**BEFORE THE CONTROLLER OF PATENTS**
**MUMBAI**

**Present: Mr. P. H. Kurian**

Compulsory License Application No. 1 of 2011

**IN THE MATTER OF:**

NATCO PHARMA LIMITED: .....APPLICANT

Represented by: Ms. Rajeshwari H., Advocate & Patent Agent

AND

BAYER CORPORATION ..... PATENTEE/OPPONENT

Represented by: Sh. Sudhir Chandra Aggarwal, Senior Advocate.
Sh. Sanjay Kumar, Advocate & Patent Agent
Ms. Arpita Sawhney, Advocate
Sh. Rahul Kumar, Advocate

**APPLICATION FOR COMPULSORY LICENCE UNDER SECTION 84(1) OF THE PATENTS ACT, 1970 IN RESPECT OF PATENT NO.215758.**

1. **Overview**

The patent system is a carefully crafted bargain that rewards an inventor in lieu of his contribution towards the society. The inventor is granted an exclusive right for a limited period: a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using,

offering for sale, selling or importing for those purposes that product; and b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process. The benefit derived by the society, *inter alia*, in granting such a comprehensive right to the inventor for twenty years, is the enrichment of knowledge in public domain, which can be utilized to invent further. This cycle goes on and on to take the nation towards socio-economic prosperity. Without the presence of a Patent system, the inventor will not be encouraged to disclose his invention to public and may prefer to keep it as a trade secret, which may result in innovative sluggishness, thereby adversely affecting the prosperity of a nation.

From its very nature, a right cannot be absolute. Whenever conferred upon a patentee, the right also carries accompanying obligations towards the public at large. These rights and obligations, if religiously enjoyed and discharged, will balance out each other. A slight imbalance may fetch highly undesirable results. It is this fine balance of rights and obligations that is in question in this case.

2. **History of compulsory licenses**

When TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement was introduced in 1994, it reduced the discretionary powers of WTO Members to customize key elements of their national intellectual property regimes. In January 1995, when WTO came into existence, the TRIPS Agreement, building on the existing multilateral treaties administered by the World Intellectual Property Organization (WIPO), introduced minimum standards for

protecting and enforcing intellectual property rights to an extent previously unseen at the global level, including new monitoring and dispute settlement mechanisms. Article 27.1 of the TRIPS Agreement requires WTO Members to make patents "available for any inventions, whether products or processes, in all fields of technology", which includes patents for pharmaceutical processes and products. At the same time, TRIPS also provides a reasonable fetter on the rights of the Patentee in the form of Article 30 and 31, in line with Paris Convention, thereby allowing member countries to enact provisions, *inter alia*, for granting compulsory license to prevent the abuse of patent right.

Compulsory License (CL) under the Patents system is an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the State. The WTO states compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It has been in existence since the 1830s. CL has been reported to be popular in Britain as early as 1850s. Later, this system was recognized by the international community through the Paris Convention of 1883. It is also one of the flexibilities on patent protection included in the TRIPS Agreement.

Provisions for granting a compulsory license exists in the Patent Laws of various countries such as Canada, France, UK, USA, Australia (developed countries), and Zimbabwe, Ghana, Brazil, Equador, Malaysia, Thailand and India (developing countries). In fact, compulsory licenses are being issued by developed as well as developing countries even in recent times.

India joined TRIPS and the deadline for complying with TRIPS obligations was January 1, 2005. The Patents Act, 1970 was amended

thrice to make it fully TRIPS compliant i.e. in 1999, 2002 and finally in 2005. The Patents Act, 1970, as enacted originally, contained a provision for grant of a compulsory license, in case the aforementioned balance is disturbed. However, vide the Patents (Amendment) Act, 2002, the provisions relating to compulsory license, i.e. Chapter XVI of the Patents Act, 1970 was substituted with a completely new one. The Patents (Amendment) Act, 2005 allowed product patents to be granted for drugs, which was not allowed under the 1970 Act.

Present case is the first of its kind in the history of Patents Act, 1970, wherein the provisions of Section 84 have been invoked by the Applicant herein for seeking the grant of a compulsory license. As such, there is no precedent to guide this tribunal. Relevant persuasive material has been submitted by both parties. In order to appreciate all the issue involved in the present litigation, the hearings went on for three days for a total of eighteen hours. Reasonable research has also been conducted by this tribunal to study, *inter alia*, the provisions of the International Agreements and Conventions on Intellectual Property Rights as well as laws of other TRIPS member countries to arrive at this order. This includes the articles published by WHO, UNDP, Mr.Carlos M. Correa, University of Buenos Aires, & Professor Shamnad Basheer, The West Bengal National University of Juridical Sciences, Kolkata.

3. **The Patentee**

M/s. Bayer Corporation, 100 Bayer Road, Pittsburg, PA 15205-9741, USA (hereinafter referred to as 'patentee'), an internationally renowned manufacturer of innovative drugs, invented a drug called 'Sorafenib' (Carboxy Substituted Diphenyl Ureas) useful in the treatment of advanced stage liver and kidney cancer in the 1990s. The patentee first applied for a patent in the United States Patent and Trade

Mark Office on 13.01.1999 and subsequently filed a PCT International Application on PCT/US00/000648 in the 12.01.2000. The Patentee entered the national phase in India on 05.07.2001. After examination under the provisions of the Patents Act, 1970, a patent was granted on 03.03.2008. The Patentee has also obtained patents in many other countries for the same drug including members of the European Patent Office.

In the meanwhile, the Patentee developed the drug and launched it in 2005 under the trade name Nexavar (hereinafter referred to as the 'drug') for treatment of Renal Cell Carcinoma-RCC (kidney cancer) and subsequently got additional approval for treatment of Hepatocellular Carcinoma-HCC (liver cancer) in 2007. The Patentee received the regulatory approval for importing and marketing the drug in India and launched it in India in the year 2008.

4. **The Applicant**

The Applicant herein M/s. Natco Pharma Ltd, Natco House, Road No. 2, Banjara Hills, Hyderabad-500033, Andhra Pradesh, India (hereinafter referred to as 'Applicant') is a reputed Indian generic drug manufacturer. The Applicant has developed the process to manufacture this drug and received a license from the Drug Controller General of India for manufacturing the drug in bulk and for marketing it in the form of tablets in April 2011.

5. **The drug**

'Sorafenib tosylate', which is a compound covered by Patent No.215758 and sold under the brand name NEXAVAR by the Patentee is used for the treatment at the advanced stages of kidney and liver cancer. The drug stops the growth of new blood vessels and targets

other important cellular growth factors. It is pertinent to mention that the drug is not a life-saving drug, but a life extending drug i.e. in case of kidney cancer, the life of a patient can be extended by 4-5 years, while in case of liver cancer the life of a patient can be extended by about 6-8 months. The drug has to be taken by the patient throughout his lifetime and the cost of therapy is Rs.2,80,428/- per month and Rs.33,65,136/- per year.

6. **The Application and initial developments**

The Applicant filed an Application for Compulsory License (hereinafter referred to as the "Application") on 29.07.2011 under Section 84(1) of The Patents Act 1970 (hereinafter referred to as the Act) r/w Rule 96 of the Patent Rules 2003 (hereinafter referred to as the "Rules") in respect of the Patent No. 215758. The Applicant being a leading manufacturer and distributor of various drugs in India approached the Patentee with a request for a voluntary license to manufacture and sell the drug, which did not materialize. The Applicant proposed to sell the drug at a price of Rs.8800/- for one month therapy as compared to the price of about Rs.2,80,428/-, which was being charged by the Patentee at the time of making the Application. Three years had lapsed since the date of grant of patent when the Application was filed. The Applicant is also a *person interested* within the meaning of the Act. Upon arriving at a conclusion that a *prima facie* case under Section 87(1) of the Act has been established, vide order dated 9.8.2011, the Applicant was directed to serve a copy of the Application upon Patentee and the Application was published in the official journal published on 12th August, 2011. On 23.08.2011, the Patentee filed a request seeking an extension of time by one month to file the notice of opposition and the same was allowed

in the interest of justice. The Patentee then filed an 'interlocutory petition' dated 07.10.2011 seeking stay in this matter on the ground that an infringement suit was pending before the Hon'ble High Court of Delhi against the Applicant w.r.t. the same Patent. The request of the Patentee was refused vide order dated 27.10.2011. The Patentee filed a petition seeking extension of time to file a review petition and another petition for staying the proceedings on the ground of pendency of a contempt petition against the Patentee in the Hon'ble High Court of Delhi. Both the petitions were refused vide my order dated 21.12.2011.

Meanwhile, the Patentee preferred Writ Petition No. 2194/2011 in the Hon'ble High Court of Judicature at Bombay challenging the said Order dated 9.8.2011. The Writ Petition was disposed of by the Hon'ble High Court of Bombay with the following order dated 11.11.2011:

*"Considering the said aspect of the matter, the above petition is not entertained by this Court, with a liberty to the petitioner to file appropriate petition before the Delhi High Court, especially when it has been observed by the Delhi High Court in Injunction Application No.7343 of 2011 that in view of the pendency of the application before the Controller of Patent, both the parties agree not to proceed further with the present proceedings. Considering the said aspects, the above petition is disposed of with a liberty to the petitioner to move the Delhi High Court regarding the subject matter. Time to file reply before the Controller of Patent is extended till 18.11.2011. Such extension is given without prejudice to the rights and contentions of the parties and with a view to see that the petitioner in the meanwhile, can approach the Delhi High Court by way of appropriate proceedings. It is clarified that we have not expressed any opinion on the merits of the case and the points raised by both the sides in this petition are explicitly kept open."*

The Patentee thereafter exercised his constitutional right by approaching the Hon'ble High Court of Delhi by way of Writ Petition

No. 8062/2011, thereby challenging the aforementioned order dated 9.8.2011. The Hon'ble High Court of Delhi disposed of the said Writ Petition with the following order dated 16.11.2011:

*"The petitioner impugns the order dated 11.08.2011 passed by the Controller of Patents, Patent Office, Mumbai in C.L.A. No.1 of 2011. It has been pointed out to learned senior counsel for the petitioner that the impugned order merely records a prima facie view that a case under Section 84(1) of the Patents Act has been established. The petitioner is still entitled to contest the said proceedings before the Controller of Patents.*

*Learned senior counsel for the petitioner submits that before arriving at the said prima facie view, the Controller of Customs has not conducted any enquiry and not recorded any evidence. It shall be open to the petitioner to raise all such pleas before the Controller of Patents in answer to the notice. In view of the aforesaid, the petitioner wishes to withdraw this petition. The petition is accordingly dismissed as withdrawn."*

Subsequently, the Patentee filed a notice of opposition on Form-14, along with evidences and the conditions for license, under Section 87(2) of the Act read with Rule 98(1) of the Rules on 18.11.2011, within the timeline as extended by the Hon'ble High Court of Bombay.

