



REPORT

RTI APPLICATIONS AND “WORKING” OF FOREIGN DRUGS IN INDIA?

APRIL 2011

ANNEXURE D

SpicyIP Report prepared by Professor Shamnad Basheer (Founder of SpicyIP and MHRD Prof of IPLaw, NUJS), with the assistance of Sai Vinod N (SpicyIP Blogger and NUJS Student)



RTI APPLICATIONS & "WORKING" OF FOREIGN DRUGS IN INDIA?

ANNEXURE D

Form 27 Statements filed by the Patentees of the following drugs are attached below:

S. No	PATENT NO.	NAME OF THE DRUG	YEAR
1	203937	Dasatinib	2008
2	203937	Dasatinib	2009
3	215758	Nexavar	2008
4	215758	Nexavar	2009
5	215758	Nexavar	2009
6	213457	Entecavir	2008
7	213457	Entecavir	2009
8	198952	Pegasus	2009
9	207233	Viraferonpeg	2008
10	196774	Tarceva	2008
11	196774	Tarceva	2009
12	196774	Tarceva	2010
13	209251	Sutent	2009



सत्यमेव जयते
भारत सरकार

पेटेंट कार्यालय - बौद्धिक सम्पदा भवन

एस.एम. रोड, नजदीक अन्टॉप हिल डाकघर, अन्टॉप हिल, मुंबई - ४०००३७, भारत.

Government of India

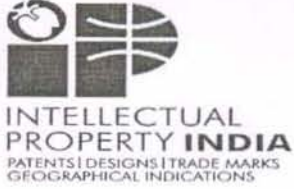
Patent Office - Boudhik Sampada Bhawan

S. M. Road, Near Antop Hill Post office,
Antop Hill, Mumbai - 400037, India

दूरभाष Tel: ☎ 022-24141026
022-24150381
022-24137701

फॅक्स Fax: ☎ 022-24130387

Email: mumbai-patent@nic.in
Website: www.ipindia.nic.in



No. RTI/6909/MUM

Date : 10/01/2011

To,
Prof. Shamnad Basheer,
Ministry of HRD Chair on IPR Laws,
West Bengal, National University of Juridical Sciences,
NUJS Bhavan, 12 LB Block,
Salt Lake City, Sector III,
Kolkata - 700 098

Subject : Information sought under RTI Act, 2005

Sir,

With reference to your RTI application dated 16/12/2010, received in this office on 22/12/2010, in respect of Patent No. 203937, 215578, 213458.

The details requested for statement regarding working of the Patented Invention i.e. Form - 27 from the year 2007 to 2010.

I am enclosing herewith Form - 27 year wise as follows :

1.	203937	2008, Form -27 enclosed and for the year 2009 Form - 27, is filed but not traceable. We will supply the same as soon as possible.
2.	215578	Form - 27 enclosed for the year 2008, and 2009
3.	213458	Form - 27 enclosed for the year 2008 and 2009

Thanking you,

Yours faithfully,


(N. Ramachander)

Asstt. Controller of Patents & Designs
Central Public Information Officer

COMMERCIAL SCALE IN INDIA

[See Section 146(2) and rule 131]

In the matter of Patent No. **203937**
of 12/04/2000I/We, **BRISTOL-MYERS SQUIBB COMPANY**the patentee(s) under Patent No. **203937** hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year 2008 .

- (i) The patented invention:
[] Not worked

If not worked: reasons for not working and steps being taken for working of the invention:
Nothing in particular

If worked: quantum and value (in Rupees) of the patented product:
Not applicable

Manufactured in India:
Not applicable

Imported from other countries (give countrywise details):
Nil

- (ii) the licenses and sub-licences granted during the year:
Nil

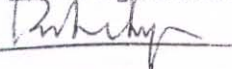
- (iii) state whether public requirement has been met partly/adequately/to the fullest extent at reasonable price:
Not applicable

The facts and matters stated above are true to the best our knowledge, information and belief.

