सत्यमेव जयते
भारत सरकार
पेटेंट कार्यालय - बौद्धिक सम्पदा भवन
एस.एम. रोड, नजदीक अन्टॉप हिल डाकघर, अन्टॉप हिल , मुम्बई - 400 037
Government of India
Patent Office, Boudhik Sampada Bhawan
S.M. Road, Near Post office,
Antop Hill, Mumbai – 400 037, India

INTELLECTUAL PROPERTY INDIA
PATENTS | DESIGNS | TRADE MARKS
GEOGRAPHICAL INDICATIONS

दूरभाष Tel 022-24137701
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Email: mumbai-patent@nic.in
Website: www.ipindia.nic.in

संख्या /Letter No: GPM/RTI/ 94 दिनांक /Date: 15 / 10/ 2012

15/10/2012.

To,

**N. Sai Vinod,**
**Ministry of HRD Professor in IP Laws,**
**National University of Juridical Sciences,**
**Salt Lake City,**
**Sector III,**
**Kolkata – 700 098.**

**Sub : - Supply of Information sought under RTI Act, 2005 – reg.**

**Ref :- Photocopies regarding Compulsory License.**

Sir,

With reference to your application under Right to Information Act, 2005 dated 14/09/2012, and letter dated 13/10/2012, pertaining to photocopies of Compulsory License, I am forwarding herewith total 259 pages in the file under Section 84(1), 91, 92(1) and form – 17.

Yours faithfully,

**Encl : As above.**

**(N. Ramchander)**
**Asstt. Controller of Patents & Designs**
**& Central Public Information Officer**

## BEFORE THE CONTROLLER OF PATENTS, MUMBAI

**IN THE MATTER OF:**

Natco Pharma Limited ... APPLICANT/PETITIONER

**VERSUS**

Bayer Corporation ...RESPONDENT/PATENTEE

**INDEX**

Form 21

CBR रकम 7/07 ...दि...29/7/2011 के तहत भरा हुए।

रोकड़िया

FORM 17

THE PATENTS ACT, 1970
(39 of 1970)
&
THE PATENT RULES, 2003

**APPLICATION FOR COMPULSORY LICENCE**
[*See* sections 84(1), 91, 92(1) or 92A; rule 96]

We, **NATCO PHARMA LIMITED,** of NATCO House, Road No 2, Banjara Hills, Hyderabad 500 033, Andra Pradesh, India;

hereby apply for the grant of a compulsory licence under Patent No. **IN 215758, (formerly IN/PCT/2001/00799/MUM), dated 28.03.2008,** granted to **BAYER CORPORATION** of 100 Bayer Road, Pittsburgh, PA-15205-9741, USA on the following grounds namely:-

As enclosed herewith

We declare that the facts and matters stated herein are true to the best of my knowledge, information and belief.

The details of the documentary evicence in support of my/our interest and the grounds stated above are given below:

As enclosed herewith

Our Address for service in India is, **Rajeshwari and Associates,** 1039, First Floor, C- Block, Sushant Lok-I, Gurgaon -122002, Haryana, India

Rajeshwari

RAJESHWARI H
OF RAJESHWARI & ASSOCIATES
ADVOCATE/AGENT FOR THE APPLICANT

Dated this 28th day of July 2011

To
The Controller of Patents,
The Patent Office,
At Mumbai.

