

# Revocation

Who  
can  
do  
it??

- Any Interested person.
- High court may revoke patent – If patentee doesn't allow Government to make use of it.

# Grounds of revocation-

- Prior claiming .
- Wrongfully obtained patent.
- Subject of claim not invention.
- Lack of novelty in invention.
- Invention is obvious or no inventive step.

# Grounds of revocation-

Complete specification doesn't sufficiently or fairly describe invention & method of it .

Claims not clearly or sufficiently defined.

Patent obtained on false suggestion or representation.

Inventions anticipated by traditional knowledge.

Failure to disclose - foreign application.

# Revocation of patent in public interest [section 66]

Central government is of opinion that patent or its mode is **mischievous** to the state or **prejudicial** to the public , after giving patentee an opportunity to be heard.

# Revocation of patent non working

- According to section 85 of patents act  
The Central Government or any interested person after expiration of 2 years from date of order granting the first compulsory license apply to controller for an order of revoking patent on ground that
  - i. Patented invention not worked in territory of India
  - ii. Reasonable requirements of public – not satisfied
  - iii. Patented invention – not available at reasonably affordable price

# Restoration of lapsed patent [section 60]

Patent has ceased to have effect under section 53[2] – because of **non payment of renewal fees within prescribed period**, the patent & any specified patent of addition

Restored

If an application is made within 18 months of date on which patent lapsed

- Application that failure to pay renewal fee was unintentional
- Form 15
- Supporting evidence

# Compulsory Licenses

## [ section 84 ]

- Any interested party/person may apply for compulsory license to work the patented invention on failure by patentee – 3yrs of date of grant
  1. On grounds –
    - A. Reasonable requirement of public – Not satisfied
    - B. Not available – At reasonably affordable price
    - C. Not worked in territory of India


## 2. Controller shall take into account

- A. Nature of invention.
- B. Time elapsed since grant of patent.
- C. Measures taken by patentee or licensee – full use of invention.
- D. Applicants ability – work invention to public advantage.
- E. Capacity of applicant – to undertake risk providing capital & working of invention.
- F. Efforts made by applicant to obtain license from patentee on reasonable terms & conditions.

**Above clause shall not be applicable in case of national emergency or extreme urgency**

# First case of compulsory licensing being obtained in India

- International drug manufacturing firm **Bayer Corporation** (the patentee) Vs Indian pharmaceutical company **Natco Pharma Limited** (the applicant)
- Bayer obtained a patent on ***Nexavar (Sorafenib)*** – *used in liver and kidney cancer treatment.*
- A pack of 120 cost **Rs. 2.8 lakh INR**

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- The drug Nexavar (Sorafenib) is the **patented product** of M/s Bayer Corporation
  - **R&D cost** incurred was **exorbitant** , hence there should be no Compulsory Licensing.
  - **When the world sales were \$934 million in 2010 the Indian Sales was almost negligible.**

- Nexavar cost - cost of cancer drug Sorafenib 200mg tablet varies vastly in branded and generic category.
- **Branded Category- Rs 280,428 per patient per month.**
- The generic drug – **Natco** is providing the same **at Rs 8,880/-**

**Bayer was charging almost 45 times the Per Capita Income of India**

- Requirement of about 23,000 bottles per month in India.

Year	2008	2009	2010
No of bottles imported	Nil	200	Nil

- The importance of the time period lies in the fact that the Government of India granted Bayer a patent on the drug Nexavar in the year 2008 after assessing that Bayer would fulfil the “Reasonable requirements of the Public” during that period.
- Also, Bayer did not manufacture the drug in India as it focused on imports of its bottles.


- The Controller cited that the drug was “Exorbitantly priced” and thus was out of reach of majority of the population.
- The Controller also added that the drug was not available throughout the country was only available in major metropolitan cities like Chennai, Delhi, Kolkata and Mumbai
- The Controller also cited that the supply of Nexavar was short even in the previously mentioned cities and this was highly significant to the case as the drug was a “Life saving drug” and not a “Luxury Item”.

# Patented Invention not worked in India – Section 84(1)(c)

- The Controller also cited that the invention (Nexavar) was **not “worked”** in India. Natco argued that even though Bayer had manufacturing facilities in India, it did not manufacture the drug in India.
- Bayer said it did not do so because of economic reasons and argued that **“worked in the territory” could not mean “manufactured in India”**.
- Bayer added that the **“strategic decision” of manufacturing the drug in Germany** was valid as had the drug had **“small global demand”**.

# Verdict of the Case

- On 9<sup>th</sup> March, 2012, The Controller of Patents in his judgment awarded the first compulsory license in the pharmaceutical industry in India
- The Compulsory License for the drug Sorafenib/ Nexavar is granted by the controller on the basis of the following terms:
  - **Natco has very limited rights** to manufacture and commercially sell the drug.
  - Natco **cannot sublicense** to another party. It is a **non-assignable and non-exclusive license** with no right to import the drug. The compulsory licensed drug can be sold only for the **treatment of liver and renal cancer**.

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- Natco cannot use this license for alternate or subsequent use of the drug.
  - Natco has to pay the **royalty** for the drug at a rate of **6% of net sales** to the patent owner Bayer.
  - Has to provide the drug free of cost to at least **600 “needy and deserving” patients** per year

# Form filling

- Form 1 – Application for grant of patent
- Form 2 – Provisional / complete specification
- Form 3 – Statement & undertaking under section 8
- Form 4 – Request for extension of time
- Form 5 – Declaration as to inventorship
- Form 6 – Claim or request regarding change in applicant for patent
- Form 7 – Notice for opposition

# Form filling

- Form 7 A – Representation for opposition for grant of patent
- Form 9 – Request for publication
- Form 10 – Application for amendment of patent
- Form 12 – Request for grant of patent
- Form 15 – Application for restoration of patent
- Form 17 – Application for compulsory license