7. **Hearings**

The parties were heard on 13.01.2012. During the course of hearing, counter allegations were raised by both the parties that evidence has not been filed on affidavits. The parties were also informed by me during hearing that the evidence filed by both the sides are not conclusive and that there is a need to lead further evidence on crucial aspects to assist the tribunal in arriving at a conclusive finding. Parties agreed to the same. Accordingly, in the interest of justice, leave was granted for filing further evidence to both the parties and the

matter was adjourned to 27th March 2012. Both the parties were given full opportunity to present their side of the case. As the hearing could not be concluded on 27th March, 2012, the same was continued on 28th March 2012, on which day the hearings were concluded.

8. **Preliminary issues raised by the Patentee and decision thereof**

a. On the first day of hearing, the Patentee submitted that the Applicant has specifically raised only the ground mentioned in S.84(1)(a) of the Act and has failed to mention the grounds enumerated under S.84(1)[(b) and (c)] of the Act. This objection appears to be of a hyper-technical nature as it is found that in the Application all the grounds mentioned in S.84 of the Act have constructively been raised by the Applicant and must accordingly be adjudicated.

b. The Patentee also contended that the provisions of Section 84(6)(iv) have not been satisfied and that the Application is required to be rejected on this ground alone. The Patentee's contention is that from the tenor of the letter dated December 6, 2010 sent by Applicant seeking voluntary license, it appeared that the Applicant was fulfilling the requirements for filing an Application for compulsory license. Accordingly, this letter cannot be termed as an effort on reasonable terms and conditions. The Patentee further contended that the Applicant failed to mention any terms and conditions that he was willing to accept. Furthermore, the Patentee states that the Applicant was given a time of 14 days to return if he had anything to say.

I am of the view that the Applicant could have been more humble in writing the said letter dated December 6, 2010 so as not to hurt

the sensitivities of the Patentee. Patentee, vide Para 9 of the reply stated as follows:

'In view of what has been stated above, our client does not consider it appropriate to grant voluntary license to manufacture and market the product, Nexavar to NATCO.'

As the Patentee categorically refused to grant a voluntary license, I don't think that the Applicant could have taken further efforts for grant of a voluntary license. Hence, I am of the view that the requirements of Section 86(4)(iv) have been satisfied.

c. The Patentee raised a further objection that the Controller's order dated 09.08.2011 was erroneous as the Applicant did not make out a *prima facie* case and the Controller ought not to have passed an order under Section 87(1) of the Act, without first giving an opportunity to the Patentee to be heard in the matter. It was also argued that this violates the basic principle of natural justice as no *prima facie* case was made out (without there being any evidence) and the Patentee ought to have been given an opportunity to point that out and show the Law on the point of natural justice.

In this regard, while considering the Application, the Form-27 filed by the Patentee was also considered by me. As per the Form-27 submitted by the Patentee, I found that in 2008 the Patentee did not import the drug at all, while in 2009 and 2010 the Patentee imported in small quantities. The quantities imported by the Patentee *prima facie* appeared to be grossly inadequate. In view of this and the submissions made by the Applicant in his Application, and on satisfaction that a *prima facie* case has been made out, an order under Section 87(1) of the Act was passed. The Act does not envisage a hearing for the Patentee while issuing an order Section 87(1), particularly in view of the fact that no right, title or interest

of the Patentee is affected by the said order and also because unnecessary delay is not in the interests of public. However, that does not in any way mean that the patentee is prejudiced. The Act affords full opportunity to the Patentee to present his case in the best possible manner, before any order affecting his right, title or interest is passed. Accordingly, I find no force or substance in the submissions of the Patentee that before passing the said order, which merely records a *prima facie* satisfaction of the Controller, an opportunity of hearing should have been granted to the Patentee and this issue is decided accordingly.

d. The Patentee raised a contention that the Applicant has suppressed the fact that M/s. Cipla, another generic drugs manufacturer in India, has been selling the generic version of the drug Sorafenib in India since April-May 2010. This suppression of fact by the Applicant shall entail rejection of the Application on this ground itself. The Applicant replied to this contention and submitted that they were aware of the alleged infringing sale by M/s. Cipa and that the Patentee has filed a infringement suit against M/s. Cipla, which is pending. The Applicant further argued that the failure of the Patentee to discharge his obligations under the Act has led to this Application. The presence of Cipla is not a material consideration so far as this Application is concerned as the alleged infringing sale by Cipla cannot rescue the Patentee and hence there has been no material suppression of any relevant fact. I find merit in the Applicant's pleadings and hence there is no ground for rejecting the Application on this ground. However, the other arguments made by the Patentee relating to sales of M/s. Cipla will be discussed later in the relevant paragraphs below.

9. **Main issues to be decided in the case**

Now I proceed to dwell upon the pleadings by the Applicant and Patentee on the three substantial issues in this Application [Section 84(1)(a, b and c)], i.e. whether,

a. the reasonable requirements of the public with respect to the patented invention have not been satisfied.
b. the patented invention is not available to the public at a reasonably affordable price.
c. the patented invention is not worked in the territory of India.

I will take up the afore-mentioned grounds one by one through consideration of the pleadings by parties, appreciation of evidence on record and my decisions thereof.

10. **Reasonable requirements of the public.**

Section 84 of the Act states as follows:

***"84. Compulsory licenses. –***

*(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely –*

*(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied.....'*

Applicant's submissions

The Applicant has made the following submissions through pleadings and by way of written arguments along with evidence on affidavits. Applicant's submissions in brief are as follows:

a. The reasonable requirements of public have not been fulfilled with respect to Patent No. 215758. As per the data gathered and published in GLOBOCAN 2008 (a publication by GLOBOCAN project of the World Health Organization), the approximate patient base in India, in case of liver cancer is about 20000 (14516 men, 5628 women), while in case of kidney cancer the patient base in India is about 8900. In India, in 90% of the patients, the disease of liver cancer is detected at a late/advance stage. Hence, assuming that 80% of the patients in liver cancer alone require Sorafenib, 16,000 patients having liver cancer are eligible for Sorafenib. Similar is the case with kidney cancer. When one compares the demand with the working statement (Form-27) filed by the Patentee a clear picture of the demand not being met clearly emerges:

| | **Total Patients** | **Demand for 80% of patients** | **Bottles per month (required)** | **Bottles Imported in 2008** | **Bottles Imported in 2009** | **Bottles Imported in 2010** |
|---|---|---|---|---|---|---|
| Liver Cancer | ~ 20,000 | ~ 16,000 | ~ 16,000 | -Nil- | ~ 200 bottles | Unknown |
| Kidney Cancer | ~ 8,900 | ~ 7,120 | ~ 7,120 | | | |

b. Patentee imports and sells the drug in India and has not taken adequate steps to manufacture the product in India to make full use of the invention. The drug is exorbitantly priced and out of reach of most of the people. The product is available only in limited quantities. It is available in pharmacies attached to certain hospitals and that too only in metro cities such as Mumbai, Chennai, Kolkata and Delhi. The product is often out of stock or not available in common pharmacies even in metro cities. The product in question is not a luxury item but a life saving drug and it is highly important

that substantial part of the demand be met strictly. In the present case, even 1% of the public does not derive benefit of the patented drug.

c. The Patentee received FDA approval for the product in 2005 and launched the same in the world market around 2006. The sales figures for the years 2006-2011 obtained from public records show that the Patentee not only launched the product all over the world in 2006 but made thumping sales which has grown by leaps and bounds every year.

**Sales figures of the drug:**

| | 2006 | 2007 | 2008 | 2009 | 2010 |
|---|---|---|---|---|---|
| Sales per year (Worldwide) | $165m | $371.7m | $677.8m | $843.5m | $934m |
| Sales in India | Nil | nil | Nil | 16 crores | unknown |

These figures clearly demonstrate the neglectful conduct of the Patentee as far as India in concerned. It shows that although the Patentee has fully developed and launched the product in various parts of the world and reported sales atleast since 2006, and despite the fact that the Patentee had filed its application in India in 2000, the Patentee clearly neglected India and did not launch until 2009. The Patent was granted in 2008 and from then till 2011 the Patentee did not bother to fulfill the demand to comply with the duty imposed by the Act.

d. The Patentee only imports the drug into the Indian market and does not manufacture the drug by itself in India, though it does manufacture and sell other products in India. The worldwide sales in various countries over the last three years has exceeded USD

2454 million whereas in India the sales did not exceed USD 32-40 million.

e. On the Patentee's submission that CIPLA entered the market with an infringing product, which was priced at about Rs.30000 against the Patentee's price of Rs.2,80,000, and this has undercut his market share thereby preventing him from selling in sufficient numbers. The Applicant submitted that the presence of Cipla in the market is irrelevant since:

   i. The demand in the market for the drug Sorafenib has to be fulfilled by the Patentee and not by the third parties; the sales by Cipla are not reflected in the working statement filed by the Patentee nor in the annual returns filed by the Patentee which clearly reflects the fact that Cipla's sales are of no relevance;

   ii. Cipla faces a suit for injunction and its sales are that of an infringer which cannot be taken into account;

   iii. Cipla could be injuncted anytime and the supply by Cipla may stop totally. Public cannot be held to ransom or left at the mercy of such uncertain supply.

