly indicated that the appellant did not consider it appropriate to grant voluntary licence. Therefore, the offer was made and it was rejected. The 3rd respondent is not required to make another request when its efforts had failed. The law does not require that. On a consideration of these two documents, the Controller was of the view that the 3rd respondent had made an effort but it could have been "more humble in writing and not hurting the sensibility" of the patented persons. They are after all rivals in business and we do not think there would be room for such sensibilities. The requirement of law was fully met and we reject this ground.

17. Next we come to the failure to file evidence. The appellant submitted that the 3rd respondent had not given evidence to support its compulsory licence application. To this, the 3rd respondent's case was that Section 84(3) merely requires the application to contain a statement setting out the nature of the applicant's interest together with the particulars as may be

prescribed and the facts upon which the application is based. Form-17 requires the applicant to state the grounds and documentary evidence to support its interest. According to the learned counsel, there is no specific requirement to support the compulsory licence application and in the present case both the parties filed their evidence from July, 2011 to June, 2012 at different points of time.

18. Form-17 does not seem to indicate the filing of evidence. While the 3rd respondent could have filed documentary evidence along with the application, it is clear that all the evidence was required to be filed before the Controller before he made the decision. When the matter came up for hearing, not only did the Controller have the evidence based on which the 3rd respondent made his application, the appellant also knew what was the evidence he had to meet. Therefore, if there is any lapse, it is a procedural lapse and on that ground, the order cannot be set aside.

19. With this, we come to the end of the technical objections. Now we have the main issues. The issues of CIPLA's presence and the request for adjournment are intrinsically linked with them. At the end we will deal with the terms of the licence and the conduct of the 3rd respondent.

20. Before going in to the merits of the matter, we return to the Ayyangar Report. It is true that this report was before TRIPS Agreement, but it has not lost in its significance a whit. Whenever a question arises in regard to Patents we will learn much if we read it. The Ayyangar Report quotes from Edith Penrose's Economics of International Patent System and says that, "Any country must lose if it grants monopoly privileges in the domestic market, which neither improve, nor cheapen the goods available, nor develop its own productive capacity, nor obtain for its producers at least equivalent privileges in other markets." We also have the relevant provisions of International Conventions. Article 27(1) protects the patented right without discrimination as to the place of invention, the field of technology and whether the products are imported or locally produced. Article 30 provides limited exceptions to exclusive rights conferred by a patent provided they do not unreasonably conflict with the normal exploitation of the patent, taking into account the legitimate interest of third parties. Article 31 of TRIPS deals with other use without authorization of the right holder and lists the provisions which shall be respected while authorizing such use. Next, Article 5 of the Paris Convention says that the importation by the patentee into the country where patent has been granted …… shall not entail forfeiture of the patent. Article 5A (4) deals with compulsory licence. We also refer to the Doha Declaration which addressed the difficulties which Members with insufficient or no manufacturing capacity in the pharmaceutical sector could face in making effective use of compulsory licensees under the TRIPS Agreement. We have also seen that the Members affirmed their full right to use the TRIPS flexibilities in this regard especially in connection with the Members' right to protect public health and in particular, to promote access to medicines for all. This then is the running theme; public health and access to medicine, a facet of Right to Life.

21. Now, we come to our own Act, Chapter XVI. Section 82 defines "patented article" which includes any article made by a patented process and patentee includes an exclusive licensee. Section 83 deals with general principles applicable to working of patented inventions. They are as follows:

> "**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.

22. We must particularly note from the above;

= that patents are not granted for an import monopoly of the patented article and,

= the grant of patent shall not impede protection of public health and,

= the grant of patent must balance the rights and obligations and finally,

= it must make the benefits of patented invention available at reasonably affordable price to the public.

We cannot ignore these markers when we decide the appeal.

23. The words "patented invention" are not defined. Section 84 deals with compulsory licence and there are three conditions which need to be satisfied for the grant of compulsory licence. It must be noted that it is enough even if one condition is satisfied. Section 84(1) (a), (b) and (c) are separated by the disjunctive "or". Section 84(2) gives this right even to a licence holder under patentee and he shall not be estopped from raising the grounds under Section 84(1) and seeking a compulsory licence. This application must contain a statement setting out the nature of applicant's interest together with such particulars as may be prescribed and the facts upon which the application is made. Form-17 deals with the application for compulsory licence. Section 84(4) deals with the Controller's power, to grant licence if the grounds under Section 84(1) have been met and to decide the terms upon which the licence is granted. Section 84(5) is consequent to the order under Section 84(4). Section 84(6) refers to the factors which the Controller would take into account while considering whether a compulsory licence should be granted and they are, (a) the nature of invention; (b) the time which has lapsed since the grant and the measures taken by the patentee or the licensees to make full use of the invention; (c) the ability of the applicant to work the invention to the public advancement; (d) the capacity of the applicant to provide capital and working the invention; and (e) whether the applicant had made efforts to get a voluntary licence from the patentee. The Controller need not take into account the matters which are subsequent to the compulsory licence application. The Explanation says that the reasonable period that is

required to decide if the compulsory licence applicant has been successful in his efforts to obtain a voluntary licence is a period not ordinarily exceeding a period of six months. Section 84(7) specifies the conditions which lead to the presumption or the creation of legal fiction that reasonable requirements of the public have not been satisfied, and they are as follows:

> "**84.Compulsory licences** –
>
> (1) to (6) xxxx
>
> (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 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."

Section 86 deals with applications for adjournment by patentee and invoking the power under this Section, if the Controller is satisfied that the time for working of the invention on a commercial scale to an adequate extent or for enabling the invention to be worked on a commercial scale to the fullest extent as it is reasonably practical is not adequate, he may adjourn the further hearing of the application for a period not exceeding 12 months in the aggregate. This Section contains a proviso. Section 86(2) appears to be a guide for the discretionary power of the Controller and provides that adjournment would not be granted, unless the 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.

24. While Section 83 deals with the general principles applicable to the working of patented invention, Section 89 deals with the general purposes for granting compulsory licences. So, one might say that Section 83 is the "why" of grant of patents and Section 89 deals with the "why" of

compulsory licence. Section 90 deals with what are the terms and conditions that the Controller shall try to secure while settling the terms and conditions of compulsory licences. Section 93 states that this order shall operate as a deed between the parties concerned. Section 94 deals with the termination of compulsory licences.

