INTELLECTUAL PROPERTY APPELLATE BOARD, CHENNAI

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

Friday, the 14th day of September, 2012

M.P.Nos.74 to 76 of 2012 & 108 of 2012 in OA/35/2012/PT/MUM

Hon'ble Smt. Justice PRABHA SRIDEVAN -- CHAIRMAN

Hon'ble Shri D.P.S.Parmar -- Technical Member (Patents)

Bayer Corporation,
100 Bayer Road, Pittsburg,
PA 15205-9741, U.S.A.
…. Appellant/applicant in
MPNos.74to76/12 &
MP108/12

Represented by: Shri P.S.Raman & Shri Sudhir Chandra Agarwal Senior counsel for M/s.Perfexio Legal with Shri Sanjay Kumar, Ms. Arpitha Sawhney

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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 1to3/respondent 1to3 in MP Nos.74to76/12 & MP108/12.

Represented by: Shri C.V.Ramachandramurthy --- CGSC for R1 & R2

Ms.H.Rajeswari for M/s.Rajeswari & Associates --- for R3

ORDER (No. 223 of 2012)

Hon'ble Smt. Justice Prabha Sridevan, Chairman

The impugned order was passed within the jurisdiction of Mumbai, but on request and by consent, the matter was heard at Chennai.

2. Very few orders have set off as many waves of interest all around the pharmaceutical world and the IP world as the order impugned herein. The Controller General accepted the grounds raised by the 3rd respondent for grant of compulsory licence for the appellant's patented invention. The appellant alleges

however that it is an illegal and unsustainable order, and has pressed for stay pending appeal on the ground that, a prima facie case had been made out, the balance of convenience is in favour of stay, and public interest will not be jeopardised.

3. The patented invention is a product called Sorafenib Tosylate sold as Nexavar. It is a palliative medicine for hepato-cellular carcinoma and renal cell carcinoma. The disease affects a very small percentage of the population. The drug is administered only on the prescription and supervision of oncologists and the patients are at stage IV of the disease and the drug admittedly improves the quality of life in the last months of the afflicted ones. After a long process of research and the necessary expenditure, the appellant arrived at this invention, and obtained patent in other countries, before getting a patent in India in 2008. The appellant manufactures the drug outside India, and the sale of Nexavar in India is only by import. The price at which the drug was sold by the patentee when the application for Compulsory Licensing was filed was, at Rs 2,80,000/- per month. The dosage is four tablets per day. CIPLA, who is not a party before us, is in the market, selling the same drug as Soranib, at Rs.30,000/- a month at the time of this application, and now at Rs.5400/-. The suit filed by the appellant against CIPLA for infringement before the Delhi High Court is pending. No injunction has been granted, the parties having agreed to get on with the trial. CIPLA therefore continues to sell the product till date. The relevance of CIPLA's presence is raised as an important issue in this case. CIPLA has sought for revocation of the patent. The 3rd respondent herein, NATCO is also sued by the appellant, and in turn NATCO has also applied for revocation. CIPLA and NATCO are both generic drug manufacturers in India with a large market presence. These are the bare bones of the case. Since we are dealing only with the interlocutory application, we are avoiding the flesh and trimmings.

4. Both Mr. P.S.Raman and Mr. Sudhir Chandra Agarwal ,senior counsel argued for Bayer, Ms.Rajeswari argued for NATCO and Mr. C.V.Ramachandramurthy appeared for the respondents 1&2.

5. On the side of the appellant, it was submitted that pending the appeal, the status quo ante must be preserved, other-wise the purpose of filing the appeal would be lost. So, stay should be granted. If the drug is made available in the market at reasonably affordable price and not necessarily by the patentee, then S.84(1)(b) of the Patents Act will not arise; similarly if public requirement is met even by someone other than the patentee, then S.84(1)(a) will not arise. It was because CIPLA was selling the drug at a very low price that the appellant could not work the invention. CIPLA did not have the cost burden that the appellant had to bear, so it could sell at any price. In these circumstances, S.84 (1) (c) will not arise either. According to the appellant, the appellant's drug is available in 334 Medical institutions in 102 hospitals. The Controller ought to have granted adjournment as provided in S. 86(1) to give time to the appellant to work the invention. The refusal to grant the adjournment contrary to law is a good reason for grant of stay. It was submitted that the word "work" in S.84(1)(c) includes import and not necessarily local manufacture as is evidenced by Form 25 and the appellant has provided enough evidence of "working." Even import of small quantity and a de minimis proof of working will suffice. The appellant could not have started working at once, they had to get the approval of the authorities, break the market resistance and win the confidence of the oncologists. The Controller General erred in not fixing the price taking into account the indices mentioned in S.90 e.g.; the royalty and other remuneration, the expenditure incurred by the patentee etc. According to the appellant, the expenditure incurred is in the range of 1 billion Euros and it is not possible to