Dated this 28 day of March 2009

BRISTOL-MYERS SQUIBB COMPANY

by his/their Agent and Attorney



(R. P. Bhattacharya)
of DePenning & DePenning

FORM 27
THE PATENTS ACT, 1970
(39 OF 1970)

&

THE PATENTS RULES, 2003
STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON A
COMMERCIAL SCALE IN INDIA
[See Section 146(2) and Rule 131(1)]

In the matter of Patent No. 203937 of 2001

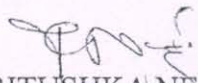
We, BRISTOL-MYERS SQUIBB COMPANY, a Corporation of Delaware, BRISTOL-MYERS SQUIBB COMPANY, P.O. Box 4000, Lawrenceville-Princeton Road, Princeton, New Jersey 08543-4000, United States of America

The patentees under Patent No. 203937 hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year 2009:

- (i) The patented invention:
() Worked () Not worked (Tick mark the relevant box)
- (a) If not worked reasons for not working and steps being taken for working of the invention: _____
- (b) If worked: quantum and value (in Rupees), of the patented product: Rs. 160,236K which works out to US\$ 3,483,000
- (i) Manufactured in India: -
- (ii) Imported from other countries. (give Country wise details): _____
- (ii) The licences and sub-licences granted during the year: NIL
- (iii) State whether public requirement has been met partly/adequately/to the fullest extent at reasonable price: "The current demand for the product is being met fully at a reasonable price. Additionally, the product is being provided under a Patient Assistance Program. The Patentee has established a Research and Development center in India."

The facts and matters stated above are true to the best of our knowledge, information and belief.

Dated this 27th day of March, 2010.


[RITUSHKA NEGI]
OF REMFRY & SAGAR
AGENT FOR THE PATENTEEES

TO
THE CONTROLLER OF PATENTS
THE PATENT OFFICE, MUMBAI

The Patents Act, 1970
(39 of 1970)

**STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON
COMMERCIAL SCALE IN INDIA**
[See Section 146(2) and rule 131]

In the matter of Patent No. **215758**
of 12/01/2000

I/We, **BAYER PHARMACEUTICALS CORPORATION**
the patentee(s) under Patent No. **215758** hereby furnish the following statement regarding the working of the
patented invention referred to above on a commercial scale in India for the year 2008 .

- (i) The patented invention:
[] Not worked

If not worked: reasons for not working and steps being taken for working of the invention:
Nothing in particular

If worked: quantum and value (in Rupees) of the patented product:
Not applicable

Manufactured in India:
Not applicable

Imported from other countries (give countrywise details):
Nil

- (ii) the licenses and sub-licences granted during the year:
Nil

- (iii) state whether public requirement has been met partly/adequately/to the fullest extent at
reasonable price:
Not applicable

The facts and matters stated above are true to the best our knowledge, information and belief.

Dated this 23 day of March 2009

BAYER PHARMACEUTICALS CORPORATION
by his/their Agent and Attorney



(R. P. Bhattacharya)
of DePenning & DePenning

ORIGINAL

FORM 27
THE PATENTS ACT, 1970
(39 OF 1970)

&

THE PATENTS RULES, 2003

STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON A
COMMERCIAL SCALE IN INDIA
[See Section 146(2) and Rule 131(1)]

In the matter of Patent No. 215758 of 2001

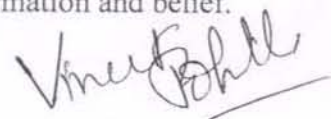
We, BAYER CORPORATION, a Corporation of the State of Indiana of 100 Bayer Road,
Pittsburg, Pennsylvania 15205, USA

The patentees under Patent No. 215, 758 hereby furnish the following statement regarding the
working of the patented invention referred to above on a commercial scale in India for the year
2009 :

- (i) The patented invention:
() Worked () Not worked (Tick mark the relevant box)
- (a) If not worked reasons for not working and steps being taken for working of the
invention: N.A.
- (b) If worked: quantum and value (in Rupees), of the patented product:
Imported: 4,665;
Net Sales: 1,679; Rs. 163,895,944
(i) Manufactured in India: NIL
(ii) Imported from other countries. (give Country wise details): Germany
- (ii) The licences and sub-licences granted during the year: NIL
- (iii) State whether public requirement has been met partly/adequately/to the fullest extent at
reasonable price: The Patentee believes that the public requirement is being met
adequately.