2

| Sl. No. | Particulars | Page Nos. |
|---|---|---|
| 2(vi) | Annexure-F: A copy of the printout of the GLOBOCAN 2008: Cancer Incidence, Mortality and Prevalence India, IARC Press, 2008. | 142-145 |
| 2(vii) | Annexure-G: A copy of the printout of the American Foundation for Urologic Disease. | 146-169 |
| 2(viii) | Annexure-H: A printout of Harvard Center for Cancer Prevention. Your Disease Risk: Kidney Cancer. Available at: http://www.diseaseriskindex.harvard.edu/update/hccpquiz.pl?lang=english&func=show&quiz=kidney&page=fact_sheet | 170-171 |
| 2(ix) | Annexure-I: A copy of the printout of Cancer Research UK. http://www.cancerhelp.org.uk/help/default.asp?_Page=4917#chemo | 172-177 |
| 2(x) | Annexure-J: A copy of the printout of American Cancer Society. Detailed Guide: Kidney Cancer. Available at: http://www.cancer.org/docroot/CRI/content/CRI_2_4_4x_Targeted_Therapies_22.asp?rnav=cri | 178-225 |
| 2(xi) | Annexure-K: A printout of the URL http://www.advfn.com/nasdaq/StockNews.asp?stocknews=ONXX&article=40430330&headline=uk-watchdog-says-bayer-liver-drug-nexavar-too-expensive | 226-228 |
| 2(xii) | Annexure-L: Copies of Awards and Certificates. | 229-232 |
| 2(xiii) | Annexure-M: A copy of the patent filed by NATCO. | 233-244 |
| 2(xiv) | Annexure-N: A copy of the manufacturing license granted to NATCO. | 245-247 |
| 2(xv) | Annexure-O: A copy of the letter dated 06.12.2010. | 248-250 |

FORM 17

THE PATENTS ACT, 1970
(39 of 1970)
&
THE PATENT RULES, 2003

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As enclosed herewith

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The details of the documentary evidence in support of my/our interest and the grounds stated above are given below:

**As enclosed herewith**

Our Address for service in india is, **Rajeshwari and Associates,** 1039, First Floor, C- Block, Sushant Lok-I, Gurgaon -122002, Haryana, India

Rajeshwari

RAJESHWARI H
OF RAJESHWARI & ASSOCIATES
ADVOCATE/AGENT FOR THE APPLICANT

Dated this 28th day of July 2011

To
The Controller of Patents,
The Patent Office,
At Mumbai.

1

## BEFORE THE CONTROLLER OF PATENTS, MUMBAI

**IN THE MATTER OF:**

Natco Pharma Limited ... APPLICANT/PETITIONER

**VERSUS**

Bayer Corporation ...RESPONDENT/PATENTEE

**APPLICATION UNDER SECTION 84(1) OF THE PATENTS ACT, 1970 (AS AMENDED) FOR GRANT OF COMPULSORY LICENCE**

**The Applicant abovenamed humbly submits as under :**

1. About the Applicant:

The Applicant herein is a company incorporated under the Companies Act 1956 and having its registered office at Natco House, Banjara Hills, Hyderabad. The Applicant was incorporated in the year 1981 and since then it has been in the business of research, development, manufacturing and marketing of pharmaceutical substances and finished dosage forms for Indian and International markets. From a humble beginning with 20 employees, the company has grown over the years into one with more than 2000 employees, including well trained scientists and researchers. The Applicant Company's core area of expertise lies in manufacture and development of anti-cancer drugs.

Further details about the Applicant are set out and explained later in the present application.

2. Subject matter of the present application:

The present application for compulsory licence is being preferred in respect of a product called 'Sorafenib' which is a compound said to be covered by Indian patent no. 215758 granted on 03.03.2008 to the Patentee. It is belived that the active pharmaceutical ingredient 'sorafenib' is covered by this Patent. A copy of the Indian patent no.215758 granted on 03.03.2008 is annexed herewith at **Annexure-A.** The Applicant prays for leave to file certified copy of the Patent in due course. The said product being an inhibitor of several Tyrosine protein kinases (VEGFR and PDGFR) and RAf kinase is used for the **treatment of primary kidney and advanced primary liver cancer.** The said product is marketed under the brand name NEXAVAR by the Patentee. The **Nexavar cost of therapy per month is Rs.2,80,428/-**. A copy of the product label of Nexaver is annexed herewith as **Annexure-B**.