break down the different components that make up the same. In pharmaceutical industry it is impossible to allocate the different components, because of the nature of the industry. The senior counsel referred to the paper book to show how the research process progresses culminating in the invention. According to the appellant, the Controller-General could have fixed the reasonable price on the base price at which Bayer had pegged it, both in the context of S.84, and S.90. The three grounds in S.84 are not water-tight, there is intrinsic evidence that they are over-lapping. It was incumbent upon the Controller General to have worked out a reasonably affordable price and since he has not done that the order is ex facie illegal. The Controller–General ought to have considered the nature of the drug, the manner of administering the drug, the demand for it, etc. Even in S.92 (1) (ii) the statute envisages "the patentee deriving a reasonable advantage from their patent rights." The Controller-General has not understood the implication of Compulsory Licence. CIPLA's sale is legal sale and the Controller-General erred in not taking CIPLA's sale into account. Ground-reality should have weighed with the Controller and not hyper-technicality while granting the compulsory license. If the drug is available at Rs.5,400/- albeit from CIPLA, why should a compulsory license be granted to NATCO? So the balance of convenience is in favour of grant of stay. In any event, NATCO is being under-cut by CIPLA. As regards S.84 (1) (c) the word "manufacture' which was there in the (old) S.90 (a) (ii) is now omitted. Art.27 of TRIPS makes it clear that patent rights are to be enjoyed "whether products are imported or locally produced." When there is a conscious "deletion" of the word "manufacture" it has to be taken note of. Reasonably affordable price cannot be fixed ignoring the cost burden of Bayer. There is no justification for fixing Rs.8000, which itself is beyond the reach of 99% of our population. Further Bayer has A PAP and on the recommendation of the oncologist the patient after paying for the 1st dose gets the subsequent doses free of cost. S.84 (7) (e) is an antidumping provision, S.84 (1) (c) has not been correctly construed by the Controller-General. The applicant ought to have applied to the patentee for grant of license; it is only when the patentee was unwilling to grant the same the application for compulsory license can be made. But the request of NATCO was a perfunctory notice, more like a threat. In response the appellant had replied on a negotiating note, the door was not closed and yet NATCO did not avail of it. It is a discretionary relief, and so it should not be granted when CIPLA's sale fulfils public need. It is NATCO which is getting a bonanza from this order. The public interest, public requirement and supply at reasonably affordable price have all been met by CIPLA, so there was no justification for this order. It is only the patentee who is injured and put to loss and that cannot be the intent and purpose of the law. The order must be stayed.

6. The appellant also filed another M.P.No.108 of 2012 to show that the licensee has committed breach by violating the terms and conditions of the order. NATCO had sold the drug in Pakistan and China. This was another reason why BAYER pressed for stay.

7. The learned Counsel for NATCO took a preliminary objection to the latter M.P.No.108 of 2012. She submitted that in regard to that the appellant had filed an application for termination of the compulsory license before the Controller. Any observation by us will affect the decision making process of the Controller. Without prejudice to this, it was submitted that an enquiry was initiated in this regard and that NATCO had informed its distributors that export was not permitted. The documents do not show that the sales were by NATCO. There is no evidence of any direct sales by NATCO.

8. Coming to the issue of stay, it was submitted that, in this case grant of stay would amount to disposal of the main matter and therefore the interests of justice required that the final hearing may be expedited instead of granting an interlocutory relief especially since public interest is involved. There was no glaring perversity, the termination proceedings before the Controller will be prejudiced if stay is granted.