25. The presence of CIPLA is a very crucial issue. CIPLA is allegedly an infringer against whom a suit has been filed by the appellant. It is pending before the Hon'ble Delhi High Court. At the time when the compulsory licence was granted, CIPLA was selling its "offending products" at Rs.30,000/- per month and according to the learned senior counsel, this price has been steadily falling. Learned senior counsel submitted that if the presence of CIPLA is not considered relevant, a grave injustice would be caused to the appellant. It was submitted that the presence of CIPLA was a factor that should be taken into reckoning to see if the reasonable requirement of the public is met. According to the appellant, the patented invention is not Nexavar but Sorafenib Tosylate. It was submitted that if this third party had effectively met the entire demand for the drug, then there would not be a grant to another entity. It was also submitted that in a given case, the infringer itself might apply for compulsory licence and that would result in injustice. It was also submitted that the Hon'ble Delhi High Court did not in fact, grant an order of injunction against CIPLA. It had directed CIPLA to maintain accounts of its sales of the infringing products. Therefore, if the appellant succeeds in the suit, the sales made by CIPLA shall be deemed to be the sales by the appellant for ascertaining the damages, if the appellant fails in the suit, CIPLA's product would be considered legal and the reasonable requirement of public with respect to patented invention would have been met by an alternate product. If the subject patent is declared invalid, then compulsory licence application itself would become infructuous. Therefore, the 2nd respondent ought to have considered the presence of CIPLA while arriving at his decision. According to the learned senior counsel, until CIPLA is declared an infringer, its presence cannot be considered illegal. In any event, the legitimacy of the third party is irrelevant for deciding whether the applicant has met the need of the public, when the entire sales made by the third party, is accountable. According to the learned senior counsel, the patients who buy the product from either the third respondent or CIPLA, would not need to buy the appellant's product and therefore, one must combine the sales of the appellant and CIPLA to see, if that supply met the requirement of the public. According the appellant, the consequence would be outrageous, if CIPLA's sales is not taken into account. It would be an incentive to infringe patents. It was further submitted that by the Government granting the marketing approval to CIPLA, what would actually happen was that CIPLA would take away the patentee's market leading to the grant of compulsory licence alleging patentee's inability to meet the market demand and if that were the case, generic companies will be able to get compulsory licences for all patented products and this cannot be the intention of the legislature. He also referred to CIPA Guide to the Patents Act by the Chartered Institute of patent Attorneys (Sixth Edition) where it is stated that "also, it does not seem that the meeting of the demand has to result from the activities of the patentee or his licensees; meeting a demand by an infringing product would also seem to avoid application to the provision." There was a reference to the affidavit of Dr.Manish Garg where it was stated that the combined sales of the appellant and CIPLA has catered to 44% of the current patient pool and also to the affidavit of Dr.Ashish Gawde. Learned senior counsel also submitted that the 3rd respondent's case of uncertainty of supply by CIPLA was not an acceptable argument.

26. Learned counsel for the 3rd respondent, on the other hand, submitted that CIPLA's presence cannot be recognized in any circumstance and the obligation of the working requirements must be met only by the patentee and not by any third party. It was submitted that when the appellant had

issued statements that CIPLA was an infringer and was fully pursuing a civil suit against CIPLA. It is impossible to accept its case that CIPLA's sales should be taken into account. Learned counsel submitted that it was not the appellant's case that CIPLA is its licensee and that its sales are legal. It was submitted that the appellant cannot treat the sales of CIPLA illegal and claim damages for infringement and in the same breadth, ask the said sales to be treated as its own for the purpose of deciding whether the reasonable requirement as mandated by the statute has been met. Learned counsel submitted that the consent order passed by the Hon'ble Delhi High Court does not legitimize CIPLA. It was passed without deciding the rights of both the parties i.e., the case of appellant that CIPLA is an infringer and the case of CIPLA that it is not. It is submitted that in Form-27 filed by the appellant, the sales of CIPLA was not referred to which means that for the working of invention and meeting the requirements of public, the sales by the appellant alone is relevant. According to the 3rd respondent, CIPLA's sales were sales at risk and it may at any time stop its production, if CIPLA finds the manufacture unviable. When allegedly the appellant has been selling its products in India since 2006 and CIPLA had entered the market only in 2010, the appellant cannot take CIPLA's sales into account to show that the requirement of the public had been met.

27. The Controller rejected the appellant's case on the ground that in a compulsory licence application, it is only the patentee who is relevant and not any other person. He had referred to the infringement suit filed by the appellant against CIPLA to stall it from making its sales. The Controller had also stated that CIPLA may be injuncted by any time by the Hon'ble High Court. According to the learned senior counsel, this was an unsustainable presumption. The application had been closed and there is no question of reviving it now and the Court had directed the parties to proceed with the trial. The Controller had also taken into account, for argument's sake, the sales made by CIPLA, and held that even then the requirement had not been met. The Controller refused to include CIPLA's sales for the purpose of S.84.

28. According to the appellant, CIPLA infringes its patent and that is why the suit has been filed. Section 83 deals with patented invention. The words, 'patented invention' have not been defined anywhere in the Act. The words, 'patented articles' have been defined in Section 82 of the Act. The words, 'invention' and 'new invention' have been defined in Section 2(1) (j) and 2(1)(l) respectively. Section 83(1) deals with why patents are granted that is, to encourage inventions, Section 83(1)(a) must refer to patentees since it gives the reason why patents are granted. Section 83(1)(b) also refers only to the patentees. Section 83(1)(c) relates to the protection and enforcement of patent rights and hence must refer only to the patentees. Patent right belongs only to the intellectual property rights owner and not a third party, whether he is an infringer or not. Section 83(1)(d) refers to patents granted and that they should not impede the protection of public health and refers only to the patentees. Section 83(1)(e) again refers to only patentees. Section 83(1)(f) specifically refers to patentees or persons deriving title or interest and so does Section 83(1)(g). When the law refer to patentees, it means the patentees or persons legally claiming the patent and no one else. Therefore, when Section 83(1)(g) states that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public, it clearly indicates that the *quid pro quo* for the grant of patent is the duty of the person to whom the patent was granted to make the benefit of his invention available to the public at reasonably affordable price. Therefore, the words 'patented invention' can only mean what the patentee or his licencee markets and nothing else. Section 89 which is about the general purposes for granting compulsory licence says that the general purpose is to secure that the patented invention is worked

on a commercial scale in the territory of India without undue delay. Section 84(6) refers to the ability of the applicant (the compulsory licence applicant) to work the invention to the public advantage and Section 84(6)(iii) refers to the capacity of the applicant(compulsory licence applicant) to undertake the risk in providing capital and working the invention. Therefore, whenever the words, 'patented invention' are used, they refer to;

= the invention that must be made available to the public by the patentee;

=the invention in respect of which reasonable requirements of the public must be satisfied by the patentee; and;

= the invention which the patentee must work in the territory of India.

