

**THE PATENTS 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)]

1. Details of the Patentee/Licensee

- A. PATENT NO.
- B. DATE OF GRANT
- C. TITLE OF THE INVENTION
- D. INTERNATIONAL PATENT CLASSIFICATION
- E. NAME OF THE PATENTEE(S)/LICENSEE(S)
Details of incorporation (if applicable)
- F. ADDRESS
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- G. NATIONALITY

2. Details of Working of Patented Invention

- A. STATEMENT FOR THE YEAR
- B. COMMERCIALISATION OF THE PATENTED INVENTION

Describe how the patented invention has
been commercialized, including through
incorporation into products/processes
and/or through licenses etc.

C. RELATED PATENTS/INVENTIONS

(i) Does the commercialisation of the patented invention require it to be worked along with any other patented (or patent pending) invention owned by the patentee or their licensee(s)?

YES		NO	
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(ii) If yes, furnish details of such related patent(s) or application(s) in India

(iii) Whether the patented invention is declared to be a 'standard' by any Standard Setting Organisation? If yes, provide details.

3. Extent of Commercial Working by the Patentee or Licensee (as the case maybe)

A. **FOR PHARMACEUTICAL DRUGS** INN
 [IPC CODE] Trade Name

If Worked:

A. **Finished Formulation*** Dosage

Manufactured in India

Quantum Packs Sold
 No. of Tablets per Pack

Value MRP (Per Pack)
 Total Sales (INR)

Imported (Country Wise)

Quantum Packs Sold
 No. of Tablets per Pack

Value MRP (Per Pack)
 Total Sales (INR)

B. **API*** **Manufactured in India**

Quantum Manufactured (in Kg)
 Sold (in Kg)

Value MRP (per Kg)
 Total Sales (INR)

Imported (Country Wise)

Quantum Manufactured (in Kg)
 Sold (in Kg)

Value MRP (per Kg)
 Total Sales (INR)

C. Patient Requirement

(i) What is the requirement of the drug per patient per month/year on average (indicate total number of packs along with number of tablets per pack)?*

- (ii) What is the estimated availability of the drug to the patient population?
- (iii) Provide details of Patient Assistance Programmes (PAPs) launched by the Patentee/Licensee.
- (iv) Indicate the total number of patients eligible & availing PAPs.

* **NOTE:** If other modes of dispensing drug or formulation used, then substitute “pack” and “tablet” with such alternative mode in above entries.

If Not Worked:

YES		NO	
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- (i) Whether an application for manufacture/import of the patented invention has been filed before the Drugs Controller General of India (DCGI)?

Granted / Pending / Clinical Trial

- (ii) Provide the current status of the application.

B. OTHER SECTORS

If worked:

Provide details of patented products and/or processes

Manufactured in India

Quantum	Unit of Measurement
	No. of Units
Value	MRP (Per Unit)
	Total Sales (INR)

Imported (Country Wise)

Quantum	Unit of Measurement
	No. of Units
Value	MRP (Per Unit)
	Total Sales (INR)

If it not practicable to list information for any of the above particulars, please state so with

details on why this is so? And
 provide alternative modes of
 description to highlight the mode
 and manner in which the patented
 invention has been worked.

If not Worked:

- (i) Provide reasons for not
 working
- (ii) Steps taken for working
 (including status of any
 regulatory or statutory
 approvals if necessary)

4. Licensing & Other Related Working Information

A. LICENSING INFORMATION

- (i) Name & Address

- (ii) Nature of License

EXCLUSIVE		NON-EXCLUSIVE	
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- (iii) Term of License
- (iv) Scope of License Manufacture / Import / Sale / Packaging / Others
- (v) Rate of Royalty

B. PATENT INFRINGEMENT SUITS

- Forum / Court
- Filing No.
- Names of Defendants
- Current Status

C. PUBLIC FUNDED RESEARCH

- (i) State whether the discovery and development of the patented invention (including its incorporation into any product/process) has been or received public funds in any manner?

YES		NO	
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- (ii) If yes, please state the extent and source of public funding.

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

Dated this day of 20....

Signature