Further, the mandate of law is not just to supply the drug in the market but to make it available in a manner such that substantial portion of the public is able to reap the benefits of the invention. If the terms are unreasonable such as high cost of Rs 2,80,000/-, availability is meaningless.

f. Availability of the drug is not to be measured in terms of mere Field Force or field strength of the Patentee. If the drug is so highly priced that the ordinary public cannot afford it, then it is a fact that the product is not available to the public on reasonable terms and

presence of an army in the field is of no consequence and such high price becomes a barrier to availability of the drug, which is precise evil that the legislation is designed to curb.

The number of patients and the actual demand for the drug far exceeds the supply thereof by the patentee. Furthermore, price of the patented product is too high and simply unaffordable by the common man making the product inaccessible and out of reach. Hence, the demand for the patented product has not been met on reasonable terms.

In view of the above, the reasonable requirements of the public with respect to the patented invention have not been satisfied and this makes out a fit case for the grant of Compulsory License.

Patentee's submissions

The Patentee has made the following submissions through pleadings and by way of written arguments along with evidence on affidavits. Patentee's submissions in brief are as follows:

a. Estimated incidence for kidney cancer in India as per GLOBOCAN 2008 is 8900 patients and mortality is 5733 patients, which accounts 64.4% of total patients. Of the 8900 patients of kidney cancer around 90% account for RCC, which equals to approximately 8010 patients.

   Around one third (33.33%) of the initially diagnosed RCC patients are affected with the stage IV disease (33.33% of 8010= 2669). This means there are approximately 5341 stage I, II, III patients, and about **2669** stage IV patients. In 25% of patients having surgical resection for localized disease (stage I, II and III) with a curative intent, recurrence occurs (25% of 5341= 1335). These **1335** patients (from stage I, II and III) eventually may progress to

stage IV RCC. Therefore, the total number of patients falling under stage IV of RCC is approximately 2669 + 1335 = 4004 patients. Therefore, the total number of patients with RCC, entitled for treatment with the drug is approximately **4004**.

Hepatocellular Carcinoma (HCC) is classified into early, intermediate, advanced and terminal stage. As per the HCC trials conducted globally, the drug is used in advanced cases of HCC. Therefore, in practice it is being used in advanced HCC based on the available global clinical trial data.

Estimated incidence of HCC in India as per GLOBOCAN is 20,144 patients and mortality is 18043 patients which accounts 89.5% of total patients. Approximately 24% of the patients are in advanced stage of HCC, which require systemic treatment like sorafenib. (This accounts to approximately 4,838 patients out of 20144 total HCC patients.) Therefore, the total number of patients of HCC entitled for treatment with the drug is approximately **4838**.

The total number of patients eligible for the drug are 4004 (RCC) and 4838 (HCC) i.e. a total of **8842**. Alternative treatments are also available to the patients and the Applicant has not agitated this fact.

b. The Applicant has provided misleading statistics and a list of cities that are covered by Field Force and Distributors and the list of cancer treatment centers in India has been provided as Annexure-4 to the Notice of Opposition. On perusal of the said annexure, it is evident that the Patentee's Field Force and Distributors do cater to all the cancer treatment centers in India. In addition, the following procedure is followed by the Patentee to ensure that the drug is available wherever it is required:

   i. Distributors supply to hospitals, pharmacies, retailers and patients.

ii. Distributors supply to outstation towns, cities where the drug is required.

iii. For outstation patients, supply is done through courier.

c. Further, the treatment with the drug should be supervised by Doctors who have experience of anticancer treatments (Oncologists). Hence, the allegation of the Applicant that it is not available in villages is of no consequence as it has to be made available in cancer hospitals and institutes, which duty the Patentee has duly performed. Further, it is available at 50 places in 278 hospitals and institutes. Hence, the drug is accessible to the public at large.

In view of the above, the issue of requirement vs. availability is being appropriately taken care of by the Patentee.

d. The Applicant has erroneously and impermissibly linked the issue of price of the drug to this ground i.e reasonable requirements of the public have not been satisfied. Section 84(7) of the Act clearly lays down as to when the reasonable requirements of public shall be deemed not to have been satisfied. It was further submitted that none of the deeming provision under Section 84(7) relates to the price of the drug or availability to the public at a reasonably affordable price, which is a ground under Section 84(1)(b) of the Act.

e. The purpose behind Section 84(1)(a) is to enhance access to patented inventions. However, access to a patented invention is not identical to affordability thereof and cannot be on the identical footing. For example, for access to medicine, existence of trained healthcare staff and infrastructure, cultural acceptability of treatment, accessibility of healthcare facilities, quality of care and insurance facility all play a role in access. In other words, the

parameters/criteria of establishing accessibility or lack thereof and affordability or lack thereof are different. The aforesaid submission is further strengthened by the fact that the Patents Act provides two different/specific grounds Section 84(1)(a) [lack of accessibility] and Section 84(1)(b) [lack of affordability] for the grant of Compulsory License. As such, the aforementioned two grounds cannot be mixed as has been done by the Applicant in the present case. It has to be appreciated that the grounds are distinct and separate.

f. The Patentee in their affidavit submitted through Dr. Manish Ram Mohan Garg, Country Medical Director, that the availability of the drug in India has been considerably enhanced due to its sale by M/s. Cipla. The affidavit reveals the following table of sale by M/s. Cipla and the Patentee during the year 2011:

| | Q1A | Q2A | Q3A | Q4 E* | Total |
|---|---|---|---|---|---|
| Cipla No. of boxes | 532 | 1071 | 1358 | 1725 | 4686 |
| Growth % | | 101 | 27% | 27% | |
| Bayer boxes | 119 | 179 | 138.5 | 157 | 593 |

*projected for Q4 based on growth trend of last quarter.

The Patentee submitted further data in the form of table through the affidavit giving projections of sales by them and M/s. Cipla upto the year 2015.

| | 2011 | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|---|
| Total No. of Patients (Cipla + Bayer) | 3908 | 4844 | 6034 | 7544 | 9463 |
| Total No. of HCC + RCC patients eligible for Sorafenib | 8842 | 8842 | 8842 | 8842 | 8842 |
| | 44% | 55% | 68% | 85% | 107% |

Based on the above figures, the Patentee argued that the reasonable requirements of the public is being fulfilled by Patentee and M/s.Cipla cumulatively currently and will be fulfilled in future as well. Hence, there exists no case for grant of compulsory license under Section 84(1)(a).

Decision

I have carefully gone through the pleadings of the parties, the affidavits, oral as well as written submissions, and the relevant provisions of the Act. The Applicant has relied upon the GLOBOCAN 2008 for the incidence of Liver and Kidney Cancer in India. The Patentee too has extensively referred to the same statistics. In the absence of any other evidence on record as to the incidence of the two types of cancer, I am constrained to accept the statistics available in the GLOBOCAN 2008 and the projections of incidence given therein.

Patentee by his own logic has derived a figure of number of patients who are eligible for this drug to be around **8842.** The Applicant submitted that both these cancers are generally diagnosed in India at an advanced stage. Given the state of healthcare infrastructure in the country and the income level of its people, I find merit in the argument of the Applicant. I am accordingly of the view that the number of patients requiring treatment by this drug will be much higher than the figure derived by the Patentee.

I am not inclined to accept the argument of the Patentee that the sales of Patentee combined with that of M/s. Cipla satisfy the reasonable requirements of the public. The Application for a compulsory license is filed against the Patentee or his licensee, if any, and it is their conduct that is relevant in this case. The conduct of any

other person, especially an alleged infringer, cannot by any stretch of imagination be considered in this case. This view flows from Section 86(6)(i), which states as follows:

*"In considering the application filed under this section, the Controller shall take into account, -*

*(i)……the measures already taken by the patentee or any licensee to make full use of the invention;"*

If the conduct of the Patentee is considered with reference to this provision, it follows that the Patentee tried his best to prevent M/s.Cipla by preferring an infringement suit against them, which is at an advanced stage. In such circumstances, the Patentee appears to be indulging in two-facedness by adopting one stand before this tribunal and another stance before the Hon'ble High Court of Delhi, in order to defend the indefensible.

M/s.Cipla is an alleged infringer, as per patentee's own submissions, and accordingly cannot discharge the obligations of Patentee under the Act. The Patentee appears to have treated M/s.Cipla, in this case, as if they are their licensee. M/s. Cipla may be injuncted at any time by the Hon'ble Court. Such an uncertain supply by an alleged infringer cannot be considered while deciding this matter, as it involves the lives of cancer patients, which in my opinion cannot be left to the uncertainties of legal proceedings.

The Patentee has submitted an affidavit of Dr. Garg and has submitted a patient coverage during 2011. It is pertinent to mention that the Patentee refrained from giving the patients covered by his drug and simply submitted a patient coverage by him and M/s.Cipla together. It is noted that the Form-27 for 2009 filed by the Patentee does not provide any logical information about the sales. Form-27 for the year 2010 discloses that the Patentee did not import any 'sale pack'

but imported only 340 units [60 tablets pack] of 'support pack' and 340 units [60 tablets pack] of 'sample pack', both having an 'invoice value' of Rs.10,045,692. It appears to me, from the Form-27 filed by the Patentee for the year 2009 and 2010, that only an insignificant quantum of the drug was made available by the Patentee to the public during these two years. As discussed above, I am not inclined to buy the argument of the Patentee by taking shelter of M/s. Cipla's supply.

The Patentee has arrived at a figure of 8842 cancer patients according to his logic and has compared this figure with the combined sales achieved by him and M/s.Cipla. The Patentee has submitted that they have sold about 593 boxes during the year 2011. It is an admitted fact that a liver patient's life is extended by 6-8 months and a kidney cancer patient's life is extended by 4-5 years upon treatment with the drug. Even if I consider that on an average a patient requires three packets (3 months), the patentee would not have supplied the drug to more than 200 patients in 2011. By his own admission, the Patentee has submitted the number of patients eligible for Sorafenib is 8842 per year. Hence, the Patentee has made available the drug only to a little above 2% of the eligible patients. The Applicant submits that the annual requirement of the drug is about 70000 boxes.