The facts and matters stated above are true to the best of our knowledge, information and belief.

Dated this 31.03.2010.



[VINEET ROHILLA]
OF REMFRY & SAGAR
AGENT FOR THE PATENTEEES

TO, THE CONTROLLER OF PATENTS
THE PATENT OFFICE, MUMBAI

The Patents Act, 1970
(39 of 1970)

**STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON
COMMERCIAL SCALE IN INDIA**
[See Section 146(2) and rule 131]

In the matter of Patent No. **213457**
of 26/01/2001

I/We, **BRISTOL-MYERS SQUIBB COMPANY**
the patentee(s) under Patent No. **213457** hereby furnish the following statement regarding the working of the
patented invention referred to above on a commercial scale in India for the year 2008 .

- (i) The patented invention:
[] Not worked

If not worked: reasons for not working and steps being taken for working of the invention:
Nothing in particular

If worked: quantum and value (in Rupees) of the patented product:
Not applicable

Manufactured in India:
Not applicable

Imported from other countries (give countrywise details):
Nil

- (ii) the licenses and sub-licences granted during the year:
Nil

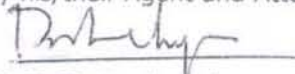
- (iii) state whether public requirement has been met partly/adequately/to the fullest extent at
reasonable price:
Not applicable

The facts and matters stated above are true to the best our knowledge, information and belief.

Dated this 19 day of March 2009

BRISTOL-MYERS SQUIBB COMPANY

by his/their Agent and Attorney


(R. P. Bhattacharya)
of DePenning & DePenning

The Controller of Patents
The Patent Office
Mumbai

FORM 27
THE PATENTS ACT, 1970
(39 OF 1970)
AND
THE PATENT RULES, 2003
STATEMENT REGARDING THE WORKING OF THE PATENTED
INVENTION COMMERCIAL, SCALE IN INDIA
[See section 146(2); rule13 (1)]

In the matter of Patent No 213457 of Bristol-Myers Squibb Company

We, Bristol-Myers Squibb Company,

The patentee under patent 213457 hereby furnish the following statement regarding the working of the patented invention referred to above on a Commercial scale in India for the Year 2009.

The patent invention:

{} Worked { } Not worked

> 230,000,000 INR of the patented product:

(i) manufactured in Ireland and the United States and exported to India.

(ii) the licenses and sublicenses granted with details of license deeds - none

(iii) information with regard to meeting public requirement
The current demand for the product is being met fully at a reasonable price. Additionally, the product is being provided under a Patient Assistance Program. Furthermore, Bristol-Myers Squibb Co. has established a Research and Development center in India."

The fact and matter stated above are true to the best of my/our knowledge, information and belief.

Dated this 14th day of June 2010



Signature
Mrs. L. Balasubrahmanyam
Authorised Agent for Applicant

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

Form-27

The Patents Act, 1970
(39 of 1970)

**STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON
COMMERCIAL SCALE IN INDIA**

[See Section 146(2) and rule 131(1)]

In the matter of Patent No. **198952**
of **15/05/1997**

I/We, **F. HOFFMANN-LA ROCHE AG**

the patentee(s) under Patent No. **198952** hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year **2009**

- (i) The patented invention:
[] worked [] not worked (tick relevant box [])

If not worked: Not applicable

If worked: quantum and value (in Rupees), of the patented product:

Quantum (imported): Pegasys (1's) – 47574 packs.

Quantum (sold in India): Pegasys (1's) – 44432 packs.