9. On merits, it was submitted that, nowhere in Chapter XVI the word 'compensation' is used so the expenditure incurred by the appellant is not the criterion, nor does this Chapter intends that the patentee be enabled to recoup the amount spent. Royalty is a factor and in cases where "licence of right" is granted the royalty is not more than 4%, and therefore the terms imposed by this order are justified. It was submitted that the theme running through this chapter is public interest and it is not intended to give the patentee a hunting-licence to hold tightly a monopoly over the drug without supplying the public. That is not the object of the patent. She referred to S.146 which imposes a duty on the patentee to periodically furnish information regarding the extent to which the invention has been commercially worked in India, and the penal consequences of default are spelt out in S.122, which makes it clear that the duty is mandatory. It was submitted that the law gives the patentee a breather to make sure he satisfies the requirements of S.84 (1); the compulsory applicant cannot apply until after the expiration of three years from the date of grant of the patent. The learned counsel referred to the reports filed based on Indian patients recording their profile e.g. they are generally not young, they are dependents, they come from lower income families, and the disease is in an advanced stage. This chapter casts an obligation on the patentee alone to fulfil the conditions regarding, working in India, satisfying public requirements, and making available the invention at a reasonably affordable price. The patentee cannot rest on CIPLA to evade the consequences. The tabular column provided by them makes it clear that there is no adequate supply; the number of patients served by the appellant is very small. Even if the appellant supplies in full, the requirement of section 84 is that the supply should address the public need, if it does not, it fails the S.84 test. If the submission that S.84 tests can be fulfilled by anyone, not necessarily the patentee is accepted then S.82 is meaningless. She read out the definition of "patented article" and "patentee" in S.2 (the definition Section) and in S.82. It was submitted that S.84 must be seen through the prism of S.83. The argument that CIPLA meets the requirement of the public at a reasonably affordable price is a tacit admission of the appellant's default. If Bayer wanted CIPLA's presence to be factored in while considering the public interest angle, then it should have included the sales of CIPLA in Form 27 for "working". The patentee should meet more than 50% of the public need to satisfy S.84 (a). The words "reasonably affordable" are used only in our legislation and they should be properly understood. CIPLA's presence is subject to litigation and there is no assurance that it will continue to supply at the present price or the present rate, no condition binds it like the conditions imposed in the impugned order upon NATCO. Therefore CIPLA's presence is not a reason to grant stay. It was submitted that the words "reasonably affordable" should be understood leaning towards the ordinary man to whom Rs.2.84,000 is clearly not affordable. The learned counsel referred to documents to show that even a country like UK had found the price of Nexavar too high. It was submitted that the PAP is not the criterion for testing whether the S.84 test, but the price at which the patented invention is available in the market. It was also submitted that nowhere in the Act does differential price find a mention. The argument that Bayer's expenditure must be taken into reckoning , cannot be accepted, since this Chapter is concerned only with public health/interest and the safeguards of the patentee's interest is only in S.92(1). It is to be noted that

while S.102 uses the word 'compensation' it is not found in this Chapter. It was also submitted that the drug in question was treated as an Orphan Drug, and the appellant must make available the development cost to acquire the status, and hence the submission that the cost component for this drug cannot be segregated is not acceptable. It was submitted that "other relevant facts" in S. 90 would include tax benefits. The expenses claimed also included expenses not attributable to Sorafenib, and also post-patent expenses so that cannot be relied on. The "reasonably affordable" price is fixed by testing it against the affordability of the invention by the public. It was submitted that the words "not worked" in S.84 (1) (c) takes its colour from S.83 (a). She read out extracts from the Parliamentary debate and submitted that though the word "worked" included imports as well, the Act leaned towards local manufacture. If 'worked' meant imports the patentee must show it had imported to satisfy the test of "working on a commercial scale", or to meet the demand adequately. It was submitted that this was an appeal and unless the refusal to grant an adjournment was totally perverse it cannot be a ground for interference. Further that provision can be invoked only if non-working was the only ground for seeking a compulsory license. It was submitted that the Act does not say that the request for voluntary license must be made in a particular manner. It was submitted that the law does not require the Controller to fix the price. In any event, the public interest is the only criterion and it will suffer if stay is granted.

10. The Counsel for Union of India submitted that there was no violation of principles of natural justice, nor violation of law. The impugned order was passed in accordance with law and therefore must not be stayed. In other aspects he adopted the arguments of the 3rd respondent's counsel.

11. In Reply, both the Senior Counsel submitted that if stay is granted only NATCO's interest will suffer and the law is only concerned with public interest which will not suffer since CIPLA is there which is a legitimate presence. The various grounds for granting compulsory license cannot be dealt with separately since they overlap. The law requires the patentee only to work the invention in India, the words "fullest advantage" are not used in S.84 (1), and that the public requirement has been met. The order must be stayed.

12. The documents that were placed for consideration:-

1) Bayer's undertaking to sell the drug at an average price of Rs.30,000/-per month.

2) The affidavit giving a list of cities and hospitals covered by Bayer to ensure accessibility.

3) The letter from NATCO asking for voluntary license and BAYER's reply.

