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Drug Patents and Generic Pharmaceutical Drugs

By Dr Ananya Mandal, MD

When a pharmaceutical company first develops a new drug to be used for a disease condition, it is initially sold under a brand name by which the clinicians can prescribe the drug for use by patients. The drug is covered under patent protection, which means that only the pharmaceutical company that holds the patent is allowed to manufacture, market the drug and eventually make profit from it.

In most cases, the drug patent is awarded for around twenty years in the United States. The lifetime of the patent varies between countries and also between drugs. Since the company applies for a patent long before the clinical trial to assess a drug's safety and efficacy has commenced, the effective patent period after the drug has finally received approval is often around seven to twelve years.

Once the patent has expired, the drug can be manufactured and sold by other companies. At this point, the drug is referred to as a generic drug. According to guidelines in most countries, including those from the US FDA, generic drugs have to be identical to the branded drug in terms of efficacy, safety, usage, route of drug administration, pharmacokinetics and pharmacodynamics.

Therefore, a drug can be manufactured as a generic drug when the following apply:

- Its patent has expired
- The company that would manufacture the generic drug certifies that the patents held on the drug are either unenforceable, are invalid or would not be infringed upon
- There has never been any patents on the drug before
- In countries where the drug has no patent protection

Once the generic drug is on the market, the monopoly of the patent holder is removed. This encourages competition and results in a significant drop in drug costs, which ensures that life-saving and important drugs reach the general population at comparative prices.

The company holding the initial patent may, however, renew the patent by forming a new version of the drug that is significantly changed compared to the original compound. However, this may require new clinical trials and re-application of the patent. Furthermore, the new compound may have to compete with the original generic molecule on the market, unless the drug regulators find faults and remove the original from the market altogether.

Reviewed by [Sally Robertson, BSc](#)

Sources

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