**3. Hepatocellular Carcinoma Fact Sheet**

A. **The Disease**

Hepatocellular carcinoma (HCC), also known as primary liver cancer, is the most common form of liver cancer and is responsible for 80 percent of the primary malignant liver tumors observed in adults (source: World Cancer Report, 2008 IARC Press 2008, page 180 to 185 is annexed herewith as **Annexure-C**). For patients diagnosed with HCC the prognosis is poor because symptoms usually do not appear until a late stage in the disease (A print out of the hyperlink Mayo Clinic,

http://www.mayoclinic.com/health/liver-cancer/DS00399/DSECTION=treatments-and-drugs is annexed herewith as **Annexure-D**) In other words, most cases of HCC are detected only at a very late stage.

B. **Key Statistics**

- HCC is the fifth most common cancer worldwide (source: page 180) with a five-year relative survival rate of about seven percent.
- HCC disproportionately affects men, with four times as many men developing HCC as women.
- HCC causes more than 700,000 deaths annually worldwide.
- In 2008 approximately 20,144 cases of HCC were reported in India, and more than 18,043 Indians died of HCC;

  The above information has been obtained from the following sources, copies of which are annexed hereto as **Annexure-D, E, F,** respectively:

  1) Mayo Clinic Report.
  2) World Cancer Report 2008 IARC Press, 2008 (page 224 to 229).
  3) GLOBOCAN 2008: Cancer Incidence, Mortality and Prevalence India, IARC Press, 2008.

**4. Renal Cell Carcinoma Fact Sheet**

**A. The Disease**

- Renal cell carcinoma (RCC) is the most common type of kidney cancer in adults, causing 85 percent of all kidney cancers. (source: American Foundation for Urologic Disease is annexed hereto as **Annexure-G**)

- Despite advances in understanding the growth mechanisms of many different tumor types, kidney cancer is still not fully understood. It is believed that both the Ras signaling pathway and angiogenesis may play a role in kidney cancer.

**B. Key Statistics**

- Kidney cancer disproportionately affects men, with roughly twice as many men as women developing the disease annually.
- The risk of kidney cancer increases with age. Over 90 percent of cases are diagnosed after age 45. The average age among newly-diagnosed kidney cancer patients is 66. (source: Harvard Center for Cancer Prevention. Your Disease Risk: Kidney Cancer. Available at: http://www.diseaseriskindex.harvard.edu/update/hccpquiz.pl?lang=english&func=show&quiz=kidney&page=fact_sheet)
- At the time of diagnosis, normally the cancer has already metastasized (spread to distant body locations) in about one-third of people with kidney cancer. (source: American Foundation for Urologic Diseases)
- For patients with early-stage kidney cancer, the five-year survival rate is between 70 and 98 percent (source: Globocon 2008). In later-stage disease, when the cancer has metastasized, the five-year survival rate is between 15 and 18 percent. (source: American Foundation for Urological Diseases)
- In 2008, about 8,900 Indians were diagnosed with kidney cancer, and about 5,733 died from the disease. (source: Harvard Center for Cancer Prevention. Your Disease Risk: Kidney Cancer. Available at: http://www.diseaseriskindex.harvard.edu/update/hccpquiz.pl?lang=english&func=show&quiz=kidney&page=fact_sheet) (source:

GLOBOCAN 2008: Cancer Incidence, Mortality and Prevalence in India IARC Cancer IARC Press, 2008)

The above information has been collected from the following sources, copy of which are annexed hereto as **Annexure-G** and **Annexure-H** respectively:

i) American Foundation for Urologic Diseases.

ii) Harvard Center for Cancer Prevention. Your Disease Risk: Kidney Cancer. Available at: http://www.diseaseriskindex.harvard.edu/update/hccpquiz.pl?lang=english&func=show&quiz=kidney&page=fact_sheet.