From the conclusions drawn about the probable number of patients requiring the drug, the annual requirement could lie between 9000*3=27000, which is the Patentee's figure, and 70000 boxes per annum, which is the Applicant's figure.

For argument sake, even if I consider the sale 4686 packets during 2011 by M/s.Cipla, the supply in India was not anywhere near the requirement.

In the aforementioned circumstances, the Patentee's conduct of not making the drug available as per the requirements of public in

India during four years, since the grant of Patent, is not at all justifiable. This is inspite of the fact that the Patentee was already marketing the drug in other parts of the world from 2006 onwards. It is not the case of the Patentee that he had to develop the drug before launching the same in the Indian market or had no means to market the drug. The Patentee has a considerable Field Force and Distributors, being an old and established force in the Indian market. In the year 2009, the sales of Patentee in India were only Rs.16 Crores, as per the Applicant, which appears to be incorrect as the Form-27 filed by the Patentee for the year 2009 discloses a possible sale of Rs.2 Crores only. It is also not the case of the Patentee that there is no demand for the drug because as per their own submission, there is a requirement for at least 8842 patients. Even after the lapse of three years, the Patentee has imported and made available only an insignificant proportion of the reasonable requirement of the patented product in India.

It is also pertinent to refer to Section 84(7) of the Act, which states as follows:

*"(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 license or licenses on reasonable terms,—*

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

In the circumstances of this case, it is also clear that Section 84(7)(a)(ii) in invoked beyond doubt. Accordingly, I hold that the reasonable requirements of the public with respect to the patented

invention have not been satisfied in this case and consequently a compulsory license be issued to the Applicant under Section 84 of the Act.

11. **Reasonably affordable price**

Section 84 of the Act states as follows:

***"84. Compulsory licenses. –***

*(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely –*

*……..*

*(b) that the patented invention is not available to the public at a reasonably affordable price …..'*

Applicant's submissions

Price of the patented product is too high and simply unaffordable by the common man making the product inaccessible and out of reach – hence the demand for the patented product has not been met on reasonable terms.

The Applicant submitted through the affidavit of Sh. C. Rammanohar Reddy, the Editor of Economic and Political Weekly that there are a number of ways for determining the affordability of a drug. These include the following two methods, as described in following published papers:

i. Shanti Mendis et al, "The availability and affordability of selected essential medicines for chronic diseases in six-low and middle income countries", [Bulletin of the World Health Organization, April 2007, 85(4)]:

As per this approach, the number of days a lowest paid government worker would be required to work to purchase from the public sector, a month's course of medicine at the standard or common dose, has to be considered. It has been argued that in the case of the present drug such a Government Worker would have to work for three and a half years to be able to purchase the drug at a price of Rs.2,80,000. By this time, going by that fact that the life-expectancy is not more than four months, such a government worker would not be able to afford it.

ii. Laurens M. Niens et al, "Quantifying the Improvershing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World", PLOS Medicine, August 2010, Volume 7, Issue8:

As per this approach, the author has opined that the impoverishment effect of the medicine should be considered i.e. the percentage that would be pushed below a certain income level when having to purchase the medicine. According to the official Government of India norms, a family of five with an income of more than Rs. 4805 (Rs.57,660 a year) in urban areas and more than Rs. 3924 (Rs.47,088 a year) in rural areas, is deemed to be above poverty line. At present an estimated 72% of the population is above this very low poverty line. Hence, a medicine that costs Rs.2,80,000 a month will push a large proportion of the population into poverty. It is also suggested that the price should be arrived at after taking into account the manufacturing costs, administrative expenses, taxes etc. and

should provide for a certain minimum profit which would incentivize a company to sustain manufacture and sale of the drug in the market.

Applicant has also submitted an affidavit by Mr. James Packard Love, Director, Knoweldge Ecology International, a non-profit organization located in Washington DC, USA, and co-chair of the Trans-Atlantic Consumer Dialogue (TACD) Policy Committee on Intellectual Property Rights. It was submitted that Mr. James Love is an invited expert on intellectual property issues in meetings and consultations organized by the World Intellectual Property Organization (WIPO), World Health Organization (WHO), the World Trade Organization (WTO), the United National Program on Development (UNDP), the United Nations Conference on Trade and Development (UNCTAD), the UN Human Rights Council, the Hague Conference on Private International Law, the UNITAID, the World Bank and other multilateral and regional bodies. Mr. James Love has also served as an advisor to several national governments on Intellectual Property issues, including the Competition Commission in South Africa where he was the principal consultant to evaluate a complaint that the prices for AIDS medicines were excessive. It has been deposed that the World Bank estimates of Indian Gross National Income per capita for 2010 is $1330, which is approximately Rs.60,455. The present pricing of the drug shatters the notions of cost-effectiveness.

Bayer had received an FDA designation under the US Orphan Drug Act in 2004. The clinical trials that were related to the orphan drug indication, "treatment of renal cell carcinoma", were eligible for a 50 percent orphan drug tax credit, lowering the net cost of the investments to Bayer. There is no publicly available information on the

amount of tax credit received by Bayer. The credit was available during the period of the most extensive spending on clinical trials, and for the largest and most expensive trials that were undertaken. The issue of lack of transparency in the reported expenditures on R and D was also raised by Mr. James Packard Love. It has been submitted that while the outlays on research and development related to the drug were not trivial, the revenue from the sales were much larger. In 2006, its first year on the market, Onyx, with whom the Patentee entered into a drug development agreement, reported that in the year 2006, its first year on the market, the drug generated $165 million in sales, an amount nearly equal to all joint outlays on R and D from 1994 to 2004. In 2007, Bayer reported the sales of the drug as $371.7 million. By 2008, the sales were reported at $ 678 million, i.e. a total of $1.2 billion within three years of approval as an 'orphan drug'. It has been submitted that if the Patentee has raised the issue of R and D, then it must also open the doors to look at the revenues and profits from the drug. The deponent has also demonstrated as to how various methods can be utilized for calculating royalty.

In conclusion, the Applicant has submitted that the pricing adopted by the Patentee is exorbitant for its patented life-saving product and is an abuse of its monopolistic rights and such practice is unfair and anti-competitive and has requested for grant of a compulsory license on this ground.

Patentee's submissions

It was submitted that innovation based products cost a price over generics, but this price pays for the pipeline (i.e. the future innovation) and competition. The higher price of the drug covered by the subject patent as compared to generic version thereof is justified

inasmuch as for the Patentee, it also involves the Research and Development (R&D) cost of innovators as against the Applicant who merely copies the drug discovered by the Patentee thereby taking advantage of the R & D carried out by the Patentee.

The affidavit filed by Mr. Herald Dinter elaborately explains the complete process to discover and develop a drug. It has been explained that quite a large amount of money is spent in failed projects, which is about 75% of the total R & D cost. The marketed product must pay not only for its own R & D cost but also for the cost of the underlying failed R & D, and further must underwrite the additional R & D for the next generation of innovations. The Patentee and its collaborator continue to invest major sums into further development of Sorafenib. Its potential for treatment of cancers, other than renal and kidney cancer is under investigation in large Phase III trials (e.g. breast cancer, thyroid cancer and non-small-cell-lung cancer). It is therefore important to understand that R & D on a new drug does not at all stop when the drug is launched in the market but actually continues with considerable investments. In conclusion, it is neither possible nor – if it were somehow possible – would it be reasonable to look at past R & D expenditure for a launched product to decide whether its current price is reasonable. Rather one has to take into account the total R & D spending of a company and the need and desire to finance such R & D sustainably to ensure ongoing innovation in healthcare. In 2010, the pharmaceutical division of Bayer invested almost € 1.8 bn or 16% of its net sales into R & D for pharmaceuticals, and 6200 employees worked in the R & D divisions of Patentee globally. Since, the year 2007, the cumulative R & D spending of Patentee was € 8 bn. In this period, 2 NMEs and one new combination

product were brought to the market. It thus takes investments of more than €2 bn to bring an NME to the market.

It was submitted that Nexavar has been granted an 'orphan drug' status in the US and Europe. The exact criteria to meet the orphan drug status vary between jurisdictions. In the US, for example, Nexavar was granted 'orphan drug' status on the basis of having fewer than 200,000 patients for each of its indications. In Europe, one of the criteria for a drug to qualify for an orphan designation is that it must be intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than 5 in 10,000 people in the EU. Therefore, the number of patients for cancer drugs (especially for orphan cancer indications as in the present case of Nexavar) is small when compared to the overall R & D investment of the originator. Further, if one compares this drug vis-à-vis other Oncology brands of innovation based companied, it will be found that the pricing is similar to other comparable drugs.

The Patentee desires to sustainably fund further research in areas of unmet medical needs, which research is in public interest. Replacing the innovation based product with a generic will damage India and Indian patients in the long run as the Patentee as an originator provides more than just the drug product, e.g., education of practitioners on use of the product, pharmacovigilance (observing/evaluating/improving the safety of medicines) etc.

It is the Patentee, being the innovator and having invested resources in developing/marketing the innovation based product, who would decide as to what would constitute a "reasonably affordable price" for such product. It needs to be appreciated that if a higher price of the patented drug with huge investment in R & D by an originator is a good enough argument for the Applicant to request for the grant of

Compulsory License, it will always be applicable and will always circumvent the objective of the Patents Act, which cannot be the intention of the Legislature.

Patents Act provides that the patented invention should be available to "public" at a "reasonably affordable price". "Reasonable" must mean "reasonable" to the public i.e., patients and the patentee as well. If it is not read in this manner, the word "reasonable" would not have been present there. Balance needs to be created. Therefore, the cost of R&D and the cost of manufacture, both have to be taken into account while determining "reasonable affordable price".

There can be no "reasonably affordable price" below the expense incurred in the development of the product and the cost of manufacture is a reasonable element of commercial gain. "Reasonably affordable price" has to be used to balance the interest of the consumer/public without compromising on the interest of the innovator. "Reasonably affordable price" does not relate to the lowest price relative to the cost of manufacturing alone. "Reasonably affordable price" must necessarily take into account the cost of R&D and reasonable gain.