4) An article on palliative treatment in advanced HCC.

5) An article on characteristics of HCC.

6) Affidavit relating to internal assessment of RCC/HCC statistics.

7) Form 27 filed by BAYER.

8) "Policy Options for Improving Medicine Availability and Affordability" an article which shows that though increasingly countries are putting in place health insurance systems, only a small minority of people in low and middle income countries are covered by such schemes.

9) Affidavit of Harold Dinter stating that Bayer's price falls within the reasonable corners of being affordable price.

10) The presentation of Dr. Jorg Thomaier regarding method of calculating spending, how cost burden should be shared and the duty of stakeholders.

11) The article on "Regulatory framework for the treatment of orphan diseases" and the Orphan drug legislations in other countries to show that the tax benefits of the patentee must be taken into account.

12) The affidavit of James Love that Bayer has declined to give evidence regarding its outlays, and how much money Bayer and Onyx (with whom Bayer had a drug development agreement), that there is no publicly available information regarding its tax credit, the number of clinical trials sponsored by Bayer alone, and that the income generated from sales of Nexavar was equal to all joint outlays from 1994 to 2004, and finally how to calculate the percentage of royalty.

13) The Parliamentary debates regarding the words "reasonably affordable"

13. The Controller-General, ordered the compulsory license by a detailed order. He held that:-

- The reasonable requirement of the public in India was not met, though Bayer had made thumping sales elsewhere and that if the drug is so highly priced to be out of reach to the ordinary public, then it is not available to the public on reasonable terms. He held that Patentee cannot take shelter under CIPLA's supply and that it is what the Bayer has made available to the public that is relevant. So the supply of the drug to a little above 2% of the eligible patients will not meet the S.84 (1) test. The Controller had calculated that Bayer would have supplied 200 patients in 2011 as against an eligible 8842.

- The Controller General held that the reasonably affordable price will have to be construed with reference to the public and the price of Rs 2,80,000 per month for one person is out of reach to the common man which is why the drug was not bought by them, and so it fails the S.84(1)(b) test.

- The Controller General held on a consideration of the history of the TRIPS negotiations and agreement and held that, "worked in the territory" means "manufactured to a reasonable extent in India" and since even after the lapse of four years , the Patentee failed to do so and also to grant voluntary license to anyone S.84(1)(c) was attracted.

- The Controller General was not satisfied that Bayer had taken steps with promptitude to work the invention on a commercial scale to an adequate extent, and refused to invoke S.86 to grant adjournment.

- He did not agree to consider Bayer's offer to sell the drug at Rs30, 000/- which was given pending application since the law did not require him to take into account matters subsequent to the making of the application.

- He then proceeded to grant the compulsory license subject to the terms and conditions set out in the impugned order.

14. We are concerned only with the stay petition. However the counsel on both sides advanced their arguments as if they were arguing the appeal itself. We therefore have to deal with them but it is only on a prima facie consideration.

Bayer's product is called Nexavar.

Cipla's product is called Soranib.

Natco's product is called Sorafenat

We need to understand the background of the law. Compulsory Licensing is a tool for balancing the individual monopoly property rights and the public's access to the benefit of the invention. So the entire Chapter must be understood with this insight. In the article "Recent Federal Supreme Court decisions on Experimental Use and Compulsory Licensing (CASRIP Newsletter - Summer 1996, Volume 3) Michael Kern writes, "One should not forget that patents represent an interventionist instrument, ultimately for the sake of community welfare." Art.8 (1) of the TRIPS agreement allows the members to take steps for protection of public health and nutrition, and promotion of public interest vitally important to their socio-economic and technological development. While honouring their international obligations the Member countries can ensure that their national interests are not imperilled. So, public interest which includes public health, public welfare etc is a check on the proprietorial rights of the IP owners.

15. The Act originally gave to the patentee the exclusive right to make, use, sell, etc. the invention in India. [S.48 (old)]. So no one else could claim to be the owner of the IP right. Now, that section has been tweaked. The present S.48 gives the patentee the exclusive right to prevent another from making, using, selling etc that product where it is a product patent, or making, using, selling etc the product made from the process where it is a process patent. This change is stressed by the appellant to buttress their submission that, therefore the product marketed by CIPLA is legal, and must be taken into reckoning for looking at the public interest angle.

"Working" of the invention.

16. It was submitted that the word "working" or "worked" should not be restricted to local manufacture. S.82 defines the words "patented article", but in the crucial section in this Chapter viz., S.84 (1), those words are not used, but only the words "patented invention." But in S.83 and S.84 (7) those words are used.

