THE ROLE OF COMPULSORY LICENSING IN COMBATTING COUNTERFEIT DRUGS IN NIGERIA.

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A Project Paper Submitted to Ghazali Shafie Graduate School of Government, Universiti Utara Malaysia in fulfilment of the requirements for the Master of Commercial Law.

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ABSTRAK

Kewujudan ubat-ubatan tiruan yang membawa implikasi negatif kepada masyarakat umum, pihak kerajaan dan syarikat-syarikat farmaseutikal menggesa campurtangan undang-undang bagi menangani masalah tersebut. Justeru, objektif kajian ini ialah untuk mengenalpasti bagaimana peruntukan lessen wajib menurut peruntukan undang-undang yang berkaitan boleh digunapakai untuk menangani masalah percambahan penghasilan ubat-ubatan tiruan di Nigeria. Bagi menjawab persoalan tersebut, kajian ini menggunapakai kaedah doktrinal undang-undang dengan mengkaji peruntukan undang-undang berkaitan iaitu termasuklah Perjanjian TRIPS sebagai rangka asas perundangan di peringkat antarabangsa, akta-akata berkiatan di Nigeria iaitu *Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004* dan *the National Agency for Food and Drug Administration and Control Act, CAP N1 Laws of the Federation of Nigeria 2004* serta kes undang-undang yang berkaitan. Kajian ini mendapati bahawa kebenaran lesen wajib kepada pihak ketiga di bawah undang-undang paten mempunyai kesan positif dalam dalam memerangi ubat-ubatan palsu sebagai amalan yang merangsang persaingan sihat di kalangan syarikat-syarikat farmaseutikal yang seterusnya boleh menurunkan harga ubat-ubatan tulen yang dipatenkan dan pada masa yang sama tidak menggalakkan orang ramai daripada membeli ubat-ubatan tiruan. Kajian ini mengesyorkan bahawa pihak berkuasa di Nigeria harus menggalakkan amalan lesen wajib ke atas ubat-ubatan berpaten bagi membantu orang ramai mendapatkan akses kepada ubat-ubatan yang berkualiti serta mampu dibeli.

Kata kunci: lessen wajib, ubat-ubatan tiruan, paten, ubat-ubatan berkualiti.

ABSTRACT

The negative implication of the existence of counterfeit drugs to the public, government and pharmaceutical companies urge legal interruption to curb the problem.

The objective of this study is to identify how the relevant laws on compulsory licensing can be used to address the proliferation of counterfeit drugs in Nigeria.

In answering the question, this study employed doctrinal legal method by examining the relevant legal provisions dealing with counterfeit drugs that include TRIPS Agreement as the basis of international framework and the Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004 and the National Agency for Food and Drug Administration and Control Act, CAP N1 Laws of the Federation of Nigeria 2004.The content analysis is used in analyzing the data collected in this research.

The study found out that the concept of compulsory licensing practised under the patents law has the positive effect in enhancing access to affordable drugs through the authorization given 3rd party which subsequently stimulate to a healthy competition among pharmaceutical companies.

The study thus recommended that the authority in Nigeria should encourage the practise of compulsory licensing over patented drugs in order to assist the public to get access to a good quality and affordable drugs.

Keyword: **compulsory licensing, counterfeit drugs, quality and affordable drugs and patenting of drugs.**

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DEDICATION

This project paper is dedicated to my Uncle and Father – in – Law; Alhaji Bala Shehu Muhammad. May Allah (SWT) continue to grant you eternal rest and may Jannatul Firdaus be your final place of abode. Ameen.

DECLARATION

I, MUSA IBRAHIM UMAR, solemnly declare that this project paper is the product of my own endeavour and that all sources have been adequately and duly acknowledged and that all the inadequacies in this project paper are the product of my own shortcoming. And that this project paper has not been submitted in this faculty or elsewhere.

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LIST OF ABBREVIATION

CIPR - Commission on Intellectual Property Rights

FDAC - Food and Drugs Administration and Control

MDGs - Millennium Development Goals

NAFDAC - National Agency for Food and Drug Administration and Control

HIV / AIDS- Acquired Immune Deficiency Syndrome / Human Immunodeficiency Virus

TRIPS agreement - Trade Related Aspects of Intellectual Property Rights

WHO - World Health Organization

CHAPTER ONE:

OVERVIEW OF THE STUDY

1.1. INTRODUCTION

The importance of drugs in the medical parlance cannot be overemphasized as they play a prominent role in the diagnosis, treatment and prevention of different types of diseases as well as in the restoration of the health of the patients who consumed them.[1] Furthermore, the provision of affordable, accessible and safe drugs constitutes one of the determinants used in ascertaining the effectiveness of a health care system.[2]

Globally, Article 25 of the United Nation's Universal Declaration of Human Right 1948 confers upon every human being with the right to be provided access to medical care.[3] Regionally, Article 16 of the African Charter on Human and Peoples' Right (Ratification and Enforcement) Act 1990[4] also confers upon every person with the right to have his physical and mental wellbeing protected.

In Nigeria, several statutory provisions imposed a duty on the government to evolve policies that are tilted towards the enhancement of the citizen's health status. For instance section 17(3) (d) of the 1999 Constitution of the Federal Republic of Nigeria

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