Value (Imported): 100,10,700 CHF or Rs. 450,881,928 (CHF 1 = INR 45.04 as on 31.12.2009)

Value (sold in India): Rs. 4263.89 Lakhs.

Manufactured in India: No.

Imported from other countries. (give country-wise details): Yes.

- (ii) the licences and sub-licences granted during the year : Nil.
- (iii) state whether public requirement has been met partly / adequately / to the fullest extent at reasonable price. Yes, according to the estimation of the patentees.

The facts and matters stated above are true to the best of our knowledge, information and belief.

Dated this 12th day of March 2010

The Controller of Patents
The Patent Office
At Chennai

F. HOFFMANN-LA ROCHE AG
By his/their Agent and Attorney


(R. P. BHATTACHARYA)
of DePENNING & DePENNING

The Patents Act, 1970
(39 of 1970)

**STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON
COMMERCIAL SCALE IN INDIA**
[See Section 146(2) and rule 131]

In the matter of Patent No. **207233**
of 24/03/1999

I/We, **SCHERING CORPORATION**

the patentee(s) under Patent No. **207233** hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year 2008 .

- (i) The patented invention:
[] Worked

If not worked: reasons for not working and steps being taken for working of the invention:
Not applicable

If worked: quantum and value (in Rupees) of the patented product:
Information not readily available. Information will be provided if asked for.

Manufactured in India:
No

Imported from other countries (give countrywise details):
Yes; imported from Ireland.

- (ii) the licenses and sub-licences granted during the year:
Nil

- (iii) state whether public requirement has been met partly/adequately/to the fullest extent at reasonable price:
Yes; according to the estimation of the patentees.

The facts and matters stated above are true to the best our knowledge, information and belief.

Dated this 30 day of March 2009

SCHERING CORPORATION

by his/their Agent and Attorney


(R. P. Bhattacharya)
of DePenning & DePenning

Filed on 30.03.2009 by Depenning & Depenning

Form-27

The Patents Act, 1970
(39 of 1970)

**STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON
COMMERCIAL SCALE IN INDIA**

[See Section 146(2) and rule 131(1)]

In the matter of Patent No. **196774**
of **13/03/1996**
in the name of **PFIZER PRODUCTS INC, USA**
and **OSI PHARMACEUTICALS, INC, USA**

We, **F. HOFFMANN-LA ROCHE AG of Basel, Switzerland**

the **licensee(s)** under Patent No. **196774** hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year **2008**.

- (i) The patented invention:
[] worked [] not worked (tick relevant box [])

If not worked: Not applicable

If worked: quantum and value (in Rupees), of the patented product:

Quantum: Tarceva Tabs 100 mg (pack of 3 strips) – 504 packs
Value : Rs. 25233120 (approximately).

Quantum: Tarceva Tabs 150 mg (pack of 3 strips) – 1287 packs
Value : Rs. 79220000 (approximately).

Manufactured in India: No.

Imported from other countries. (give country-wise details): Yes.

- (ii) the licences and sub-licences granted during the year : Yes.
- (iii) state whether public requirement has been met partly / adequately / to the fullest extent at reasonable price. Yes, according to the estimation of the licensees.

The facts and matters stated above are true to the best of our knowledge, information and belief.

Dated this 24th day of March 2009

The Controller of Patents
The Patent Office
At Delhi

F. HOFFMANN-LA ROCHE AG
By his/their Agent and Attorney


(R. P. BHATTACHARYA)
of DePENNING & DePENNING

Filed on 25.03.2010

by DePenning & De Penning

Form-27

The Patents Act, 1970
(39 of 1970)

**STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON
COMMERCIAL SCALE IN INDIA**

[See Section 146(2) and rule 131(1)]

In the matter of Patent No. **196774** *537/DEL/1996*
of **13/03/1996**
in the name of **PFIZER PRODUCTS INC, USA**
and **OSI PHARMACEUTICALS, INC, USA**

We, **F. HOFFMANN-LA ROCHE AG of Basel, Switzerland**

the **licensee(s)** under Patent No. **196774** hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year **2009**.