17. The principles regarding the "working of patented inventions' are set out in S.83. They are:-

a) Patents are granted for the encouragement of inventions and ensuring that inventions are worked in India on a commercial scale as early as is reasonably practicable.

b) It is not a vehicle to give the patentee a monopoly in importing the patented article.

c) The protection of the patent rights must lead to better technological innovation, technology transfer and dissemination, users and producers should benefit by the technology. Importantly, the IP protection should promote social and economic welfare, and balance the rights and obligations.

d) The grant shall not be detrimental to public health; rather it should act as an instrument of promotion/protection of public health.

e) The grant shall not counter the Central Govt's health measures.

f) The IP right shall not be abused by the patentee or anyone claiming under him, nor can the patentee act in manner that undermines trade or international transfer of technology.

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

18. The respondent did not contest the position that "working" includes importing; only it was qualified that the Act leaned towards local manufacture. In *Glaverbel S.A. vs Dave Rose and others* (**2010 (43) PTC 630)** the Hon'ble Delhi High Court wondered "to what extent can import of goods be considered

actual commercial working of the inventions." It left open the question to be tested at the time of trial. In addition we have provisions like**, S.83(b)** which says that patents are not granted to facilitate the patentee's monopoly on imports, **S.84(7)(d)** which speaks of working in the territory of India on a commercial scale to an adequate extent, **S.84(7)(e)** which says that the reasonable requirement of the public will be deemed not to have been satisfied , if the working of the invention in India is prevented or hindered by import of the patented article, by the three categories of persons mentioned in the section, **S.86(2)**which refers to adequate or reasonable steps to start the working of the invention in the territory of India and so on. For the purpose of deciding the stay petition, we are accepting that the appellant's imports amount to "working", but at the time of final hearing we may need to examine the meaning of "working" in greater depth.

Non grant of adjournment under S.86.

19. The Controller's power to grant adjournment is given under Section 86. This power is exercised to enable the invention to be worked to an adequate extent or to the fullest extent that is reasonably practicable. The Controller was of the opinion that the three years' time given under the Act during which no application for compulsory licence can be filed had not been availed of by the Bayer to start working the invention. The correctness of this may be relevant at the time of the final hearing, but not a ground for grant of stay. This is so especially, since the main weapon in Bayer's armour is that CIPLA is adequately supplying the drug to the public at a reasonably affordable price and there is no question of public interest being jeopardised warranting the grant of compulsory licence, this refusal to adjourn the matter cannot be a reason for grant of stay.

NATCO did not seriously request Bayer to grant license.

20. The next ground is that the request for voluntary license by the NATCO was perfunctory and when the appellant left the door open for negotiation NATCO did not avail of it and instead straight away applied to the Controller. The Act does not indicate how long the compulsory license applicant must "woo' the patentee to get the license, it only states that Controller shall take into account whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and whether the efforts have failed within a reasonable period as "the Controller may deem fit". The applicant asked, the patentee replied that it was fully compliant with the fundamental objectives of patent law and therefore it does not consider it appropriate to grant license to the applicant. Clearly "*Barkis was not willin' "* . Whether this request by NATCO met the statutory requirement is an issue we will decide at the time of final hearing, this objection is not sufficient for grant of stay.

Public Interest/Public requirement/Affordability.

21. Finally, it narrows down only to "public interest/public requirement/access to the people", which can be said to be the leitmotif of this Chapter. So we must examine this angle and whether the appellant has made out a prima-facie case .The Senior Counsel for the appellant reiterated that the three grounds in S.84 cannot be put in water-tight compartments, they intermingle. This is correct, for if the invention is not worked at all, then obviously, the public requirement will not be satisfied, if the price is not reasonably affordable the public requirement will not be satisfied; on the other hand, if the public requirement is satisfied or the price is reasonably affordable to the public then, obviously the patentee has worked the invention.

Public interest and affordability cannot be separated.