"Public" denotes different sections of public. "The Rich class", "the middle class" and "the poor class". A blanket CL cannot be granted thereby giving the opponents patented drug to all sections of "public" at the same price. Therefore, a method will have to be devised in order to make it "reasonable" for the patentee and to make it "reasonably affordable" for the different sections of "public".

"Treating unequal as equal" is discriminatory and is not permissible under law. Placing "the rich class" and "the lower class" in one category at the expense of the patentee is unreasonable and cannot

be the intention of the legislature. In case of a drug, if R&D is not to be killed, this device has to be implemented.

The word "reasonable" necessarily mean affordable to patients, which necessarily is relative *vis-à-vis* to the paying capacity of the patient. "Reasonably" means "reasonable" to the patients and patentee as well. The Patents Act does not envisage the grant of CL unless the product is not reasonably affordable. It will be within the jurisdiction of the Controller (implied power) to reject, resurrect or keep in abeyance an application for the grant of CL if the patentee is willing to meet the "reasonable requirement" and provide the patented product at "reasonable affordable price to the public". It cannot be the intention of the legislature to lower the price for those patients who can afford the opponent's drug. "Reasonableness" is a relative term which has to be interpreted in the circumstances of each case.

The term "affordability" is the capacity to pay. Different classes/sections of the public have vastly different capacity to pay. What may be "affordable" for one class/section may not be "affordable" to another class/section. The phrase "available to the public at a reasonable affordable price", therefore, must be interpreted to mean as to whether the treatment is "affordable" to a particular class/section of public. Therefore, in modern times, one of the means whereby the treatment can become "affordable" is by way of insurance cover. In other words, treatment as a whole is "affordable" including the drug (being one of the factors of treatment) by an insurance cover. Therefore, "affordability" has to be judged from the cost to be incurred on the insurance cover. Question now that arises for consideration is not whether the patient can afford the drug at a given cost but whether the patient can afford the insurance cover. "Affordability" is also

required to be judged as to whether the patient can afford insurance cover.

In India, insurance cover is accessible to any person by the following modes:

(1) Voluntary health insurance schemes or private-for-profit schemes;

(2) Employer-based schemes;

(3) Insurance offered by NGOs / community based health insurance, and

(4) Mandatory health insurance schemes or government run schemes (namely ESIS, CGHS).

In the affidavit of Mr. Pradeep Kumar Sharma, Business Unit Head, Specialty Medicine, it has been stated that the New India Assurance Company Limited (NIA) offers an insurance policy which is extremely cheap as compared to general health insurance policies. Two such policies are currently offered by NIA and the maximum sum insured is of Rs. 75000 for the first policy and Rs. 3,00,000 for the second policy. A policy offered by ICICI Prudential secures coverage of Rs. 10 lakhs.

It was submitted that "reasonably affordable price" is the notional price, which has to be determined, and it cannot be obviously lesser than the royalty if fixed under Section 90 (1) (i) and (ii) of the Patents Act.

a. The application for Compulsory License must establish that the drug is not available at "reasonably affordable price". If it is available at "reasonably affordable price", a CL cannot be granted. It is a condition precedent, sine qua non for an application for grant of CL to be adjudicated upon. The applicant has chosen to show that the opponent's drug at Rs. 280,000 per month is not "reasonably affordable price" and has suppressed the fact that

Cipla's same drug is available to public approximately Rs. 30,000 per month.

b. The very bulk of sales of Cipla's drug at approximately Rs.30,000 itself is an evidence to show that it is at least "reasonably affordable price" for those patients who cannot afford the opponents' drug at its original price. The application is laible to be dismissed on this ground alone.

c. The CL ought to be dismissed at as threshold as the Applicant has been guilty of suppressing the fact that Cipla's product was available in the market which is a material fact to adjudicate upon the core issue involved vis-à-vis "reasonable affordable price". The suppression of material fact is a fundamental flaw and is certainly not an innocent one. The Applicant ought to have compared its price with Cipla's price and determined as to how Cipla's price is not "reasonably affordable price". The core issue before the Learned Controller is that Cipla's drug at its quoted price is not a "reasonable affordable price". The pleading of the Applicant is completely silent on this issue. Accordingly, the Applicant has failed to discharge the burden and therefore, the Learned Controller should use the discretion in favour of the patentee/ opponent in rejecting CL application. This fact was well within the knowledge of the applicant and inspite it chose not to disclose the said material fact thereby approaching the Learned Controller with unclean hands. It is further submitted that the motivation for the applicant appears to make a quick profit at the expense of the opponent's R&D.

d. It is submitted that in the absence of an injunction from Hon'ble Delhi High Court in CS (OS) No. 523 of 2010, Cipla is another entity apart from the opponent in the market selling the product

covered by the Subject Patent for Rs 27,960. It is further submitted that it is the case of the applicant that the demand of Nexavar is not being met as it is not available to public at "reasonably affordable price". The provisions regarding CL no-where mention that demand is required to be met by only the patentee.

Patentee has further submitted that the intention behind Chapter XVI of the Patents Act is that the patentee should not be allowed to charge exorbitant price so long as it is making a reasonable profit. There is no *suo motu* power upon the Learned Controller to grant CL. It is only upon an application made by "any person interested", that the Learned Controller may grant CL. Emphasis in this regard is laid on the word "may" appearing in Section 84 (4) of the Patents Act, the Learned Controller has a discretion as evident from the said provision. Further, it is submitted that Section 90 (1) (i) of the Patents Act is important in construing "reasonable affordable price". It is submitted that law does not envisage the grant of CL unless the hurdle/condition under the said clause is crossed. The cost of R&D that the patentee has incurred has to be taken into account while fixing royalty. It has no relationship whatsoever with the fact that patentee has already earned/ profited so much on Nexavar as has been the case of the applicant. The "reasonable affordable price" cannot be less than the royalty to be fixed by the Learned Controller. "Reasonable affordable price" does not merely depend upon the purchasing power of the public. It will have to be determined on the basis of cost incurred by the patentee on the R&D with some reasonable gain/profit to it. It is submitted that the affidavit of Mr. James Love does not further the case of the applicant as if his deposition is accepted, every time an application for CL will be filed, the Learned Controller shall call for the balance sheets of the patentee. That can certainly not be the intention of the legislature. In

any event, it is admitted case of the applicant that even its quoted price is too high.

Decision

I have carefully gone through the pleadings of the parties, the affidavits, oral as well as written submissions, and the relevant provisions of the Act to decide on the issue as to whether the patented invention is not available to the public at a reasonably affordable price in this case.

The Patentee has vehemently argued on 'reasonably affordable price' and has suggested that reasonableness has to be judged with respect to public as well as to patentee. The Applicant has argued that the 'reasonably affordable price' has to be interpreted as reasonable to public. Both the parties have also submitted that 'reasonably affordable price' is a notional price and has to be arrived at from the facts and circumstances on a case by case basis. Patentee has also argued that the sales made by M/s.Cipla at a price of about Rs.30000/- is a relevant factor to be considered in this case. Patentee also submitted that affordable to public is required to be considered as affordable to different classes/sections of public. On this point, I fully agree with the Patentee. I only wonder why the Patentee did not execute this concept by offering differential pricing for different classes/sections of public in India. Further, the Patentee in their affidavit submitted that they offer this drug at a similar price (subject to variation in exchange rate etc.) to patients all over the world.

As I have already decided that the sales by M/s. Cipla cannot be considered in these proceedings, I need not further dwell upon this issue. While deciding this case, I need to only decide as to whether the drug was available to the public at a reasonably affordable price or not.

I do not fully agree with the submission of Patentee that reasonably affordable price has to be construed with reference to the public as well as patentee. I am of the view that reasonably affordable price has to be construed predominantly with reference to public. Given the 'admitted facts' in this case, I need not go into these issues in detail as the admitted facts fully enable me to decide this issue.

As concluded in 10 above, during the last four years the sales of the drug by the Patentee at a price of about Rs.2,80,000/- (for a therapy of one month) constitute a fraction of the requirement of the public. It stands to common logic that a patented article like the drug in this case was not bought by the public due to only one reason, i.e. its price was not reasonably affordable to them. Hence, I conclude beyond doubt that the patented invention was not available to the public at a reasonably affordably price and that Section 84(1)(b) of the Patents Act, 1970 is invoked in this case. Consequently, a compulsory license be issued to the Applicant under Section 84 of the Act.

12. **Patented invention not worked in the territory of India**

Section 84 of the Act states as follows:

***"84. Compulsory licenses. –***

*(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely –*

.....

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

Applicant's submissions

The patented product is being imported into India and hence the product is not worked in the territory of India to the fullest extent that is reasonably practicable. As per the Act, the law expects the Patentee to work the invention in the country to the fullest extent possible. The provision of 'working' is to be read in the context of principles stipulated under Section 83[(a) and (b)] of the Act and with reference to the debates in the Lok Sabha.

It is pertinent to note that Patentee has been working the Patent in other countries since 2006; however, the Patent has not been exploited in India and no reason has been ascribed for such neglect. This is especially in view of the fact that the Patentee claims to have manufacturing facilities in India for several products, including Oncology products. As such there is no hurdle preventing the Patentee from working the Patent in India. A comparison of the working statement with the Patient base would clearly show that the Patent has not been worked in India.

Patentee's argument that even minimal working would satisfy the requirements of Section 84(1)(c) is flawed and fallacious for the reason that the expression "working" in Section 84 has to take color from Section 83(a). If the argument of Patentee were to be accepted then it would render Section 84(1)(c) otiose. As per Heydon's Rule, where two different interpretations are advanced, the one that suppresses mischief and advances the cause of the Act should be taken. Accordingly, the correct interpretation of Section 84(1)(c) would be that minimal working is no working at all and the invention must be worked to the fullest extent to escape from the rigours of Section 84(1)(c).

