

UNIVERSITI TEKNOLOGI MARA

**PARALLEL IMPORT OF DISPENSED MEDICINES: AN ANALYSIS
OF THE LAWS AND PRACTICE IN MALAYSIA**

**ZURAINI BT MOHAMAD REDHUAN
HAIRANIE BT SA'BAN
JACKLYN ANAK KIYUN**

Submitted in Partial Fulfillment of the Requirements
for the Master in Enforcement Law

FACULTY OF LAW

December 2011

ABSTRACT

Through the rapid growth of technology, communication and transportation that shade the countries geographical boundary, parallel import has becoming an important issue for international trade and management. Parallel import is the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent. This study examines the law governing the practice of parallel import and observes the fundamental factors that persuade consumers' attitude towards parallel import in Malaysia and other countries. Some laws and regulations that are discussed in regards of parallel import are Trip Agreements, Doha Declaration, Patent Act and Free Trade Agreement. This study is aims to analyse the provisions on parallel import where the issue of non-counterfeit product imported from another country without the permission of the intellectual property owner will be analyse. The law will not only protect the right of original manufacturer, it will also prevent customer from consume hesitant prescribed dispensed medicine. The study adopts a qualitative method where the Poison Act 1952, Customs Act 1967, Patents Act 1983, Sale of Drugs Act 1952, Trade Mark Act 1976, Control of Drugs and Cosmetics Regulations 1984, Custom (Prohibition of Imports) Order 1998, Customs Duties Order 1996 and Customs Regulations 1977 are analysed and interviews are conducted with the Custom officers and officers from Pharmacy Department (National Pharmaceutical Control Bureau and Pharmacy Enforcement Unit). The research reveals that, there are loopholes in the laws and policies as there is no specific provision for parallel import to control the parallel importation of dispensed medicine in Malaysia. The research suggests ways to improve the laws on parallel import of dispensed medicine in Malaysia.

ACKNOWLEDGEMENT

A very special thanks our helpful supervisor, Dr. Nuraisyah Chua Abdullah for her extreme patience and hard work in taking our words, ideas and ridiculous whims. The supervision and support that she gave truly help the progression and smoothness of the dissertation. The co-operation is much indeed appreciated.

Our gratitude goes out to our colleague who always ready to give constructive information in regards to our topic on parallel importation through the interviews. We are greatly indebted to customs and excise officer in Malaysia, India, Kenya and Turkey for their passion in replying our enquiries by emails.

Not to forget, we would like to express our gratitude to our family for giving us life in the first place, for their continuous unconditional support and understanding to pursue our interests.

TABLE OF CONTENTS

DECLARATION	i
ABSTRACT	ii
ACKNOWLEDGEMENT	iii
TABLE OF CONTENTS	vi
INDEX OF ABBREVIATION	
CHAPTER 1 : GENERAL INTRODUCTION	
1.0 Background of Study	1
1.1 Problem Statement	3
1.2 Objectives of Study	4
1.3 Literature Review	5
1.4 Methodology	8
1.5 Scope and Limitation	9
1.6 Significance of the Study	9
CHAPTER 2 : THE LAWS AND POLICIES GOVERNING DISPENSED MEDICINE IN MALAYSIA	
2.0 Introduction	10
2.1 Development of Dispensed Medicine	10
2.2 The Backgrounds on the Laws and Policies of Dispensed Medicine	11
2.3 Laws and Regulations Governing Dispensed Medicine in Malaysia	13
2.3.1 Poison Act 1952 and Poisons Regulations 1952	13
2.3.2 Sale of Drugs Act 1952	15
2.3.3 Control of Drugs and Cosmetics Regulations 1984	15
2.4 Procedures on Approval of Dispensed Medicine in Malaysia	17
2.5 Procedures in Importation of Dispensed Medicine	21
2.5.1 The Royal Malaysian Customs (RMC)	21
2.5.2 The Pharmacy Enforcement Unit of the Ministry of Health	22
2.5.3 Royal Malaysian Police	23
2.6 Conclusion	24
CHAPTER 3 : PARALLEL IMPORT PRACTICES AND LEGAL ISSUES IN MALAYSIA	
3.0 Introduction	26
3.1 Laws and Policies Governing Import of Dispensed Medicine in Malaysia	26
3.1.1 TRIPS Agreement and Doha Declaration	27
3.1.2 Patents Act 1983	29
3.1.3 US-Malaysia Free Trade Agreement (FTA)	31
3.2 Parallel Import Practices	31
3.2.1 Hand Carry	31
3.2.2 Parcel Post	33
3.3 Conclusion	37