**5. Position in India:**

It is submitted that at this point to the knowledge of the Petitioner, who has been in this field of treating cancer patients for over 20 years, there are at least 1,00,000 patients in India suffering from different forms and types of renal cell carcinoma and hepatic cell carcinoma. On an average, about 30,000 patients are diagnosed every year and added to the patient pool. Over 24000 patients die in India every year on account of these diseases.

**6. Treatment.**

**Treatment-Liver Cancer**

- Treatment options for HCC depend on the stage of the malignant disease, underlying liver function, which is a determinant of the usually co-existing cirrhosis, as well as the patient's overall condition.
- The three main types of treatment for liver cancer are surgery (including liver transplantation), locoregional treatment modalities and

chemotherapy. Sometimes two or more of these methods are combined.

- Surgery offers the only chance to treat liver cancer. If the cancer is found at an early stage and the rest of the liver is healthy, surgery with or without liver transplantation may be curative. However, only about 15% of patients have resectable disease (source: Cancer Research UK, http://www.cancerhelp.org.uk/help/default.asp?page=4917#chemo which is annexed hereto as **Annexure-I**) Even after surgery the five-year survival rate is only about 30 to 40 percent.

**Treatment – Kideny Cancer**

- The treatment of RCC depends on the severity of the cancer and the patient's overall health.
- The primary therapy for kidney cancer is surgery, which is effective only when all of the cancer is removed. Radiation treatment is also used when the cancer has spread beyond the kidney. (source: American Foundation for Urologic Disease)
- Immune modulators, such as interferon-alpha and interleukin-2 (IL-2), are sometimes used, but response rates remain relatively low with these treatments (source: American Cancer Society. Detailed Guide: Kidney Cancer. Available at: http://www.cancer.org/Cancer/KidneyCancer/DetailedGuide/index printout is annexed hereto as **Annexure-J**)
- Chemotherapy – in some cases, since kidney cancer is resistant to chemotherapy.
- Several newer forms of therapy that target specific parts of cancer cells have been used to treat people with advanced kidney cancer. These include drugs that stop angiogenesis (new blood vessel

growth) and drugs that target other important cellular growth factors. One of such drugs is Sorafenib tosylate.

Sorafenib:

Sorafenib is prescribed by the physician, it is administered as 200mg tablet and the dosage per day is 800mg. which translates to two tablets in the morning and two tablets in the night. The tablets must be consumed till the tumor progression/ intolerable toxicity. Normally, patients with renal carcinoma may be covered and may receive insurance cover for nephrectomy; however patients do not receive any cover/assistance from Insurance companies for the use of the drug Sorafenib. The drug Sorafenib has to be taken by the patient throughout his lifetime.

| | | |
|---|---|---|
| Treatment of diseases | - | Renal cell carcinoma and hepatic cell carcinoma. |
| Drug | - | Sorafenib Tosylate. |
| Dosage | - | 400 mg, twice a day (4 tablets a day). |
| Duration of treatment | - | Lifetime. |
| Price | - | Rs.2,80,428 per month per patient. |
| Insurance | - | Nil. |

**Survival rate:**

The survival rate in case of renal and hepatic carcinoma depends entirely on the stage of the disease. In advanced metastatic renal carcinoma, the survival rate is extremely poor and patients may live for few months to 3-5 years. Hepatic cell carcinoma is even worst with a survival rate of less than 10% and life span of not more than 12 months.

From the above it is clear that the product Sorafenib which is the subject of the present application is drawn to treat a gruesome disease that hardly has a cure and patients afflicted by this deadly disease if put on Sorafenib, must be given this treatment for their entire lifetime and should be able to access this drug irrespective of their caste, creed, affordability etc.