Patentee's submissions

The local working requirements in the Patents Act are directed towards ensuring that inventions are domestically "worked" i.e. supplied to the Indian market. An attempt to impose local working requirements – in the sense of local manufacturing – on patents granted in India would be beyond the scope of the Patents Act and against the intent of the legislature. The intent of the legislature is clear from the fact that the phrase "manufactured in India" was deleted from Section 84(7)(a)(ii) of the Patents Act during the amendment to the Patents Act in 2002, thus negating the requirement of local manufacture in order to make it consistent with Article 27(1) of TRIPS Agreement. This is also relevant to Section 84(7)(e) of the Patents Act, which states that a compulsory license should be available "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." Section 84(7)(e) should be interpreted, consistently with settled proposition of law, to apply where the patentee, or other entity claiming under the same right holder, was not supplying the patented product to the market.

The economies of scale ought to be appreciated which provides valid reason for not locally manufacturing the drug. Manufacturing of the drug requires huge investment in terms of infrastructure and logistics. Nexavar is a product of small global demand and hence is required to be produced in small volumes. With a view to achieving economies-of-scale with such a small-volume product and keeping manufacturing costs at a reasonable level, the Patentee made a strategic decision to consolidate both chemical API synthesis and pharmaceutical bulk production of the product covered by the Subject Patent within its manufacturing facilities in Germany. Further,

manufacturing bundled in Germany allows for maintaining a harmonized high quality production at reasonable manufacturing costs due to volume scale. In addition, production in Germany allows for taking advantage of good infrastructure for supplying global markets as good downstream and upstream industries ensure a smooth supply chain process. The quantities required in India do not economically justify setting up a manufacturing facility by Bayer in India. However, these can, due to the local nature of their sales, be manufactured on contract manufacturing basis with other manufactures who are expert *in manufacturing those specific dosage forms.*

The Patentee also submitted a detailed list of contract manufacturers (Annexure-6 of the Notice of Opposition). It is a settled proposition of Law that importation does indeed satisfy the working requirements mandated under the Patents Act.

**Decision**

I have carefully gone through the pleadings of the parties, the affidavits and oral as well as written submissions to decide the issue as to whether the patented invention is worked in the territory of India or not. The term 'worked in the territory of India' has not been defined in the Act. Hence, one has to seek its meaning from various International Conventions and Agreements on intellectual property, provisions contained in the Patents Act, 1970, the context in which this concept appears, and also the legislative history.

It appears that the arguments of the patentee referring to the deletion of the phrase 'manufactured in India' from Section 84(7)(a)(ii) by the Patents (Amendment) Act, 2002 are misplaced. In fact, the phrase was deleted from Section 90(a) of the unamended Patents Act, 1970 [hereinafter referred to as the 'erstwhile Act']. It may be noted

that Section 84 (7) is the corresponding provision under the existing Act [hereinafter referred to as the 'amended Act']. The Patentee argues that the legislature deleted 'default of the patentee to manufacture in India to an adequate extent and supply on reasonable terms the patented article' [hereinafter referred to as the 'concept'] from Section 90(a) of the erstwhile Act, to make the Patents Act, 1970 consistent with Article 27 of the TRIPS Agreement.

It is necessary to address this crucial argument of the patentee in detail. It is pertinent to mention that Section 90 of the erstwhile Act appeared in a different context, i.e. with reference to the issue of 'reasonable requirements of public'. The deletion of this concept was one face of the coin, which is being tossed by the Patentee to suit his convenience. However, there is another face of the coin, which is that this concept was removed from 'a context', i.e. 'reasonable requirements of public', and was made a separate ground for grant of a compulsory license under Section 84(1)(c), with a substantially altered scope.

It must be appreciated that this is not a simple case where a concept is removed from one place of an Act. It is in fact a complicated case where a concept is removed from one place of an Act and is incorporated at a different place, in a different context, and with a substantially altered scope. Accordingly, it cannot be said in such a straightforward manner that the intention of the Legislature, in removing the concept from Section 90(a) of the erstwhile Act, is to totally remove the concept of local manufacturing in India. In fact, this amendment has to be decoded by considering all the International Conventions and Agreements and the Patents Act, 1970 itself.

I have considered the Paris Convention, TRIPS Agreement and The Patents Act, 1970 in detail. Even though the TRIPS Agreement

marked a new era of obligations regarding the protection and enforcement of intellectual property, WTO Members retained important policy options, flexibilities and safeguards, including the liberty to determine the grounds for issuing compulsory licenses. In addition, certain key terms relating to TRIPS obligations are not defined in the Agreement itself, which leaves considerable discretion to WTO Members as to how to apply the criteria within their national laws. The use of these policy options and other flexibilities can directly or indirectly help the low and middle-income countries to achieve a balance between intellectual property protection and specific developmental priorities, including the attainment of national public health objectives.

It may be noted that Article 2(1) of the TRIPS Agreement states that provisions of the Paris Convention shall be complied with by the member states. This implies that the Paris Convention is to be read as a part and parcel of the TRIPS Agreement. Article 5(A)(1) of the Paris Convention provides that importation of patented articles by the patentee shall not entail forfeiture of the patent. This would seem to suggest that importation could entail something less than forfeiture, such as a compulsory license. Such a conclusion is further fortified by the fact that Article 5(A)(2) of the Convention goes on to state that each member shall have the right to take legislative measures providing for the grant of compulsory licenses in order to prevent any abuse of patent rights, for example, failure to work. It is pertinent to note that the Paris Convention did not define the term 'working' and left it to the wisdom of Legislatures of member countries in a manner conducive to their socio-economic requirements.

Article 27(1) of the TRIPS Agreement, *inter alia*, states that "patents shall be available and patent rights enjoyable without

discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." When the Article 27(1) of TRIPS Agreement is read with the afore-mentioned provisions of TRIPS Agreement and the Paris Convention, it follows that importation of a patented invention shall not result in forfeiture of a patent. However, a reasonable fetter on the patent rights in the form of a compulsory license is very well within the purview of the Paris Convention and TRIPS Agreement, when there is an abuse of patent rights. It is this flexibility that the Parliament have invoked in Chapter XVI of the Patents Act, 1970 by incorporating a provision for grant of compulsory license upon failure to work the invention within the territory of India.

I now turn to the indications that the Patents Act, 1970 provides with reference to working of the patented invention. The Patentee contended that working means working on a commercial scale as is evident from Section 84(7)(e). It may be noted that while deciding 'the reasonable requirements of public', one relevant consideration, as provided under Section 84(7)(e), is that the 'working of patented invention in the territory of India on a commercial scale is being prevented by importation by the Patentee'. However, it must be appreciated that Section 84(7)(e) relates to Section 84(1)(a) and not Section 84(1)(c). Accordingly, it does not appear logical to me to accept the Patentee's contention that working means working on a commercial scale only as I find no such limitation in Section 84(1)(c). If such was the case, then there was no need to incorporate Section 84(1)(c) as a separate ground for grant of a compulsory license, as it would be an absurdity (emphasis added). Due to this, I am of the view that the term 'worked in the territory of India' cannot be restricted to

mean as 'worked in India on a commercial scale' only as submitted by the Patentee. To my mind, it is something more than that.

I now turn to Section 83, which is the over-riding legislative policy and the key to decoding the various provisions contained in Chapter XVI of the Act.

Section 83(b) states that Patents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article. Upon a reading of this provision, it becomes amply clear to me that mere importation cannot amount to working of a patented invention.

Section 83(c) buttresses this interpretation by stating that the grant of a patent right must contribute to the promotion of technological innovation and to the transfer and dissemination of technology. Section 83(f), clears all ambiguity that the patent right should not be abused and the patentee should not resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology. Upon a combined reading of Section 83(c) and (f), it is clear to me that a patentee is obliged to contribute towards the transfer and dissemination of technology, nationally and internationally so as to balance the rights with the obligations. A patentee can achieve this by either manufacturing the product in India or by granting a license to any other person for manufacturing in India. Unless such an opportunity for technological capacity building domestically is provided to the Indian public, they will be at a loss as they will not be empowered to utilise the patented invention, after the patent right expires, which certainly cannot be the intention of the Parliament. Hence it follows that 'worked in the territory of India' implies manufactured in India to a reasonable extent so that the principles

enumerated in Section 83 can be brought into effect. In the absence of manufacturing in India, Section 83 will be a dead letter.

Another indication is provided by Section 84(6) and Section 90(2) of the Act, which state as follows:

**Section 84(6)**

*"In considering the application filed under this section, the Controller shall take into account,—*

*……*

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

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

**Section 90(2)**

*'.....no license granted by the Controller shall authorise the licensee to import the patented article or an article or substance made by a patented process from abroad.....'.*

The term 'work the invention' does not include imports as a compulsory license holder has to necessarily work the patent by manufacturing the patented invention in India. If, the licensee cannot import the product into India, for working the invention under the terms of License, barring exceptional circumstances mentioned in Section 90(3) of the Act, then is implies that importing cannot amount to working for a licensee. A combined reading of these provisions implies that the same logic must apply with respect to the Patentee as well.

From all the aforementioned indications, it is clear to me that the Paris Convention and TRIPS Agreement and Patents Act, 1970 read together do not in any manner imply that working means

importation. I am therefore convinced that 'worked in the territory of India' means 'manufactured to a reasonable extent in India'.

In the instant case, the Patent was granted in the year 2008. It is an admitted fact that the Patentee does have manufacturing facilities for manufacturing drugs in India, including Oncology drugs. However, even after the lapse of four years from the date of grant of patent, the Patentee failed to do so. The Patentee has also failed to grant a voluntary license on reasonable terms to anyone including the Applicant herein to work the invention within the territory of India. Accordingly, I hold that Section 84(1)(c) is attracted in this case and consequently a compulsory license be issued to the Applicant under Section 84 of the Act.

13. **Request for adjournment under Section 86**

Patentee's submissions

The allegation against the Opponent/ Patentee is that it is not working the patent to its "fullest extent that is reasonably practicable" as it is highly priced. In order to work the patent to its "fullest extent that is reasonably practicable", the opponent is prepared to modify the current PAP thereby reducing the price of the drug for those patients who cannot afford the original price to a level by which it has been proven by Cipla's sale figures (as mentioned in the affidavit dated February 8, 2012 of Dr. Manish Garg) to cover a very large number of patients.