If it were to be otherwise, it would mean that a monopoly is granted to a person who does not make any effort to reach his invention to the public and would rest his case on the labour of a third party whom he would drag to Court with an infringement suit. Therefore, CIPLA's presence cannot be cited by the appellant to prove its case. Rightly in its Form-27, the appellant did not include the CIPLA sales because, the appellant knows that CIPLA sales can never be its own sales, and CIPLA is not its licensee nor is the sales by CIPLA blessed by the applicant.

29. Periodical statement are made by CIPLA and filed into the Court. If we take one of the affidavits of undertaking (22.9.2010), as a sample, it shows that the defendant CIPLA had undertaken to file the accounts regularly on a quarterly basis and it also shows that the defendant CIPLA had undertaken to abide by the order of the Court in respect of payment of damages. The order of the Hon'ble Delhi High Court which refused to grant injunction was subject to the defendant CIPLA maintaining the available and accurate accounts and filing the same regularly on quarterly basis. While it is true that the injunction application was closed, if CIPLA had failed to file the accounts as undertaken, it was open to the appellant to move the Court for modification of the order. This is not the reason why we hold that CIPLA's presence is not relevant, we just note that. The law is clear that, the requirements and conditions, for grant of compulsory licence must be decided with reference to the patentee alone and not a party whose presence itself is litigious. See also Section 84(6)(i) which refers to measures taken by the patentee or the licensee to make full use of the invention. Therefore, for deciding whether the conditions of Section 84 are satisfied, we will not take into account the presence of CIPLA.

30. Further, if we look at the Ayyangar Report at paragraph 612, it deals with what is the present Section 85 'revocation of patents by the Controller for non-working'. It reads that

> "I am satisfied that unless there is a residuary power vested in the Controller to revoke a patent in the event of the invention not being worked to an adequate extent in the country, the compulsory licensing provisions themselves might fail to achieve their purpose. Further, I consider that the existence of such a provision might itself serve as an inducement to the patentees so to instruct their licensees with the details of such technical information as they have and to render them such assistance as might be needed to enable them to work the invention commercially and adequately so that the patent might remain in force and the patentees derive benefit from the royalties which the licensees should be paying during the term of the patent".

From this, it is clear that the patentee is even expected to furnish details of technical information and to render assistance to the licensees so that the invention is worked commercially and adequately. This is because, it is the patentee's property and it is not in his interest to have it removed. We are only referring to the paragraph to show that the intention of the Act is that it is the patentee who should make sure that the invention is worked commercially and adequately. Otherwise, the patentee runs the risk of having the patent revoked for non-working under Section 85. The 3rd respondent also cited **Harvey's Skindiving Suits of Canada v. Poseidon Industri AB**

[1984 CarswellNat 566, 1 CIPR 288] where it was held that "working concern must be secured licit working and that working carried on by alleged infringers is unsatisfactory". We have also seen the CIPA extracts. But we need not look anywhere else. Our Act is clear and we must decide according to this law. It is self-contained and the grant of approval to CIPLA is based on a different statute and is not related to this issue. CIPLA's presence is irrelevant for deciding whether the reasonable requirement of the public has been met or whether the patented invention has been made available to the public at a reasonably affordable price or whether the patented invention has been worked in the territory of India.

31. According to the learned senior counsel for the appellant, the Controller General's reasoning regarding the reasonable requirement or adequate supply is flawed. Learned senior counsel submitted that one should take note of the nature of invention. This drug is only a palliative drug and it does not cure cancer and it keeps the quality of life at a reasonable level. The number of patients afflicted by this kind of cancer is not high and the market penetration is not easy and the appellant cannot market its product without complying with all statutory requirements. The appellant had to assess the public requirements. The appellant would have to convince the Oncologists about the merits of the medicine. The market approval was given only in January, 2008 and the appellant had only three years to work the invention. Considering the nature of invention and the number of patients and the presence of other medicines, the period given to the appellant under statute is not enough. Learned senior counsel submitted that if supplying the drug had been easy, the 3rd respondent (NATCO) should have addressed the requirements completely in one year while in two years what was covered by the 3rd respondent was only 44% of the patient pool. The reasonably affordable price should be fixed taking into account all the factors, and socio-economic conditions are not the only parameters. The affordability has to be decided considering the nature of the product and reasonably affordable price should be fixed taking into account the price at which the appellant can sell the product considering the expenditure incurred by them. The Controller had not considered the comparative data of other pharmaceutical drugs. The Controller had not taken into account specifically that palliative drug would take a long time to make an inroad. The appellant had an effective Patient Assistance Programme (PAP) which would satisfy the requirements of making it available to the public reasonably.

32. Learned senior counsel submitted that the shade of Section 84(1) (c) falls on Section 84(1) (a) and (b). There can be no simultaneous release in USA and India, since the Drug Controller in India required the manufacturer to produce the clearance in the foreign country. In the notice of opposition, the appellant had contended that none of the deeming provisions of Section 84(7) refers to the price of drug or its availability at a reasonably affordable price. It is stated that Nexavar has been granted orphan drug status in USA and Europe, because there were fewer than 200000 patients for each of its indications. Orphan drug Status was granted following an application lodged by a drug development company together with a formal dossier describing the pharmaceutical properties and clinical data. The notice of opposition also gives the cost of innovation based oncology brands of other countries, to show that Nexavar's price is similar to other comparable drugs. The notice of opposition also refers to the Patient Assistance Programme (PAP) which is a philanthropic programme where the price is fixed much lower than the commercial price on the recommendation letter of the Doctor. PAP has admittedly undergone several changes and according to the appellant, the appellant is therefore continuously trying to improve the availability of the drug covered by the patent. The appellant has also given the list of hospitals to which the invention is supplied. The notice of opposition also refers to the economy scale as a valid reason for not locally manufacturing the drug and that the word 'worked' used in the statute does not mean

local working requirements and the Controller General by attempting to impose local working requirements, granted the compulsory licence to the 3rd respondent. It is also submitted that the original price quoted by CIPLA at Rs.30,000/- per month is a good indication for the Controller General to ascertain what is the reasonably affordable price that may be fixed. But CIPLA is now selling at a price much less than the one fixed by the Controller. This really sets at naught the reasoning of the Controller in fixing the price.