7. The Patentee and Sorafenib:

Sorafenib- limited availability: It is submitted that the product Sorafenib is exhorbitantly priced and limited in availability in India as explained below:

a) Product imported: It is learnt that the Patentee Bayer Corporation imports and sells the drug sorafenib in India. To the knowledge of the Applicant, this product is not manufactured in India by the Respondent. The price of each tablet is Rs2337. As stated earlier, the average requirement per patient per month is about 120 tablets which works out to about Rs 2,80,428/- month and about Rs 33,65,136/- per year. Thus the product is exhorbitantly priced and almost out of reach of most of the people in India.

b) Limited availability: The said product 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 and in second tier or other smaller cities in India. Hence the product sold by the Patentee is extremely highly priced and is limited in availability. Currently, to the Bayer is operating with 12 distributors in India. To the knowledge of the Applicant, the Distributors are in Delhi, U.P., Punjab, Gujarat, West Bengal, Bihar, Vardman, Kerala and Tamil Nadu. There are no distributors atleast

in the states of Madhya Pradesh, Jammu and Kashmir, Orissa, Rajasthan, Haryana, Chhattisgarh, Uttarakhand, Jharkhand, Himachal Pradesh, Assam, Arunachal Pradesh, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim, Tripura, Rest of Maharastra, Goa, Pondicherry.

c) It is estimated that though the Patentee sells the product, it reaches less than 1% of patients and almost 99 % of patients who are unable to afford the drug are left to die every year.

According to GLOBOCAN data at least **30,000** patients are diagnosed every year who suffer from Liver and Kidney cancer. It is estimated that nearly **1,00,000** patients are currently suffering in India on these diseases. Of these, **less than 1% of patients are catered to by the Rspondent Bayer.** The remaining 99% of the patients do not receive any medication and thereby fall victim and die on account of this dreaded diseases.

d) Requirement Vs. Availability

As stated earlier, the approx member of patients in India suffering from RCC & HLC is about 1,00,000. Since the prescribed regimen is 2 tablets a day, the total requirement per month = 120 tablets. Bayer does not manufacture the product Sorafenib in India. The number of Sorafenib tablet in the market is far less than the requirement under demand for the patients.

e) Product Sorafenib found to be expensive in UK and US: It is important to note that in the UK, the National Health Service often subsidizes the price of important pharmaceuticals products such as

those used for treatment of cancer. The NHS, after going through the price of Nexavar [which in UK works out to about £2504.60] and the schemes offered by the Patentee [buy 3 and get one free] found that the price of Nexavar is too expensive and NHS decided not to sponsor or subsidize the said drug under its schemes. The relevant information is available at the url:

(source: http://www.advfn.com/nasdaq/StockNews.asp?stocknews=ONXX&article=40430330&headline=uk-watchdog-says-bayer-liver-drug-nexavar-too-expensive, a printout of which is annexed hereto as **Annexure-K**)

Similarly, in US, the product Nexavar is not subsidized by any authority and the price is about USD 4300per month.

8. Conclusion:

In view of the above analysis, the Applicant submits that :

a) more than three years from the date of grant of the patent no 215758 have elapsed [the patent was granted on 03-03-2008] and yet, the patentee Bayer has not taken adequate steps to manufacture in India and make full use of the invention;

b) a prima facie case of reasonable requirements of the public not being satisfied is deemed to be made out because :

   i) the number of people who need access to the product Sorafenib to prolong their life or improve their health significantly exceeds those with actual access to the drug (60 -Vs- 3000)[1-% vs. 99%], and

   ii) a substantial barrier to access the product is price: (Rs.2,80,482 per month)

It is in these circumstances that the present application for compulsory licence is being preferred.

9. Applicant's interest:

a) As stated in the foregoing paragraphs, the Applicant herein is a pharmaceutical company engaged in the manufacture of several anti-cancer products for last 20 years. Some of the products manufactured by the Applicant include Imatinib, Geftinib, Lenalidomide, etc.

b) Why the Applicant prays for grant of compulsory licence:

The Applicant herein submits that they have been performing research and development of various anti-cancer drugs. The applicant having known the plight of the cancer patients and the difficulties facilities faced by them, has decided to develop, manufacture and sell the said product Sorafenib to such needy patients irrespective of their location in India, at the lowest possible price so that access and availability of the drug is improved. The Applicant submits that this project is being undertaken is absolute bonafides, without any oblique commercial motives whatsoever.

