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)
ANNEXURE D

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

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

Sirs,

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.Ramachandran)
Asstt.Controller of Patents & Designs
Central Public Information Officer
In the matter of Patent No. 203937 of 12/04/2000

I/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-licenses 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

The Controller of Patents
The Patent Office
Mumbai
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.

[Signature]
[Name]
[Title]

[Agency]

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 COMMERCIALLY 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-licenses 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 of 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

The Controller of Patents
The Patent Office
Mumbai
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,
Pittsburgh, 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 PATENTEES

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 country-wise details):
Nil

(ii) the licenses and sub-licenses 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
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
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

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

(R. P. BHATTACHARYA)
of DePENNING & DePENNING

The Controller of Patents
The Patent Office
At Chennai
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

The Controller of Patents
The Patent Office
Chennai
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: Tarcava Tabs 100 mg (pack of 3 strips) – 504 packs
Value: Rs. 25233120 (approximately).

Quantum: Tarcava 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

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

[R. P. BHATTACHARYA]
of DePENNING & DePENNING

The Controller of Patents
The Patent Office
At Delhi
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 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® Tablets – 2268 packs of 30 Tablets
Quantum (sold in India): Tarceva® Tablets – 2089 pack of 30 Tablets

Value (Imported): 320,040 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

F. Hoffmann-La Roche AG
By his/their Agent and Attorney

(R. P. Bhattacharya)
of DePenning & DePenning

The Controlling of Patents
The Patent Office
At Delhi
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

F. Hoffmann-La Roche AG
By his/their Agent and Attorney

M. Basu
Reg. No. IN/PA-377
Depenning & DePenning

The Controller of Patents
The Patent Office
At Delhi
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