It was submitted that Cipla being in the market has cut the opponent's market share thereby preventing them to work the invention to the fullest extent that is reasonably practicable.

Section 86 in fact gives preference and the first right option to the patentee to work the patent to the fullest extent that is reasonably

practicable before any CL is granted. For this purpose, the present CL proceedings may be adjourned for one year.

It was submitted that Section 86 of the Patents Act obliges the Learned Controller to first consider and give first option right to the inventor/patentee to work the patent to its fullest extent that is reasonably practicable. If the allegation is that the patent is not being fully worked because of the high price, it is in the interest of justice that an opportunity has to be given to the inventor/patentee to reduce the price below the "reasonably affordable price" to those who cannot afford the original price.

In so far as the compliance of conditions imposed by the Learned Controller for the adjournment is concerned, in the event of non-compliance, it is submitted that the Controller can simply grant the CL on the expiry of the adjournment period under Section 86 of the Patents Act.

Applicant's submissions:

The Patentee at the time of hearing made an oral request for adjournment of the hearing under Section 86 (of the Patents Act) by 12 months so as to enable the patentee to work the invention in India to the fullest extent. In addition, the Patentee came up with a proposal that they would provide the product to deserving patients at Rs 30,000 per month and sought adjournment on that basis. Such request being a mere demurrer, cannot be entertained at all even on merits because:

- Section 86 would require the Ld.Controller to first arrive at a finding, the "**time**" that has elapsed after sealing of the patent has been "*insufficient*" to enable the patentee to work the invention in India. Further, the power to adjourn is curtailed by Section 86(2) which clearly stipulates that the adjournment shall **not** be granted

for the asking, but only upon a clear satisfaction that the Patentee has taken with promptitude, steps to work the invention in India on a commercial scale to an adequate extent.

- A proper reading of section 86 would require *fulfillment* of following conditions before any adjournment is granted:
    - Application from the Patentee conceding that they have not been able to work the patented invention after its grant, and giving reasons why they could not do so from date of grant till date of CL application and steps that they plan to take to work the patented invention in future
    - On the basis of the above, the Ld. Controller could arrive at a finding and be "satisfied" that the invention though not worked till date, could be worked in future by the Patentee.
- In the case at hand no application from patentee- only oral plea: Patentee has made no serious plea for adjournment; no specific application was filed. Even in its oral arguments, the Patentee did not concede that they could not work the invention in a timely manner after its grant and no request for working has been made so far. The argument made is a mere request for adjournment without any assurance that the Patentee shall work the invention nor any details of the mode and manner of working the invention- no change in market price or assurance of greater availability of the drug in the market has been made. In the absence of such reasons, any adjournment is unwarranted and unsustainable.
- Patentee is guilty of absolute neglect and delay: Despite launching the product in the world market in 2006, the Patentee did not launch it in India until 2009- though the patent was granted in 2008

thus the patentee waited for 2 years and no logical reason for such delay has been ascribed till date- neither Patentee has conceded to the delay nor given reasons for the delay ; The key feature of Section 86 is the time factor and the satisfaction that time was insufficient- the satisfaction of the Ld Ld Controller can be gleaned only from reasons if any and ascribed by the Patentee. And, Section 86(2) specifically intends to curb such unexplained delay. In the teeth of such intendment of the legislation, and the unexplained delay and latches by the Patentee in working the patented invention, no adjournment is warranted and not reasonable.

- Bayer as a company with all its supply infrastructure existed as of 2005, as well as 2007 as well as 2011. It is pertinent to note that the demand for the drug always existed whether in 2007 or 2009 or 2011 and the Patentee has not explained why there was delay in working the patent. Thus, the basic requirement of Section 86 remains unfulfilled making out no case for adjournment at all.
- It is pertinent to note that the law makers while framing of Sec 84 of Patents Act had given the Patentee 3 years from the date of grant of Patent as a reasonable period for the Patentee to work the invention. Failure to do so invites consequences outlined in Chapter XVI, Section 84. In this case, even though the Patent was granted in 2008, Patentee not taken any effective steps all these four (4) years to see that the Patent is worked in India as in other countries; which amply demonstrates the neglect on part of the Patentee.
- Further the Patentee, though pleads for adjournment, does not plead that "time" has been insufficient to work the invention in India- rather the Patentee vehemently contests this fact and states

that they have worked the patent in India to an adequate extent : hence, even for this reason, the request for adjournment must be dismissed in limini.

- Section 84(6)(iv) precludes consideration of matters after the date of filing of the compulsory license application: Section 84(6)(iv) clearly states that "... *but shall not be required to take into account matters subsequent to the filing of the application*" meaning thereby that the Ld Controller is only required to consider the state of affairs that existed **on the date of filing of the Application for compulsory license** and not beyond; considering any proposal by the Patentee made at the time of hearing would be beyond the scope of Section 84(6)(iv);
- Even with the proposal, product price in Open market price remains unchanged and Section 84 is only concerned with market price: Patentee maintains that it shall continue to sell the patented invention at the rate Rs. 2,80,000/- in the open market (chemist shop) to the affordable patients and the reduced price is only for certain deserving patients- the scope of inquiry under section 84 and the present application centers around whether the product is available in the open market at reasonably affordable price, and not the merits of the patient assistance program of the patentee; hence the proposal is no proposal at all and there is nothing for consideration by the Ld Controller in this respect also;
- No rational classification: No logic or rationale including criteria has been defined by the Patentee as to how the "deserving class" would be carved out from the patient base;
- Ld Controller has no power to arbitrate, mediate or settle: Ld Controller has no power under section 86 or any other provision to

settle matters in lieu of grant of Compulsory license– such powers are bestowed on a civil court under Section 151 of the CPC;

- Ld Controller has no power to classify public: Ld Controller has no power under the Act to classify the public into deserving and non-deserving for any reason whatsoever; accepting the proposal would necessarily require the Ld Controller to make such classification which is beyond the jurisdiction of the Ld Controller;
- Ld Controller has no power to grant adjournment on the basis of proposal given by Patentee- such power can be exercised only on a finding of insufficient time: It is important to note that the Ld Controller has no power to take into Account any settlement proposals and grant adjournment on that basis. Ld Controller under the Act especially Section 86 is only empowered to arrive at a finding that *time* for working has been insufficient, and on that basis grant adjournment. Hence Patentee's proposal cannot form basis for adjournment;
- Ld Controller has no power to take into account subsequent events: It is pertinent to note that Sorafenib was launched in the world in 2006; Cipla entered the market around April-May 2010 and till date, the Patentee has not bothered to work the invention. However, now, upon filing of the Application for Compulsory license, the Patentee has expressed a desire to work the invention- the material date for adjudication under Section 84 is "the "*date of the compulsory license Application*"- same can be gleaned from Section 84(6)(iv)-"*..but shall not be required to take into account matters subsequent to the filing of the date of filing of the application*" ; Section 84(a)-"*... have not been satisfied*";
- Proposal is an attempt to remedy an irrational PAP program: Under the PAP program, the patient was required to pay Rs 2-5 lakhs

upfront regardless of whether he lived or not; same has been modified and now same amount is being collected in installments [Rs 2,80,000/9= 30,000].

Decision

Section 86 of the Patents Act, 1970, under which the adjournment has been sought by the Patentee is as follows:

***"86. Power of Controller to adjourn applications for compulsory licenses, etc., in certain cases.***

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

*Provided that in any case where the patentee establishes that the reason why a patented invention could not be worked as aforesaid before the date of the application was due to any State or Central Act or any rule or regulation made thereunder or any order of the Government imposed otherwise than by way of a condition for the working of the invention in the territory of India or for the disposal of the patented articles or of the articles made by the process or by the use of the patented plant, machinery, or apparatus, then, the period of*

*adjournment ordered under this sub-section shall be reckoned from the date on which the period during which the working of the invention was prevented by such Act, rule or regulation or order of Government as computed from the date of the application, expires.*

*(2) No adjournment under sub-section (1) shall be ordered unless 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."*

The Applicant's contention that only an oral submission was made is misplaced. The Patentee has given the request in writing supported by an affidavit on the issue of modified Patient Assistance Program (PAP).

The Patentee's main contention is that due to the presence of Cipla in the market, the Patentee could not work the invention to the fullest extent that is reasonably practicable as Cipla undercut them. It is pertinent to mention that the drug was developed and marketed globally right from the year 2006, i.e. two years prior to the grant of patent in India. The present proposal of the patentee is that they are willing to offer the drug at a price of Rs. 30,000 through their PAP program. As per their own submission, the Patentee has two schemes under its PAP program. Under the first scheme termed as 1+6, the patient has to pay for one month stock of the drug and will get the supply for six months free. Under the second scheme termed as 2+10, the patient has to pay for two months stock of the drug and will get the supply for ten months free. The Patentee has proposed that they will supply the drug to needy patients based on the recommendation of the Oncologist that the patients is needy and has no means to pay.

The Patentee launched the product in other countries in 2006, as is evident from their sales provided by the Applicant, which have not been controverted by the Patentee. The Patentee got the License for importing and marketing the drug in India on 01.08.2007. The Patentee got another License from the Directorate General of Health Services to import and market the drug on 22.01.2008. Assuming that the actual permission to import and market the drug was given on 22.01.2008, the Patentee's conduct of not importing the drug till 2008 and importing in small quantities in 2009 and 2010, is beyond explanation. The Patentee has alleged that Cipla did not allow the sales to flourish. However, it is pertinent to mention that M/s.Cipla entered the market only in April-May 2010 and the Patentee had approximately 2 years after that to suitably modify its pricing strategy so as to work the invention on a commercial scale to an adequate extent. The Patentee thus took no 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.