10. Capability of the Applicant: The Applicant submits that as stated earlier, the Applicant is one of the foremost and leading pharmaceutical companies in India. The Applicant has its own manufacturing and marketing strengths as detailed below:

a. Recognition of the R&D facilities:

The Applicant submits that its R&D facilities conform to the strictest standards adopted anywhere in the world. All the facilities are GMP certified, and the Applicant follows GMP practices as prescribed by the US FDA for both API and Formulation. (Copies of Awards and Certificates are produced herewith as **Annexure-L**)

b. Facilities to manufacture sorafenib:

In so far as the product Sorafenib is concerned, the Applicant herein does have the requisite technical know-how to develop and manufacture the product Sorafenib on a large scale. The Applicant herein has applied and obtained a patent for a process of producing sorafenib, copy of which is annexed herewith as **Annexure-M**. The applicant submits that it can manufacture the product sorafenib by employing the existing facilities and does not require any additional plant/machinery or investment for the same since the Applicant is already manufacturing other anti cancer products.

c. Ability of Applicant to market the product:

The Applicant submits that they do have the abilities and capabilities to manufacture the product Sorafenib (*should the*

*licence be granted*) and cater to the needs and necessity of the entire population suffering from renal cancer and/or hepatic cell carcinoma.

d. Proposed Capacity:

The Applicant can manufacture the product at the rate of **20,00,000** tablets a day, amounting to about **6,00,00,000** tablets per month. There is a need for supply of 4,80,000 tablets a month, which this Applicant can easily manufacture and supply.

e. Proposed Price:

The Applicant proposes cost of about **Rs 74/- per tablet,** working out to **Rs 8,880/-** per month for treatment to a patient. The Applicant is also ready and willing to manufacture and offer for free the tablets to patients who cannot afford even the proposed price.

f. Marketing / Distributor Network:

The Applicant has already obtained approval from the Drug Controller General of India for manufacture and marketing of the product Sorafenib in India. A copy of the license granted is

annexed herewith as **Annexure-N**. Hence, the Applicant has the potential to manufacture and market the drug in India.

The Applicant is already supplying anti cancer products to various hospitals all over India. Its drugs are found with almost all of the chemists all over India. The Applicant has the distribution network in almost every city in India including all the districts in the country. The Applicant is ready and willing to furnish details of its distributors if so called for by the Learned Controller.

11. Efforts by Applicant to obtain voluntary licence:

The Applicant herein had made independent efforts to obtain licence to manufacture and sell the product Sorafenib in India and by virtue of letter dated 06th Dec 2010, the Applicant had requested the patentee for such licence. The Patentee refused the same vide letter dated 27th Dec 2010. The copies of the said letters dated 06th December 2010 and dated 27th December 2010 are annexed herewith as **Annexure-O** and **Annexure-P** respectively.

12. The grounds for grant of licence

The Applicant submits that in view of the facts and circumstances described above, a prima facie case that reasonable requirements of

the public not being satisfied and for grant of compulsory license is made out because:

a. the Applicant herein had made a request for licence which was turned down and refused by the Patentee point blank, without any discussion whatsoever, and on account thereof, establishment of a new trade or industry for supply of Sorafenib to needy patients is severely hampered;

b. as explained above, the number of patients and the actual demand in the market for Sorafenib far exceeds the supply thereof by the Patentee and hence the demand for the patented product has not been met to an adequate extent;

c. as explained above, the price of the patented product Sorafenib 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;

d. the Applicant bonafidely believes that the market for export of the drug to developing and under-developing countries is not being supplied or developed;

e. on account of refusal of the licence, the establishment of commercial activities in India in respect of the patented product and supply thereof to needy patients is totally prejudiced;

f. the patented product is being imported into India by the Patentee and is not manufactured within India- hence the product is not worked in the territory of India to the fullest extent that is reasonably practicable;

g. the patented product is available in limited quantities and that too only in certain select places in certain cities - hence the product is not worked in the territory of India to an adequate extent or not worked to the fullest extent that is reasonably practicable;

h. the working of the patented product in India is hindered in India due to importation of the patented product from abroad by the patentee and those claiming under him.