33. He also submitted that the words, 'reasonably affordable price' should be construed on the basis of different classes/sections of public and the concept of differential pricing should be accepted. According to the appellant, the price of any product must be reasonable to the public and to the manufacturer/innovator. There is also a reference to the Health Insurance Schemes that are available and in particular, a reference has been made to the scheme floated by the Government of Tamil Nadu wherein the members of the family whose annual income is less than Rs.72,000/- shall be entitled to free medical and surgical treatment in Government and private hospitals. As regards Onyx the original inventor, according to the appellant, all the inventors were appellant's employees and the invention was made in the appellant's laboratories during the course of employment and the appellant had paid for all initial R & D expenses and it was only at the developed stage, there was a cost split and therefore, it is the case of the appellant that it is irrelevant for deciding whether the compulsory licence has to be granted.

34. As regards orphan drug status, it was submitted that it also means the patient base is small. Reference is also made to **Schneider Electric Industries S.A. v. Telemecanique & Controls (India) Ltd. [2000 (20) PTC 633]** and **Telemecanique & Controls (I) Limited v. Schneider Electric Industries SA [2002 (24) PTC 632 (Del)(DB)]** for deciding the issue of working. According to the appellant, while it has earnestly tried to increase the patient base and improve patient assistance programmes, it would be economically unfeasible for the appellant to set up a local manufacturing facility to commercially manufacture Sorafenib Tosylate in every country where it has a patent.

35. Learned counsel for the 3rd respondent submitted that Section 83 does not only deal with general principles but it also gives the background upon which the issue of compulsory licence would be granted. The learned counsel referred to the various letters written by Oncologists to show that the cost would be a determinant. According to the learned counsel, the submission that there were only two years to penetrate the market is not correct especially for a company that was already operating in this country. Learned counsel reiterated that the reasonable requirements must be met only by the patentee and as on date, the demand was not met by the appellant. Learned counsel submitted that the Patient Assistance Programme is uncertain and it is not a part of the supply to the market and it can be withdrawn at any time. The supply as envisaged by the Act is not the discounted supply made through the Patient Assistance Programme. According to the learned counsel, the very fact that the appellant has started different Patient Assistance programmes is itself a tacit admission that it had not worked the invention adequately. The case of the appellant that CIPLA's presence should be included is another admission that only with CIPLA's supply can the appellant state that Section 84(1)(a) is satisfied. Learned counsel submitted that the concern of the countries regarding access to medicine has a relation to the price since the price could actually be a barrier. Learned counsel submitted that the case that the Controller had erred in not fixing the reasonable price is not correct. There were three prices before the Controller and he fixed, what according to him, was the reasonably affordable price. Learned counsel submitted that only if there are many suppliers in the market, the competition will drive the price down. Learned

counsel submitted that in no case of compulsory licence anywhere, the authority had fixed the price and that fixing the price would actually distort the competition. Learned counsel submitted that the research and development cost cannot be a criterion for fixing the price and that the price in India cannot be fixed as if the entire research and development cost must be reckoned from the Indian market. The appellant cannot argue that it must get back from India all that it had spent. Learned counsel submitted that the Controller had actually asked what the R & D cost was. Learned counsel submitted that no evidence was produced to enable the Controller to fulfill the mandate of Section 90(1). Learned counsel submitted that comparison with other highly priced oncology drugs may be relevant only if other details are available. Learned counsel submitted that only in the case of impossibility of manufacture in India, the patentee can rely on import alone to prove working, otherwise the working should be local manufacture and in fact, the appellant has a local factory from where other products are marketed. It is also submitted that Sections 83 and 84 are social welfare provisions and should receive broad construction and should be interpreted in a manner that advances public interest. According to the respondent, Section 83 impliedly and positively enlists the burden of the appellant and obligations to be fulfilled after the grant of patent. The demand for drug as per the data gathered from Globocan 2008 as well as the National Cancer Registry is about 20,000 for liver cancer, where the survival is less than 1% and in the case of kidney cancer, the approximate total patient base is about 8900 and the survival is about 2 to 3%. The demand for drug is seen from the tabular column in paragraph 10(a) of the Controller's order, which is as under:

	Total patients	Demand for 80% of patients	Bottles per month (required)	Bottles imported in 2008	Bottles imported in 2008	Bottles imported in 2010
Liver Cancer	~20,000	~16,000	~16,000	Nil	~200 bottles	Unknown
Kidney cancer	~8,900	~7,120	~7,120			

Dr.Manish Garg's affidavit is with regard to how much was supplied. It was submitted that the sales figure for the drug worldwide has grown by leaps and bounds and in India the working has been tardy. According to the respondent, the Patient Assistance Programme shall not be considered for the purpose of Section 84(1)(a) and the product sold in the open market is the one that has to be considered to see that reasonable requirements of the market is satisfied. It was submitted that the intention of the Parliament is that the substantial benefit of the patented invention should reach the public. Learned counsel also referred to the Parliamentary debates in this regard. Learned counsel referred to various letters attached to the affidavit of Mr.Srivatsava to show the price of Sorafenib Tosylate. According to the learned counsel, Patient Assistance Programme is itself an admission that the price of Rs.2,80,000/- is not affordable.