22. The words "reasonably affordable" can only be understood in the context of the purchasing power of the public. The need for the drug is unconnected to the price of the drug, but the net of purchasers becomes wide or narrow depending on the price, and this net of purchasers is an index of the purchasing power or the affordability. The question is not whether Bayer can afford to sell it at price X, the question is can the public reasonably afford to buy the medicine at price X. The words used are "available to the public at a reasonably affordable price" This is reiterated in Ss.83 (g), 84(1) (b), 84(2) 85, 90. And while in S.92 which deals with compulsory notification in situations of national emergency or urgency, the price will be fixed at the lowest rate consistent with the *patentee deriving a reasonable advantage* from his rights, in contrast, in S.90 which applies here, the terms are settled so that the royalty is fixed having regard to nature of invention, patentee's expenditure etc, and so that the compulsory licensee gets *a reasonable profit*. So the expenditure incurred by the patentee is relevant only to fix the percentage of royalty. The words, "reasonably affordable" must be only seen from the eyes of those who need Nexavar. The learned Senior Counsel for the appellant said that even Rs 8000/- per month will be out of reach to many Indians in view of the per capita income. True, but that cannot mean that the price shall be raised higher, for then it will go out of reach to more number of Indians. At Rs 8000 per month, more number of HCC/RCC stricken Indians will find it reasonably affordable, than if it is fixed at Rs 30,000 per month, and of course at Rs 2,80,000 it is beyond reach. So prima facie there is no error in the Controller fixing the price at Rs, 8880/- per month. According to the appellant Bayer, the Controller did not take note of their cost while fixing the price. The appellant on its own admission had taken the stand that it is impossible to give specific breakup of the cost of the medicine. The affidavit of Mr. Love has been referred to above. Of course, pending the application, BAYER had given an undertaking to sell the drug at 30,000/per month. The Controller had fixed it at Rs 8880/- per month. The question whether the Controller should have taken note of the post-litigation offer of Rs.30,000/- per month and the PAP programme and whether it is a subsequent event as contended by the respondent will be decided by us at the time of final hearing.

23. What are the kinds of inventions that will be the subject of compulsory licensing? Neither the Act nor the Chapter indicates that the patented invention in question relates only to pharmaceutical or allied inventions, but the history of the Patent regime and the language of the section indicate that the mechanism of compulsory licensing is mainly to balance patent rights with access to medicine. "Traditionally, nations have used two forms of mechanisms to balance the impact of patent monopoly as tools to make medication accessible to the population. Both the tools –compulsory licenses and price controls –are employed where public interest concerns outweigh patent- holder's rights." (Patent and Trade disparities in Developing Countries-Srividhya Raghavan). Further the words "social and economic welfare", or "public health' ,"nutrition", "national emergency" or "extreme urgency", "public health problems/crises" are all pointers towards the fact that this chapter and the powers of the Controller-General in this regard are centred around access to medicine.

24. A situation of emergency or urgency or crises is hardly likely to arise if an inventor sits tight on a new kind of mobile phones, or computers. Perhaps, an invention to create water out of nothing might! Crisis of public health are more likely to cause such situations. Another fact that has to be remembered is that, in the case of pharmaceutical inventions more than any other invention, the requirement will not fluctuate because of the non-affordability of the invention. Regardless of however steeply priced the invention is,

people will fall victim to RCC and HCC. The need/requirement is not dependent on the cost of the treatment. Disease like death is a great leveller. However, we are informed that HCC may hit the lower-income group more because it is they who consume inferior liquor more harmful to the liver, while the high income group who drink the sophisticated brands may be less vulnerable. The Act talks of reasonable affordability to the public, not affordability exclusively to the members of a special list. The applicant claims that the prognosis for both these types of cancer is poor and therefore, the need to enable access to this drug irrespective of where the patient comes from assumes importance.

25. The appellant has heavily relied on the CIPLA's presence to meet both the affordability test and the reasonable requirement test. Soranib (Cipla) is in the market. According to the appellant the **meeting of the demand need not necessarily be by the patentee or its licensees and it could even be by an infringer.** (Para 4 of the stay affidavit)If the demand is met by even an infringer the requirements of S.84 (a) shall be taken to have been met. According to the appellant the standard of reasonable affordability must be fixed by bearing in mind the over-all R&D cost balancing the interest of the consumer without compromising the interest of the innovator.(para7-12).