i. The practice adopted by the Patentee of exorbitantly pricing its patented life-saving product is abuse of its monopolisitic rights and such practice is unfair and anti-competitive;

13. The Applicant craves leave to submit certified copies of the Patent document IN 215758 in due course and any other documents as may be called for by this office.

14. The terms:

After adjudication, should the learned Controller decide to grant compulsory licence in favour of the Applicant herein, the Applicant is prepared to accept the same on the following terms:

a. the right to manufacture and sell Sorafenib shall be limited to the territory of India- the Applicant shall not use the licence for sale to other countries. Aplicant shall take all necessary steps to ensure that the product is sold and available only within the territory of India. All products under the Licence shall be marked specifically that they are for sale and use in India only;

b. the products under licence shall be manufactured only to cover patients who are afflicted by renal and hepatic carcinoma ; preferance shall be given to patients who are economically weak, government welfare schemes and those in backward areas ;

c. the Applicant agrees to pay a royalty to the Patentee at the rate as fixed by the Ld Controller;

d. Applicant agrees to make available the patented product at the most reasonable and affordable price possible. Initially the applicant proposes a price of Rs 74 per tablet which works out to Rs 8880 /- for month for the treatment.

e. Agrees to offer the drug free of cost to deserving and needy for their lifetime.

The Applicant agrees to be bound by any other terms and conditions as may be imposed by the Ld Controller.

15. C.S. (OS) No.1090/2011.

It is submitted that the Respondent Bayer Corporation, has filed Civil Suit No.1090/2011 in the High Court of Delhi against the Applicant alleging infringement of Patent No.215758. The present application has been filed without prejudice to the contentions, rights and liberties of this Applicant in the said suit.

16. In view of the above submissions, the Applicant humbly prays that:

a) the Ld Controller may be pleased to grant and issue Compulsory licence in favour of the applicant herein in respect of Indian patent no 215758 upon terms and conditions that the Ld Controller may deem fit and proper in the circumstances of the case;

(iii) such other or further reliefs be granted to meet the ends of justice.

For NATCO PHARMA LIMITED

M. ADINARAYANA
Company Secretary & G.M.
(Legal & Corporate Affairs)

[M. ADINARAYANA]
For APPLICANT

Advocate for the APPLICANT

Delhi
Dated: 28/07/2011

**VERIFICATION**

Verified at Delhi on this 28th day of July, 2011 that the contents of the Reply are based on legal advise received and believed to be true (save and except fact for which I have relied on matters of record). No part of it is false and nothing material has been concealed therefrom.

For NATCO PHARMA LIMITED

M. ADINARAYANA
Company Secretary & G.M
(Legal & Corporate Affairs)

[M. ADINARAYANA]
For APPLICANT

1

20 ANNEXURE A
215758
03/03/2008
Granted

**FORM 2**
THE PATENTS ACT 1970
[39 OF 1970]
&
THE PATENTS RULES, 2003

# COMPLETE SPECIFICATION

[See Section 10; rule 13]

"CARBOXYARYL SUBSTITUTED DIPHENYL UREAS"

BAYER CORPORATION, 100 Bayer Road, Pittsburgh, Pennsylvania, 15205, U.S.A.,

The following specification particularly describes the invention and the manner in which it is to be performed:

GRANTED

GRANTED

original
In PCT/2001/1799 mum
05/07/2001

25