36. Several affidavits have been filed by the appellant in support of its case. One is the affidavit of Dr.Manish Garg dated 9.11.2011. In this, he has referred to National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCL guidelines) version 1.2012 of kidney cancer and for Hepato-Cellular Carcinoma. According to him, the statistics provided by the compulsory licence applicant for the grant of compulsory licence is not correct and more so, since there is an alternate treatment available to the patients. Then, we have to see the affidavit of Mr.Jean-Sylvain Demelier who is the Vice President of Global Oncology Marketing for Bayer HealthCare Pharmaceuticals Inc. He has given a comparative analysis regarding the pricing of Nexavar in various countries and according to him, the price in India is similar to other developing countries. According to him, Nexavar's price is on par with other oncology products of inventing companies. According to him, the originator products are more expensive than generic ones since they also involve R & D cost as against someone who merely copies the drug. Therefore, according to

the deponent, the appellant being the inventor and having invested resources in developing the product, the same would form a part of the reasonably affordable price for the said product and the price of Nexavar fixed by the appellant constitutes a reasonably affordable price. We also see the affidavit of Mr.Harald Dinter who is the Head of Global Drug Discovery Operations. He has given evidence as to how R & D in innovative pharmaceutical industry works and describes the sequence of stages in the actual process to discover and development of a drug. According to him, the entire process is complex, lengthy and risky and therefore, expensive. According to him, "only one out of 20 substances going into especially costly clinical testing with patients will actually be launched as a product". Therefore, according to him 75% of the total R & D cost is due to failed products. He has also given the details of the appellant's R & D expenditure on pharmaceuticals and the appellant is working primarily in indications with high unmet medical need and has set itself the goal of improving patients' quality of life by means of significant innovation. According to him, R & D investments of more than two billion Euro are required to bring a new molecular entity (NME) in the market and therefore according to him, its price falls within the four corners of the reasonably affordable price. Dr.Manish Garg's affidavit dated 8.2.2012, gives a list of cities and hospitals covered by the appellant. There is yet another affidavit of Dr.Manish Garg dated 8.2.2012 which gives a periodical internal assessment of Renal Cell Carcinoma (RCC) statistics and Hepato-Cellular Carcinoma (HCC) statistics. According to him, the total number of patients with RCC and HCC eligible for Sorafenib treatment was approximately 44%. We have the presentation given by Dr.Joerg Thomaier as to 'why IPRs are essential to enable sustainable access to new medicines and pricing of innovation is fair' and this presentation speaks of the appellant's approach towards medical needs of patients who otherwise could not afford for treatment with the new drug. The 3rd respondent has filed letters from oncologists to show that the price is high.

37. Form-27 for the year 2011 has been filed on 29.3.2012 which is after the compulsory licence was ordered. In Form-27 filed for the year 2009, it is stated that 4665 packs were imported. The number of packs manufactured in India was 'NIL'. It is stated that licences and supply licences granted during that year were NIL. This Form states that 'the patentee believes that the public requirement is being met adequately'. In the year 2010, it is stated that no commercial sales packs were imported and only sample packs of Nexavar patient support packs were imported. Again, as far as the manufacture in India is concerned, it is stated as 'NIL'. The number of Nexavar sales packs imported is stated to be NIL. The number of Nexavar patient support packs imported is stated to be 340 units and the number of Nexavar sample packs is stated to be 340 units. In the Form-27 for the year 2010, it is stated that the public requirement has been met to the fullest extent at reasonable price.

38. For the grant of compulsory licence, the applicant should show and satisfy the Controller that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonably affordable price or that the invention has not been worked in India. The reasonable requirements of the public would not be deemed to have been satisfied, if the patented invention was not being worked in the territory of India on a commercial scale to an adequate extent or on reasonable terms and was not being so worked to the fullest extent that is reasonably practicable [vide: Section 84(7)(d)]. The failure to meet the demand on reasonable terms must logically mean both quantity and price. The Controller has considered the Form-27 filed by the appellant. We have already extracted the crucial paragraphs from the affidavits of Dr.Manish Garg and others. All of them have deposed that this price is reasonably affordable one for the inventor. In none of the affidavits the deponents had considered the perspective of reasonable affordability from the public eye i.e. the patients' view.

All that they would say is that the process of drug invention is long drawn and expensive, and that several trials and experiments must be made at the laboratory for hours together before the drugs are successfully launched and many of the experiments would end up in failure and loss. Therefore, they had spent huge amounts in Research and Development for invention and considering this, they fixed the price which accordingly, is reasonably affordable.

39. When we look at the Act, it states that the invention must be available to the public at a reasonably affordable price and if not, compulsory licence can be issued. As we have already observed, **Sub-sections (a),(b) and (c) of S.84(1) are separated by the disjunctive 'or' and therefore, even if one condition is satisfied, the Controller will be well within his rights to order compulsory licence.** The price at which the appellant sells the drug is Rs.2,80,000/- per month. Before the Controller, two papers were shown for determining the affordability of the drug. One Mr. James Love, Director, Knowledge Ecology International also gave evidence. In fact, we have considered this affidavit in our order dated 14.9.2012 refusing to grant stay. This affidavit refutes the R&D costs claimed by the appellant. The R&D costs and the prices of other drugs do not assist in deciding what the public can afford reasonably.

40. The reasonably affordable price necessarily has to be fixed from the view point of the public and the word, 'afford' itself indicates whether the public can afford to buy the drug and therefore, we must consider this question from the view point of whether Rs.280,000/- per month is reasonably affordable price to the public. All the evidence filed by the appellant; the affidavits, the reports, etc. relating to the cost are not relevant to decide what the public can reasonably afford. The Controller was satisfied that the 'reasonably affordable price' has to be construed with reference to the public. The appellant has taken the stand that the statistics given by the respondent regarding the number of patients and the requirements cannot be accepted in full. Even if we take the appellant's own number, we find that the supply made by it cannot be said to be adequate and the price definitely is the factor that will determine whether the public will reach out for a particular invention. The Act also refers to the working of invention on a commercial scale and if the invention is not worked in the territory of India on a commercial scale to an adequate extent, then, the deeming provision of Section 84(7) will come into play. We will decide the question whether "working" means "local manufacture" later.