26. The appellant itself concedes that it is because of the presence of CIPLA that the public requirement is met. In fact, in the impugned order, the learned Controller General has extracted the table of sale by CIPLA and the appellant during the year 2011. The number of boxes supplied by CIPLA in all four quarters put together is 4686 as compared to the appellant who has supplied only 593 boxes. The total number of patients suffering from HCC as per the data gathered from GLOBOCAN is 20000. The demand for 80% of the patients is 16000. The bottles required per month are 16000 approximately. As per the working statement (Form 27) filed by the appellant, in 2008 there was no import; in 2009, 200 bottles were imported and no data was given for 2010. As far as RCC is concerned, the total number of patients are 8900, 80% of the number is 7120 and the bottles required would be the same. But, no data is available with regard to the supply made by the patentee to the patients suffering from RCC. This is seen from the impugned order in para-10A. This is not disputed by the appellant. In fact, one of the submissions made by the learned senior counsel for the appellant is that, as per section 84(1)(c) it is enough if the appellant shows that the patented intention is worked in India. Learned senior counsel contrasted themselves with the language in section 86(1) and section 84(7)(e) where the words used ore "working of the patented invention…… on a commercial scale'" and that section 86 further uses the words, 'to an adequate extent or ……. to the fullest extent' and when the language of section 84(1)(c) is viewed from this angle, it is clear that it is enough if the patentee shows that it has worked the invention in the territory of India. Therefore, according to the appellant, even the import of 200 bottles would meet the test of section 84(1)(c) of the Act.

27. It is further the case of the appellant that the appellant was not able to work the invention in the territory of India because, CIPLA was there flooding the market with its product. The appellant's case is that it obtained its patent in 2008 and before it could start the sale of the product by obtaining necessary permission, licence and whatever else that is required to import the drug, CIPLA had come with its generic product. So, in a nutshell, CIPLA prevented the appellant working the invention in India without delay. We are unable to understand whether, according to the appellant, CIPLA rides with them or CIPLA is its rival, whether CIPLA is a friend or foe. When the grounds of section 84(1)(a) and 84(1)(b) are raised, the appellant wants us to take into the reckoning CIPLA's presence. CIPLA is satisfying the reasonable

requirement of the public and therefore, the Board should not look at the ground under sub-section (1)(a) and CIPLA's product is available to the public at a reasonably affordable price and so, the Board should not look at the ground under sub-section (1)(b). Therefore, for these two grounds of attack, the appellant takes the presence of CIPLA along with it, but for the ground of attack under section 84(1)(c), the appellant takes a stand that CIPLA is its enemy which prevented the appellant from entering the market. We cannot accept this mutually inconsistent stand.

28. CIPLA's presence in the first place may loosely be called a "litigious" presence. If injunction had been granted by the Hon'ble Delhi High Court, CIPLA will not be in the market. Though the appellant is fighting CIPLA tooth and nail before the Hon'ble Delhi High Court, it took great pains to urge before us that CIPLA's presence was a legal presence. The presence of CIPLA is subject to the outcome of the suit where the appellant alleges that CIPLA is infringing its invention. It is true that the Hon'ble Delhi High Court refused to grant injunction, but the issue of infringement by CIPLA will be decided at the end of trial. Further, CIPLA is not bound by any condition that is prescribed for the 3rd respondent NATCO by the Controller general under section 90. Tomorrow, CIPLA may withdraw its product, Soranib for commercial reasons of its own. The Controller General who has weighed the public interest in his mind rightly refused to reckon CIPLA's presence in arriving at his decision. It is for the appellant/patentee to show that it has fulfilled the obligation under the grant of patent and therefore, its right should be protected.

29. The powers of the Controller conferred by this Chapter must be viewed with the lens of section 83. Almost every sub-section in section 83 begins with the words, 'patents are granted' which means that it should be viewed only from patentee's angle. Section 83(a) indicates that the patentee must work the invention in India on a commercial scale to the fullest extent as is reasonable and practicable and without delay. Section 83(b) shows that patent is not granted to enable the inventor to enjoy monopoly for importation which means that after importing invention, the patentee cannot say that it has done what is required on them and rest with that. The patentee has a duty to make it available to the public at a price which the public can reasonably afford and in the manner that public need is satisfied. Section 83(c) says that the patentee's rights must be enforced in a manner conducive to socio and economic welfare and that there shall be a balance of rights and obligations. The words, 'rights and obligations' show clearly that what the Act is talking about is the patentee's rights and the corresponding obligations. The patentee cannot be heard to say that its duty is discharged because, the person whom the patentee attacks as its infringer, is fulfilling what the patentee is bound to do. Section 83(d) says that the patentee must not impede the protection of public health and good nutrition. Section 83(e) says that the patentee cannot counter any Governmental measures to protect public health. Section 83(f) bars abuse of patented rights by patentee. Section 83(g) clearly says that the patents are granted to make the benefit of patented invention available at reasonable affordable price to the public. This leaves us in no doubt that it is the appellant who should make the benefit of the patented invention available at reasonably affordable price to the public and it cannot take shelter under the sale by CIPLA.

