

# GSK Public policy positions

## Evergreening

### The Issue

“Evergreening” is an inherently pejorative term. It is used by some to convey the false impression that research-based pharmaceutical companies abuse the patent system by obtaining patents on what are characterised as “minor” improvements to existing medicines in order to prevent competition by delaying the legitimate market entry of generic products. The accusation is made without producing evidence that “evergreening” has had any impact on patients or markets. This paper briefly summarises GSK’s views on ‘evergreening’ and addresses the fallacies surrounding the alleged practice and its impact on access and innovation.

### GSK’s Position

- GSK rejects the accusation that later improvements unjustifiably delay generic competition. The patent system allows for generic versions of the basic product to compete with the improved product.
- GSK rejects the accusation that improvements subject to later patents are not medically important and should not be encouraged. The patent system is, amongst other things, intended to provide incentives to improve products and support innovation. The value of patented improvements is assessed by the market and clinical demand.
- GSK rejects the accusation that improvement patents are not justified within patent law. Patents for improvements to existing products, in the field of pharmaceutical and other technologies, are only available if they meet the normal requirements of patentability (i.e. that they are new, useful, and involve an inventive step) as assessed by trained patent examiners.
- Of note, patent applications relating to developments or modifications are filed not just by those who originally developed the product but also by other companies, including generic companies.

## Background

### Basic Principles of the Patent System

The patent system provides an incentive for commercial operators to incur the cost and risk of research and to disclose information that might otherwise be kept secret. It does this by providing a time-limited exclusive right to commercialise a product which is novel (in the sense that it was not known prior to the invention), useful (in that it has commercial applicability), and inventive (in the sense that it was not obvious at the time it was invented). If the alleged innovation is neither new nor inventive, no patent should be granted; and if it is granted, it can be challenged.

Patent law does not distinguish between inventions consisting of “brand new products” (for example, a new compound) and inventions relating to improvements (for example, a new formulation of the compound or a better way of making it). The same criteria for patentability apply; only if the subject matter is found to be novel, useful, and inventive will a patent be granted. Thus pharmaceutical and other companies only obtain patents on developments or modifications of products if those developments or modifications are objectively considered by an independent and skilled agency to meet the requirements for patent protection. A patent on the development or modification will only give rights to that development or modification.

The scope of the invention for which the exclusive right is granted is in broad terms commensurate with the scope of the scientific advance it reflects. Thus, a patent for a brand new product (pharmaceutical or otherwise) will give exclusive rights which are broader than a patent for an improvement of that product, which will only protect the modification. This is illustrated below.

### “Secondary” patents are not a barrier to generic competitors

Patents cannot give exclusive rights for things that are already known or obvious. Therefore, patents for modifications of existing products, sometimes referred to as “secondary patents”, are necessarily narrower in scope than what has gone before. It follows that, following expiry of an earlier patent, a secondary patent cannot preclude a generic competitor from selling products defined in that earlier patent and which are not covered by the secondary patent.

For example, if the innovator markets product X for disease Y which is covered by a patent on the molecule and a patent on a formulation and use for disease Y, once the patents for the product as launched expire, a generic competitor will be able to sell that product X for disease Y. If the originator company later develops and patents a slow-release formulation of that molecule, it will have the exclusive right to sell that formulation but a generic competitor will be able to sell the original formulation notwithstanding the slow release patent. It is the medical community and paying authorities that will decide whether any price premium for the slow release product is worth paying.

### Patents as a Reflection of Technological Progress - A GSK Example

The principles relating to requirements for, and scope of, a patent underpin the patent system and provide incentives to undertake research while allowing for legitimate competition following patent expiry. A simple example will illustrate these points.

Lamictal<sup>TM</sup> is an anticonvulsant medication (active ingredient: lamotrigine) which is sold by GSK for use in the treatment of epilepsy in adults and children. It is also used as a maintenance therapy for certain patients with bipolar disorder. The patent for the active ingredient was applied for in 1980 and expired in many countries in 2000. In some countries a patent term extension was obtained. In the UK, for example, the patent expired in 2005.

Lamictal<sup>TM</sup> was originally marketed as oral tablets to be swallowed with a little water. In 1992, a chewable/dispersible tablet formulation of lamotrigine was developed and a patent was applied for. The chewable/dispersible tablets may be swallowed, chewed, or dispersed in water or diluted fruit juice (swallowing the resulting liquid dispersion). The chewable/dispersible tablet has advantages for patients in terms of ease of use and compliance, and GSK's chewable/dispersible tablet formulation was protected by a separate, second patent (which expired in 2012).

When the original patent expired in 2000-2005, generic companies were able to copy the original oral tablet and come to market with an oral tablet containing the active ingredient, lamotrigine to compete with Lamictal<sup>TM</sup>. However, they were not permitted to copy GSK's chewable/dispersible formulation until the expiration of the second patent. The market was able to choose between Lamictal<sup>TM</sup> oral tablet, generic copies of the oral tablet, and GSK's improved chewable/dispersible tablet.

The success of GSK's chewable/dispersible tablet also prompted generics to attempt to develop formulations that would not infringe GSK's "secondary patent" and provide new formulations having a similar effect. The development of a non-infringing competitor product is often referred to as “designing around” the patent. Several competitor chewable/dispersible tablets, containing generic lamotrigine but utilising different dispersing technology from that used in the GSK product, were marketed prior to the 2012 expiry of the second patent and competed with Lamictal<sup>TM</sup> chewable/dispersible tablets.

So not only did GSK's secondary patent on chewable/dispersible formulations allow competition from “ordinary” tablets, it also allowed competition from other types of chewable/dispersible formulations which fell outside the patent. And some of these other types may themselves be patentable by competitors. So by allowing patents for secondary developments, the patent system provides incentives for companies which may not have the commercial or scientific capability to invent and develop new chemical entities to engage in incremental innovation. For example, many Indian companies, including historically generic companies, are increasingly involved in this area of activity.

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<sup>TM</sup> Lamictal is a trade mark of the GlaxoSmithKline group of companies.



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In the case of Lamictal<sup>TM</sup>, GSK believes that its chewable/dispersible product offers certain advantages over these alternative formulations. However all can compete in the same market – it is for the market to determine the success or otherwise of each product. Competitive forces can then drive further innovation.

### Conclusion

The patent system provides an incentive to innovate while allowing competition through copying after the term of the patent expires. And, importantly, it does so in a way which works well given how most innovation in fact takes place. There is relatively little “groundbreaking” innovation when compared to “improvement” innovation. Therefore, most innovation represents an improvement over what already exists. One only has to look at the advances in the last 30 years in such areas as computing, electronics, communications, pollution control etc to see that this is true.

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