41. <u>But, even assuming that we accept the case of the appellant in total that import will completely satisfy the working requirements, this import must be on a commercial scale to an adequate extent and sold at a reasonably affordable price</u>. The appellant submitted that the conditions in sub-section (a), (b) and (c) of Section 84(1) cannot be strictly set apart and one will cast a shade on the other. If there is no working, then reasonable requirements will not be satisfied. If the price is not affordable then, again, the reasonable requirements cannot be satisfied. If it is not worked on a commercial scale, then again, the Act says that the reasonable requirements would not be deemed to be satisfied. The words, 'commercial scale' are also used in Section 83(a) and the subsidized programmes that the appellant has which would depend upon certain conditions being fulfilled will not constitute 'working the invention on a commercial scale'. These programmes are at the discretion of the appellant and not the market price. Nor are the insurance schemes relevant. The R&D costs cited are neither particular to the drug nor to India. Any way what we have to look at is the market price of the patented invention; the price at which the invention is made available to the public which in the instant case is Rs.2,80,000/- per month. We repeat that the Law requires us to see whether the patentee has made available the invention to the general

public at a reasonably affordable price.

42. The Controller has held that the philanthropic proposals cannot be taken into account while construing the expression, 'working the invention on a commercial scale to an adequate extent'. Of course, he has referred to this in the context of the request for adjournment. The Patient Assistance Programmes may be welcome, but it will not satisfy the requirements of Section 84 which is only concerned with the price at which the drug is made available to the public. Section 84(6) deals with what the Controller should take into account. They include the nature of the invention and the time that has elapsed since the grant of patent and the measures already taken by the patentee to make full use of the invention. The Controller must consider the compulsory licence applicant's ability to work the invention. He must also consider the applicant's capacity to undertake the risk in providing capital and working the invention and whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions. But, the Controller shall not be required to take into account the matters subsequent to the making of the application. In this case, the appellant had brought to the notice of the Controller that there are Patient Assistance Programmes and the Controller considered the same and held that he should not take into account that because this clause in the Section requires him not to take into account the matters subsequent to the making of the application.

43. According to him, the intention of the legislature appears to be that subsequent measures by the patentee to frustrate the proceedings shall not be considered. This may not be right. If hypothetically the appellant had brought down the market price permanently to a reasonably affordable cost from the public point of view, that could not be said to be a measure frustrating the proceedings. After all, the compulsory licence procedure itself is only in public interest. Therefore, any manufacturer who, in order to market or make available the product, slashed down the price and making it available to the public to an adequate extent at a price which the public would reasonably afford, that cannot be said to frustrate the proceedings. **Here we are not concerned with the interest of the compulsory licence applicant, but only the public interest**. The grant of compulsory licence is not to favour the applicant, but only because the applicant has demonstrated that the invention has not reached the public in the manner envisaged under Section 84. Therefore, though the Controller's conclusion is right, the words at the end of Section 84(6) are not an absolute taboo to prevent the inventor from bringing down the price and making his invention available to the public. We have already referred to the paragraph from the Ayyangar Report with regard to non-working and that the provision relating to non-working has been introduced to ensure that the patentee has given necessary technical information to work the patent so that the patent is not revoked. Therefore, we must bear in mind that these proceedings are in public interest; they are neither against the inventor, nor in favour of the compulsory licensee. As we have observed earlier, the patents are granted only to benefit the public and the public must get the benefit from the invention and it hardly matters whether the invention is made easily available on a reasonably affordable price by the patentee himself pending the proceedings so long as the Controller is assured that the high price will not be restored. Here the appellant has not done that.

44. We also gain support from Section 94 which refers to termination of compulsory licence. It is possible for the patentee to make an application under Section 94 that circumstances that gave rise to the grant of the compulsory licence have ceased to exist and are not likely to recur. This means the patentee himself may permanently make the invention available to the public at a reasonably affordable price. If even after the grant of licence, the patentee has the right to move the Controller then, definitely pending proceedings, he can show that the price has been reduced and

the restoration of the earlier price is not likely to happen. The Controller was right in holding that the sales of the drug by the appellant at the price of about 280,000/- was alone relevant for the determination of public requirement and he was also right in considering the purchasing capacity of the public and the evidence available to conclude that the invention was not reasonably affordable to the public.

45. Submissions were made that with regard to palliative drugs one cannot enter the market easily and the market penetration is difficult and unless the patentee convinces all the Oncologists, they will not prescribe the patented invention to their patients any further and there are rival drugs in the market and that should also be taken into consideration. Law does not provide for the grant of compulsory licence soon after the patent is granted. It allows for a gestation period that is, three years. The law makers in their wisdom have thought that three years would be sufficient for an inventor to work his invention in the territory of India and make the supply meet the demand at a reasonably affordable price. Law has also allowed for a further one year if the inventor demonstrates that for any reason the time so granted has been insufficient to enable the invention to be worked on a commercial scale and for that, a grace period of 12 months in aggregate is provided under Section 86.

46. In this case, we find that the appellant has taken very contradictory stands. In Form-27, the appellant is fully satisfied that the public requirement has been met to the fullest extent at a reasonable price. We see from the Form-27 before us, the appellant has only taken into consideration the sales made by the appellant. Yet the appellant argued that CIPLA sales must be included to prove adequate supply. In the Form-27 filed in 2010 we also see that the appellant was fully aware of the difference between what is meant by commercial sales and what is meant by patient support sales because it is stated therein that there was no import of sales packs, but only sample of Nexavar patient support packs were imported. Therefore the appellant had not "worked" the invention on a commercial scale even if "import" alone would satisfy the working condition.

47. We must also examine what is meant by commercial sales. What we are concerned is whether it is made available to the public or the sales made by the appellant at Rs.280,000/- that is, commercial sales, that is, market price, that is, supply which the appellant makes to the public, meet the requirements or show working or reasonableness. In the year 2010, not one pack of commercial sales unit has been imported. It is, in this context, the Controller had denied the request for adjournment under Section 86. Section 86 requires the patentee to demonstrate that the patentee has taken with promptitude adequate reasonable steps to start working of the invention in the territory of India on a commercial scale and to an adequate extent. The appellant has got licence for importing and marketing the drug on 1.8.2007. The appellant had also got the licence from the Directorate General of Health Services to import and market the drug on 22.1.2008. The Controller had held that assuming that the actual permission to import and market the drug was given on 22.1.2008, the patentee's conduct of not importing the drug till 2008 and importing in small quantities in 2009 and 2010 is beyond explanation.

