

**A COMPARATIVE STUDY ON PATENT TERM EXTENSION FOR
PHARMACEUTICAL PATENT**

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The students/authors confirm that the work submitted is their own and that appropriate credit has been given where reference has been made to the work of others.

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ABSTRACT

This project paper discusses on the various system of pharmaceutical patent term extension from different countries and the situation of pharmaceutical patent term extension in Malaysia. Chapter one of this research study present a background about the laws and issues about the pharmaceutical patent term extension. Chapter two of this research discusses the situation of patent term extension in Malaysia which includes the necessity of having patent term extension and also the implication resulting from the system. In chapter three, this research discusses on the various system of patent term extension for pharmaceutical patent in selected countries which are United States, European Union, Australia, Japan, Singapore, South Korea and Taiwan. The analysis of the patent term extension can be seen through the comparative table which includes different elements in the system for example requirement for granting the extension, reasons for introduction of extension and maximum effective patent life. In the final chapter, this research laid down the recommendation and the proposed system of pharmaceutical patent term extension to be implemented in Malaysia.

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CHAPTER ONE:

A COMPARATIVE STUDY ON PATENT TERM EXTENSION FOR PHARMACEUTICAL PATENT

1.0 BACKGROUND OF STUDY

Patent is the exclusive right granted in respect of an invention. The patent offers protection by declaring that the invention cannot be commercially made, used, distributed or sold without the patent owner's consent.¹ The state will guarantee the inventor's absolute right to exploit his work in exchange for a full disclosure of the scientific and technical knowledge contained in his invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed.² Pharmaceutical patents protect manufacturers of prescription drugs, prohibiting others from producing the same drug during the length of its patent protection.

According to section 35 of Patent Act 1983 of Malaysia, the duration of a patent shall be twenty years from the filing date of the application.³ It means that, the grant of patent protection only applicable within that 20 years starting from the date of filling the application of patent. In pharmaceutical patent, before the granting of patent for a product, the pharmaceutical product needs to be approved first. For example, in United States, the pharmaceutical products are subjected to marketing approval by the Food and Drug Administration (FDA).⁴ In order to get the approval of the product, it usually takes approximately five years from the date of the application of patent. Pharmaceutical patents protect manufacturers of prescription drugs, prohibiting others from producing the same drug during the length of its patent protection.

¹ Wendy H. Schacht, John R. Thomas. "Pharmaceutical Patent Term Extensions: A Brief Explanation." 1, 2002.

² Gibbons, John H. "Patent-Term Extension and the Pharmaceutical Industry." Washington, 1981.

³ Patent Act 1983

⁴ Wendy H. Schacht, John R. Thomas. "Pharmaceutical Patent Term Extensions: A Brief Explanation." 2, 2002.