30. Therefore, when we look at section 84 of the Act, having regard to section 83, as we are directed by that section, it is clear that it is the duty of patentee to show that the patentee by its own supply has satisfied the reasonable requirement of the public and by its supply, the drug is made available at a

reasonably affordable price. The appellant cannot ride piggyback on CIPLA's sale, particularly when the appellant is fighting CIPLA before another forum regarding the same invention and the same drug.

31. Section 84(7) of the Act creates a legal fiction as to when the reasonable requirements of public shall be deemed not to be satisfied that is, the grounds under section 84(1)(a), and when we see section 84(7)(d), it reads as follows:

> "if the patented invention is not being worked in the territory of Indian on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable. "

Therefore, though section 84(1)(c) merely uses the words, 'not worked', the Act itself makes it clear that the grounds of section 84(1)(a) will arise if the working is not to the extent provided in section 84(7)(d).

32. We have already seen in the earlier paragraphs, how the words, 'reasonably affordable' must be understood. The term, 'reasonably affordable' is directly linked to the purchasing capacity of the public and therefore, while the cost burden of the appellant may have some relevance when the Controller General is fixing the percentage of royalty. What the Controller General is really guided by is that the patented article is made available to the public at reasonable affordable price. Learned senior counsel for the appellant at one juncture submitted that even Rs.8880/- may be out of reach for many patients. Then, selling the drug at Rs.2,80,000/- can by no stretch of imagination satisfy the reasonable requirement of the public, and as observed by us earlier on the basis of submissions made by both the counsel, HCC is more likely to hit the poor and lower income sections of population because of the consumption of inferior liquor which is more harmful to the health. If so, the sale of drug at Rs.2,80,000/- per month is definitely not intended to satisfy the requirements of the public. The learned Controller General noted that even after the lapse of three years, the appellant had imported and made available only an insignificant number of reasonable requirement. According to the appellant, had the matter been adjourned by one year, it could have worked its invention at a greater scale. But, we have already held that this is not a ground for stay. We have also held above that the offer of the appellant to modify it under PAP programme at the rate of Rs.30,000/- per month is an offer that was made subsequent to the application and will not be a ground for stay. In any event, when the Controller General came to the conclusion that the licensee should sell the drug at a price not exceeding Rs.8800/- for a pack of 120 tables, this offer cannot be a ground for stay. The submission made by the appellant that CIPLA is now selling the drug at Rs.5400/- per month and therefore, this order will actually enable the licensee to sell the drug at higher price is also not relevant, since we have already explained why CIPLA's presence and its operations are not relevant factors for deciding the grounds on which the compulsory licence claimed by the 3rd respondent should be decided.

33. A miscellaneous petition has been filed by the appellant in M.P.No.108 of 2012 alleging that the 3rd respondent contrary to the terms and conditions of the licence is exporting the drug to Pakistan and China. This is denied by the 3rd respondent. In any event, we are not going into the merits of this miscellaneous petition which has to be decided on the basis of evidence on both the sides in the termination application filed by the appellant before the Controller and any observation by us will hamper the discretionary power of the Controller. M.P.108 of 2012 is therefore closed.

34. The appellant has not made out a prima facie case for the grant of stay, since even its own admission is that it is CIPLA which is supplying the drug to satisfy the needs of the public. It is not the case

of the appellant that its supply is at a reasonably affordable price and satisfies the reasonable requirement of the public. As regards public interest, we have already concluded in the earlier paragraphs that CIPLA's presence is subject to litigation and CIPLA's supply cannot be taken note of. If stay is granted, it will definitely jeopardise the interest of the public who need the drug at the later stage of the disease, since it is admitted that this drug improves the quality of life. Therefore, the right of access to affordable medicine is as much a matter of right to dignity of the patients and to grant stay at this juncture would really affect them and further, it would in effect amount to deciding the main petition itself. Though this is not a reason why we are not granting stay, yet this is an additional factor. The licence is granted subject to certain conditions which the licensee is bound to comply with and the order does not deserve to be stayed.

35. For all these reasons, the interim stay prayed for is rejected and the stay petition in M.P.No.74 of 2012 stands dismissed. The documents filed along with M.P.No.76 of 2012 have been taken into consideration and hence, the said MP is ordered. Registry is directed to list the main matter, as early as possible after ascertaining the dates from both the parties. M.P.No.75 of 2012 filed to fix an early date is ordered and the main matter will soon be listed for hearing.

(D.P.S.PARMAR) (JUSTICE PRABHA SRIDEVAN)

Technical Member (Patents) Chairman