48. At this juncture, the learned senior counsel for the appellant submitted that it is not possible to comprehend how the Controller could have found fault with the appellant for not importing drug in 2008 and raised a question, if it was done, would it not mean that the appellant could smuggle it violating the law. We are not taking into account what the appellant did or did not do before 22.1.2008. The fact remains that till the application was filed which was on 28.7.2011, the appellant had three years and a bit more and the import in small quantities in 2009

and 2010 was rightly not sufficient to show that the patentee had taken with promptitude adequate and reasonable steps to work the invention. The Controller had also taken into account the fact that CIPLA entered the market only in 2010 and had observed that the appellant had approximately two years to modify its pricing strategy to work the invention on a commercial scale to an adequate extent. The Controller was therefore justified in not granting an adjournment under Section 86.

49. In any event, Section 86 gives the Controller the discretion to decide whether to grant adjournment or not. We are sitting in appeal over the order and unless the discretion is exercised perversely, arbitrarily and in a manner totally opposed to logic, we cannot interfere with it. Even if another view is possible, so long as the view taken by the original authority is a reasonable one, we will not interfere. The request for adjournment can be made only if the appellant wanted more time to work the invention. We asked the learned senior counsel whether that was not a tacit admission that the appellant had not worked the invention. He submitted that according to him, the appellant had worked the invention and even in the notice of opposition, the request was made without prejudice.

50. Next, we come to the question whether the patented invention has been worked in the territory of India. According to the appellant, attempting to construe local working in the sense of local manufacturing would be beyond the scope of the Patents Act. According to the learned senior counsel, the intent of the legislature was clear from the fact that the phrase, "manufacture in India" was deleted from erstwhile Section 90 of the Patents Act in the year 2002 which is now Section 84(7) of the Patents Act thus, negating the requirement of local manufacture in order to make it consistent with Article 27(1) of TRIPS Agreement. According to him, the quantity required in India does not economically justify the setting up a manufacturing faculty in India and that due to the low volume of sales, the drug may be manufactured on contract manufacturing basis through other manufacturers who are experts in manufacturing the drug. According to the respondent, however, the word 'working' should be read in the context of principles stipulated in Section 83(a) & (b) of the Act and with reference to the debates in the Lok Sabha and in the Ayyangar Report, paragraph-30, this question is considered and it states that "the imported product might be cheaper, but even if the cost of the article manufactured in the country might be considerably higher, it might in the long run prove an advantage to the national economy and it finally says that the costs to an under-developed country where a patent is worked wholly abroad far exceed any possible gains in any such exchange." The Report also quotes from Floyd L Vaughan who says speaking of the position of patents in America that it would be "contravention of patents law and economic injustice to the American manufacturer to allow a foreigner to take out a patent in this country merely for the purpose of reserving United States as a market for his patented product which is manufactured abroad exclusively." This report, of course, is prior to TRIPS Agreement, but it is still amazingly relevant. We must read the International Conventions and our own law harmoniously. In this regard, the Controller, while referring to Paris Convention, Article 5A(1), observed that when the convention provides that importation of patented articles by the patentee shall not entail forfeiture of the patent and that would seem to suggest that importation could entail something less than forfeiture, such as compulsory licence. He has also noted that the term "working" has not been defined in the Paris Convention and it has been left to the legislatures of the Member countries to construe the same in the manner conducive to their socio-economic requirements.

51. The Act as it stands today uses both the words "working" and "import" in various sections at the same time and not synonymously, notwithstanding the deletion of 'manufacture in India' from

Section 84(7)(e) which originally read as 'if by reason of default of the patentee to manufacture in India' and from Section 84(7)(a)(ii) which had the words, 'manufacture in India'. Section 83(b) says that the patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented articles. Section 83(c) refers to transfer and dissemination of technological knowledge. Section 84(7)(a)(iv) refers to establishment or development of commercial activities in India being prejudiced. Section 84(7)(e) speaks of working of invention being prevented or hindered by the importation. Section 84(7)(e) which refers to the working of invention in the territory of India and importation from abroad of the patented articles, clearly indicates different activities. In a given case there may be an invention which cannot be manufactured in India and it is also possible that there is an invention where the reasonable requirement of public itself is small in number and setting up a factory just for the said purpose is not practicable.

52. As we have already seen, TRIPS says that the authorization and other uses must be dealt with on a case to case basis. Therefore, we cannot decide that "the working" totally excludes import, or that "working" is synonymous to "import" and that if there is no manufacture in India, then there is no working. The repeated use of the words, 'in the territory of India' does indicate local working, but as the Controller has observed, the word 'working' has not been defined. The prohibition of discrimination in the grant of patent under the International Conventions which bar forfeiture of patent for not manufacturing locally will not come in the way of the Controller granting a compulsory licence. The Controller has rightly held that it is the ultimate step of revocation of patent which is barred. In the present case, the patent had been granted and no discrimination has been made on the ground of absence of local manufacture. The 3rd respondent had submitted that the appellant has a manufacturing facility in India and therefore, it could have manufactured the invention in India. According to the appellant, it was not economically feasible to set up a facility in India for manufacture the drug. We have earlier extracted the statement of appellant which is to the effect that it could have got it manufactured through others. In any event, we are not furnished with any evidence regarding this aspect viz., whether the appellant in its facility in India, which admittedly the appellant does not deny, could not have manufactured this drug. So, with regard to Section 84(1)(c), we find that the word 'worked' must be decided on a case to case basis and it may be proved in a given case, that 'working' can be done only by way of import, but that cannot apply to all other cases. The patentee must show why it could not be locally manufactured. A mere statement to that effect is not sufficient there must be evidence.

Therefore, while we are of the opinion that the word 'worked' has a flexible meaning, and to that extent we differ from The Controller. The appellant has not proved working and so his conclusion is right. Working cannot mean that the requirement of working would be satisfied by having import monopoly for all patented inventions. We also look at Section 84(7)(iii) which says that the reasonable requirements of public shall be deemed not to have been satisfied if a market for export of the patented article manufactured in India is not being supplied or developed. Therefore, 'working' could mean local manufacture entirely and 'working' in some cases could mean only importation. It would depend on the facts and evidence of each case.