The Patentee argued that "treating unequal as equal" is discriminatory and is not permissible under law. Placing "the rich class" and "the lower class" in one category at the expense of the patentee is unreasonable and cannot be the intention of the legislature. The Patentee was not estopped in any manner from treated equals as equals and unequals as unequals. The Patentee had four years from the date of grant to apply differential pricing for different sections of the public in India.

In my view the two essential conditions for invocation of Section 86 of the Act are as follows:

(1) the **time** which has elapsed since the sealing of the patent has for any reason been insufficient to enable the invention to be worked on a commercial scale to an adequate extent or to enable the

invention to be so worked to the fullest extent that is reasonably practicable; **and**

(2) 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.

As discussed in 9 above, the Patentee did not import the drug at all in 2008, and imported in small quantities in 2009 and 2010. In the facts and circumstances of this case, I do not believe that the time which has elapsed since the grant of the patent has been insufficient to enable the invention to be worked on a commercial scale to an adequate extent or to enable the invention to be so worked to the fullest extent that is reasonably practicable. Further, I do not also see any prompt action on the part of the Patentee to start the working of the invention in the territory of India on a commercial scale and to an adequate extent.

Another reason for non-invocation of this provision is the Section 84(6), which states as follows:

*"(6) In considering the application filed under this section, the Controller shall take into account,—*

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

*... ... ... ... ...*

*but shall not be required to take into account matters subsequent to the making of the application."*

This provision specifically bars the Controller from considering any measures taken by the Patentee subsequent to the making of the Application. The intention of the Legislature appears to be that subsequent measures by the Patentee to frustrate the proceedings shall

not be considered. In my view, the present proposal falls within the four corners of this prohibition.

The proposal of the Patentee appears to be philanthropic in nature, as per the submission of the Patentee. In the present proceedings, we are not concerned with philanthropy, which no doubt is appreciable. Such actions cannot be construed as steps to work the invention on a commercial scale to an adequate extent. The request of the Patentee for adjournment is therefore rejected.

14. **Terms and conditions**

Having decided to grant the Compulsory License under Section 84 of the Act, I now proceed to settle the terms and conditions of the License in the light of the provisions contained in Section 90 of the Act.

Applicant's submissions

Following terms and conditions are acceptable to the Applicant:

i. Right to manufacture and sell Sorafenib shall be limited to the Territory of India.
ii. The products under license shall be manufactured only to cover the patients who are afflicted by renal and hepatic carcinoma.
iii. Royalty shall be paid to the Patentee at the rate as fixed by the Controller of Patents.
iv. Initially, a price of Rs. 74/- per tablet is proposed, which works out to be Rs.8,800/- per month for therapy.
v. The Applicant also commits to give the product free of cost to atleast 600 needy and deserving patients per year.

The Applicant has also submitted the cost break-up as follows:

| Particulars | Amount (Rs.) |
|---|---|
| M.R.P. (inclusive of sales tax) | 8900 |
| Margin to distributor, stockiest and retailer (approximately 30% on M.R.P.) | 2670 |
| Cost of manufacture of the product SORAFENAT | 4856 |
| Billing price of company to distributors | 6105 |
| Margin to the company | 1250 |

The Applicant also submitted that royalty shall be paid from the margin to the Applicant.

Patentee's submissions

The Patentee has submitted the following terms and conditions:

i. Non-exclusive license to make sorafenib tosylate (API of Nexavar), to formulate into tablet form, to sell for the purpose of treating HCC and RCC in humans; all rights non-transferable and limited to the Applicant only (no right to sublicense, assign, or delegate to others) and to India only (no right to import or export);
ii. License does not include any right to represent publicly or privately that the Applicant's product is the same as the Patentee's or that the Patentee is in any way associated with the Applicant's product. The Applicant's product must be visibly distinct from the Patentee's product (e.g. in color

and / or shape); the name must be distinct, and the packaging must be distinct. The Patentee expressly does not grant any copyright or trademark rights with he license and will provide no legal, regulatory, medical, technical, manufacturing, sales, marketing, or any other support of any kind.

iii. Raising the prices, failing in market in all states in India, and failing to provide free drug to indigent persons shall each be considered a material breach;

iv. The Applicant is solely and exclusively responsible for its product and for all associated product liability, and will indemnify the Patentee, its Directors, Officers, Employees, Agents, and affiliates against any and all damages arising from or associated with the Applicant's activities. The Applicant will carry insurance in an amount sufficient to cover such damages ($10 million) and upon request will provide certificates evidencing such coverage;

v. Royalty – 15% of net sales, payable in US dollars. There are no milestones or guaranteed minimums but there are also no credits or deductions for any other fees or royalties paid to any third parties;

vi. Term is until first to occur of: a) decision by the relevant government authority that the conditions for granting compulsory license no longer exist, or b) expiration of Indian Patent 215758. This agreement will be terminated upon a) the Applicant's breach of any term, representation, or warranty if such breach is not cured within 30 days; or b) upon bankruptcy of the Applicant.

vii. There are no additional implied licenses to any other patents owned by the Patentee now or in future. There are no representations or warranties of validity or enforceability. The Patentee is not obligated to enforce against infringement by third parties;

viii. The Applicant not to challenge the validity of Indian Patent 215758 in any way, directly or indirectly;

ix. The Patentee is free to do whatever it wishes with its residual patent rights subject to the non-exclusive license to the Applicant, and is free to compete with the Applicant and to grant licenses to third parties to compete with the Applicant; and

x. The license will include such other terms as are normal in the Industry (e.g. record keeping, reporting, mechanisms for conversion from rupees to dollars, details of indemnification etc.)

Decision

**Royalty**

Article 31 (h) of TRIPS Agreement states as follows:

*"(h) the right holder shall be paid adequate remuneration in the circumstances taking into account the economic value of the authorization;...."*

The unamended Patents Act, 1970 provided for a ceiling of 4 percent royalty to be paid to the patentee in case of a compulsory license. However, this ceiling was removed by the Patents (Amendment) Act, 2002 and it was left to the Controller to decide on a case to case basis as to quantum of royalty or other remuneration to be paid to the patentee by the compulsory license holder.

Section 90(1) of the Act states as follows:

***"90. Terms and conditions of compulsory licences. –***

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

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

During the course of hearings, the Patentee submitted that the cost of making the invention and developing a new medical entity (NME), like the drug in this case, works out to be about 1.8bn€. However, the figure arrived was for the cost of R&D for five years preceding 2010. In the absence of any definite figure on the cost of developing and making it available in the market, including the cost of patenting and maintaining the patent made available to me, I am unable to arrive at the actual cost involved in making this particular invention and developing the same. However, I am inclined to believe that the Patentee has spent considerable sum of money for purpose of making and developing this invention.

I am obligated to consider the nature of this particular invention especially with regard to the possible number of consumers, who require the drug in this case in order to arrive at a reasonable royalty to the Patentee. Going by the GLOBOCAN 2008, I find that the number of patients requiring this drug in India is not very high when compared to other recently patented drugs like HIV drugs.

I have also carefully analysed the royalty practices / guidelines generally adopted globally. United Nations Development Program (UNDP) specifically recommended that rates normally 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, i.e. for a range of 2 to 6%. In the present case, I am satisfied that anything lesser than 6% would not be just and reasonable given the facts and circumstances of this case as discussed above. Hence, I hereby settle that the royalty be paid to the patentee in this compulsory as 6% of the net sales of the drug by the Licensee. I have also considered the other terms and conditions agreed by the Applicant and sought by the Patentee.

15. **ORDER**

I hereby grant a compulsory license (hereinafter referred to as 'license') under Section 84 of the Patents Act, 1970 to M/s. Natco Pharma Ltd, Natco House, Road No. 2, Banjara Hills, Hyderabad-500033, Andhra Pradesh, India (hereinafter referred to as 'licensee') in patent number 215758 (hereinafter referred to as 'patent') granted to M/s. Bayer Corporation, 100 Bayer Road, Pittsburg, PA 15205-9741, USA (hereinafter referred to as 'licensor') with the following terms and conditions:

a. The price of the drug covered by the Patent, sold by the licensee shall not exceed Rs.8880 for a pack of 120 tablets, required for one month's treatment.
b. The licensee shall maintain accounts of sale etc. in a proper manner and shall report the details of sales to the Controller as well as the

Licensor on a quarterly basis, on or before fifteenth day of the succeeding month.

c. The licensee shall have the right to manufacture the drug covered by the Patent only at his own manufacturing facility and shall not in any whatsoever outsource the production.
d. The license is non-exclusive.
e. The license is non-assignable.
f. The licensee shall pay royalty at the rate of 6% of the net sales of the drug on a quarterly basis and such payment shall be affected on or before fifteenth day of the succeeding month.
g. The license is granted solely for the purpose of making, using, offering to sell and selling the drug covered by the patent for the purpose of treating HCC and RCC in humans within the Territory of India.
h. The licensee shall supply the drug covered by the Patent to atleast 600 needy and deserving patients per year free of cost. The licensee shall annually submit in the form of an affidavit the details of such patients, i.e. name, address and the name of the treating oncologist, to the Office of the Controller of Patents and such report shall be submitted on or before 31st January of the year, in respect of the preceding year.
i. The licensee shall not have the right to import the drug covered by the Patent.
j. The license is for the balance term of the patent.
k. The license does not include any right to represent publicly or privately that the Licensee's product is the same as the Licensor's or that the Licensor is in any way associated with the Licensee's product. The Licensee's product must be visibly distinct from the Licensor's product (e.g. in color and / or shape); the trade name

must be distinct, and the packaging must be distinct. The Licensor will provide no legal, regulatory, medical, technical, manufacturing, sales, marketing, or any other support of any kind to the Licensee.

l. The Licensee is solely and exclusively responsible for its product and for all associated product liability. The Licensor, its Directors, Officers, Employees, Agents, and affiliates shall not be held liable in any manner whatsoever for any action of the licensee.

m. The Licensor is free to do whatever it wishes with its residual patent rights subject to the non-exclusive license to the Licensee, and is free to compete with the Licensee and to grant licenses to third parties to compete with the Licensee.

**Granted under my hand and seal on this the 9th day of March 2012.**

(P. H. Kurian)

Controller of Patents