- (i) The patented invention:
[] worked [] not worked (tick relevant box [])

If not worked: Not applicable

If worked: quantum and value (in Rupees), of the patented product:

Quantum (Imported) : Tarceva* Tabs – 2268 packs of 30 Tablets
Quantum (sold in India) : Tarceva* Tabs – 2089 pack of 30 Tablets

Value (Imported): 3200400 CHF or Rs. 144,146,016 (CHF 1 = INR 45.04 as on 31.12.2009)
Value (sold in India): Rs. 1368.00 Lakhs.

*The patent covers the compound 'erlotinib' which is the active ingredient of the product 'Tarceva'.

Manufactured in India: No.

Imported from other countries. (give country-wise details): Yes; imported from Switzerland

- (ii) the licences and sub-licences granted during the year : Yes.
- (iii) state whether public requirement has been met partly / adequately / to the fullest extent at reasonable price. Yes, according to the estimation of the licensees.

The facts and matters stated above are true to the best of our knowledge, information and belief.

Dated this 12th day of March 2010

The Controller of Patents
The Patent Office
At Delhi

F. HOFFMANN-LA ROCHE AG
By his/their Agent and Attorney


(R. P. BHATTACHARYA)
of DePENNING & DePENNING

Filed on 17.02.2011

by De Penning & De Penning

Form-27

**The Patents Act, 1970
(39 of 1970)**

**STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON
COMMERCIAL SCALE IN INDIA**

[See Section 146(2) and rule 131(1)]

In the matter of Patent No. **196774**
of **13/03/1996**
in the name of **PFIZER PRODUCTS INC, USA**
and **OSI PHARMACEUTICALS, INC, USA**

We, **F. HOFFMANN-LA ROCHE AG of Basel, Switzerland**

the **licensee(s)** under Patent No. **196774** hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year **2010**.

- (i) The patented invention:
[] worked [] not worked (tick relevant box [)

If not worked: Not applicable

If worked: quantum and value (in Rupees), of the patented product:

Quantum (Imported) : Tarceva Tabs – 3689 packs of 30 Tablets

Quantum (sold in India) : Tarceva Tabs – 2125 pack of 30 Tablets

Value (Imported): 3442400 CHF or Rs. 161,001,048 (CHF 1 = INR 46.77 as on 31.12.2010)

Value (sold in India): Rs. 1238.92 Lakhs.

Manufactured in India: No.

Imported from other countries. (give country-wise details): Yes; imported from Switzerland

- (ii) the licences and sub-licences granted during the year : Yes.
- (iii) state whether public requirement has been met partly / adequately / to the fullest extent at reasonable price. Yes, to the fullest extent according to the estimation of the licensees.

The facts and matters stated above are true to the best of our knowledge, information and belief.

Dated this 15th day of February 2011

The Controller of Patents
The Patent Office
At Delhi

F. HOFFMANN-LA ROCHE AG
By his/their Agent and Attorney

M. Basu
(M. BASU)
REG. NO. IN/PA-377
DePENNING & DePENNING

Filed on 31.03.2010 by ANAND AND ANAND

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

**STATEMENT REGARDING THE WORKING OF THE PATENTED
INVENTION ON COMMERCIAL SCALE IN INDIA**

[See section 146(2) and rule 131(1)]

In the matter of patent No. 209251, of


We, **Sugen Inc.**, the patentee(s) under Patent No. 209251 hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year 2009.

- (i) The patented invention:*
{} Worked { } Not worked [Tick () mark the relevant box]

*Indian Patent No. 209251 claims a pharmaceutical product imported into India from Italy, more than 7,000 units of which were sold in India in 2009.

The facts and matters stated above are true to the best of my/our knowledge, information and belief.

Dated this 30th day of March, 2010


Anand and Anand, Advocates
Agent for the Patentee

To
The Controller of Patents
The Patent Office.
Mumbai *Delhi*