53. The appellant therefore fails the test of S84(1).

54. According to the appellant, the terms and conditions were fixed in an arbitrary manner and it is a clear violation of mandatory requirements of Section 90. The Controller on the basis of the materials before him was of the opinion that Rs.8,000 was a reasonably affordable price. There is no evidence to the contrary. Now we come to the royalty issue It is submitted that the 2nd respondent had not factored in the cost that the appellant incurred which should have been under Section 90.

According to the appellant, the Controller should have added a fixed amount based on sale of each pack by the third respondent. It is also submitted that as per the bifurcation of cost of the product given by the 3rd respondent, the retailers and stockists get more than what the inventor gets which cannot be the intent of the legislature. Section 90(1) speaks of royalty and other remunerations. Under Section 90(2), while dealing with the terms and conditions of licence, the Controller must endeavour to make available the articles to the public and at the same time, this fixing of price should be made in consistent with the patentee's deriving a reasonable advantage from its patented right. The Controller has given his reasons for fixing 6% royalty and we find from the written submissions given by the 3rd respondent that UNDP specifically recommends that the rate of royalty be set at 4% and adjusted upwards as much as 2% for products of particular therapeutic value or reduced as much as 2% when the development of the product has been partly supported with public funds. The Controller has referred to this while fixing the royalty at 6%. According to the 3rd respondent, by any calculation, the fixing of 6% royalty is on the higher side. While we do not have any other document apart from the recommendations of UNDP, the grievance of the appellant is that the distributors and stockists are getting a margin of 30% while the appellant gets 6%. The appellant has a genuine reason for revision of royalty. We find that on the calculation given by the appellant, it appears that the 3rd respondent gets roughly 14% which is the margin. The Controller General directed the royalty shall be paid on the net sales of the drug and not from the margin and we think it right. In view of the all the materials viz., pleadings and evidence before us, we are of the opinion that an increase of one percent to the royalty fixed by the Controller would meet the ends of justice. Therefore, paragraph 15(f) of the impugned order alone is modified. In other respects we do not see any error.

55. Paragraph 15(h) requires the licensees to supply the drug to atleast 600 needy and deserving patients per year free of cost and that a report shall be submitted on or before 31st June every year. When the arguments were heard, we said that when this statement is filed before the Controller, a copy of the same must also be sent to us. In the affidavit filed along with such statement, the 3rd respondent stated that it had distributed the drug to 313 patients free of cost as against their calculation of 450 patients. According to the 3rd respondent, since the order was issued on March 12, 2012 to distribute the drug to 600 patients every year, if the number of patients are calculated on pro-rata basis, it would be 450 patients. The 3rd respondent has given the names of patients, name of the doctor, place where the patients were enrolled and the drug supplied. In paragraph 3 of the affidavit, it was stated that the deficiency in the number of patients would be met up by March, 2013. This is also referred to by the appellant who states that on the ground of non-compliance of the direction of the Controller General, the compulsory licence must be revoked and the appeal must be allowed. If permitted in law, the appellant is free to approach the Controller for appropriate relief. We are merely considering the legality of the impugned order.

56. Next, we come to suppression and wrong statement. The suppression is with regard to CIPLA's presence in the market and the false statement is the statement made that the applicant has applied and obtained patent for process of producing Sorafenib Tosylate, a copy of which is annexed as Annexure-M. Three factors are referred to by the appellant; (i) filing of counter claim in the civil suit; (ii) presence of CIPLA; and (iii) process patent which was alleged to have been granted but it was in fact pending. This issue is a difficult one. As regards filing of counter claim, the case of the 3rd respondent as to why it did not refer in its application is that a copy of the counter claim and documents were submitted to the Controller of Patents under a separate cover and

as regards the presence of CIPLA, according to the 3rd respondent, it was not a material fact and in any event, when the impugned order was passed, the issue of CIPLA's presence was before the Controller. As regards process patent application which is referred to as Annexure-M, it is stated that the 3rd respondent has applied and obtained patent for process and Annexure-M clearly shows that patent for process was not obtained. The best that the 3rd respondent can state here is that it did not intend to deceive, otherwise it would not have enclosed a copy of the same. We repeat, these proceedings are neither against the inventor, nor against the compulsory licence applicant, but purely based on public interest. On that reason alone we will not allow the appeal, however, we express our disapproval of the compulsory licence applicant's conduct. A party approaching a judicial forum should place on record all the facts that are known to it and it is for the judicial authority or quasi-judicial authority to decide whether it is material or not material. If the party is going to decide whether it is material or not material, there is no necessity for the applicant to approach the Controller. It is only because of the public interest we are not interfering in this appeal on this ground. The Controller order indicates that he has come to the conclusion on the basis of how he has understood the various provisions. There is no mention of this, but that does not mean that the party is absolved of the duty of truth. Mr.M.Adinarayana, who is the Company Secretary & G.M. (Legal & Corporate Affairs) of the 3rd respondent is present before us throughout the day as we dictated the order. When we found that we cannot condone the false statement and must impose costs, we required an undertaking from the 3rd respondent. Mr.Adinarayana submitted that any reasonable costs would be paid by the 3rd respondent. This statement is recorded. We also asked the counsel for the appellant present before us if the Patient Assistance Programmes of the appellant are administered by a trust so that we can direct the costs directly to be paid to the said trust. It appears that it is an internal arrangement. We therefore direct the 3rd respondent to make out a cheque for Rs.50,000/- to TATA Memorial Cancer Hospital at Parel, Mumbai (this institution has been suggested by the appellant) and it shall be handed over to the appellant with a letter stating that this is paid as per our direction and the appellant shall thereafter forward the same to the said institution. It is made clear that the above amount shall be used by TATA Memorial Cancer Hospital for poor patients. We want to impress upon the litigants as well as legal fraternity to adhere to the practice of making correct statement in the pleadings and affidavits filed before us and hence, this direction.

57. In view of the significance of the order of compulsory licence made in India for the first time, we have dealt with each of the issues in detail, though we have broadly confirmed the impugned order. In the result, for the reasons stated above, the grant of compulsory licence is confirmed and the impugned order is modified only to the extent of rate of royalty to be paid to the patentee as indicated above and in other respects, the appeal is dismissed. No costs.

(**D.P.S.PARMAR**)
Tech.Member (Patents)

(**Justice PRABHA SRIDEVAN**)
Chairman