INTELLECTUAL PROPERTY RIGHTS IN COMPARATIVE HEALTH LAW

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PART I - INTRODUCTION

CHAPTER 1: THE ROLE OF INTELLECTUAL PROPERTY RIGHTS IN THE HEALTH INDUSTRY

§ 1 - General Presentation of the Intellectual Property Rights -

A) Trademarks

1. *The functions of trademark law*
2. *Trademarks relating to Pharmaceuticals*

   (a) In Europe
   (b) In France
   (c) In the United States

B) Copyrights

C) Industrial Designs

D) Patents

§ 2 - Intellectual Property Rights in the Health Industry -

CHAPTER 2: BACKGROUND TO THE MODERN PATENT SYSTEM

§ 1 - The Nature and Origins of Patent Rights -

A) What is a patent?

1. *Exclusionary Right*
2. *Property Right*
3. *Limited duration*

B) Why granting a patent?

§ 2 - Harmonization of Patent Law -

A) International Developments

1. *The Paris Convention*
2. *The European Patent Convention*
3. *The Future Unitary Patent*
4. *The Patent Cooperation Treaty (PCT)*

B) The TRIPS Agreement as a Powerful Harmonization Tool

1. *A minimal patent protection*
2. *Access to Medicines and Compulsory Licenses*
3. *Dispute Procedure*

PART II - WHAT CAN BE PATENTED

CHAPTER 1: THE REQUIREMENTS IN EUROPE

§ 1 - Patent Subject Matter for Pharmaceutical Inventions -

A) Inventions contrary to « *ordre public* » and morality

B) Essentially biological processes for the production of plants or animals

C) Methods for treatment of the human or animal body

1. *Treatment by Therapy*
2. *Treatment by Surgery*
3. *Diagnostic Methods*
4. *Dosage Regimens*

§ 2 - Novelty, Utility and Inventiveness Requirements -

A) Novelty

1. *General principles*
2. *Novelty for Pharmaceutical Inventions — Art. 52(1) and 54 EPC*
3. *Novelty for Biotechnological Inventions — Art. 52(1) and 54 EPC*

CHAPTER 3: THE REQUIREMENTS IN THE UNITED STATES

§ 1 - Introduction -

A) General requirements

1. *What is a United States patent?*
2. *What are the conditions to obtain a patent?*

B) History

§ 2 - Patent Validity -

A) Patent eligibility

1. *Biotechnology and products of nature*
2. *Computer related invention / method of doing business*

B) Utility

1. *General principles*
2. *Utility in chemistry and biotechnology principles*

C) Novelty

1. *The Statutory Bars — AIA §102(a)(1)*

    a. **Public Use**
    b. **On Sale**
    c. **Information otherwise available to the public**
    d. **Disclosure in United States Patent Applications**

2. *The Grace Period Bars — AIA § 102(b)*

C) Non-obviousness

1. *Level of Skill in the Art*
2. *Secondary considerations*
3. *Prima Facie Obviousness Based Upon Structural Similarity*

D) Disclosure — Section 112

PART III - OBTAINING REGULARORY APPROVAL FOR A NEW PHARMACEUTICAL PRODUCT

CHAPTER 1: THE DRUG APPROVAL PROCESS IN EUROPE

§ 1 – Competent Authorities -

A) National Authority

B) The European Medicines Agency

§ 2 – Overview of the Different Community Procedures -

A) Mutual Recognition Procedure

1. *Procedure Initiated by a Member State*
2. *Procedure Initiated by a Market Authorization Holder*

B) Centralized Procedure

§ 3 – Different Types of Marketing Authorization Applications -

A) Abridged Applications

B) Orphan Drugs

C) Traditional Herbal Medicines

CHAPTER 2: THE DRUG APPROVAL PROCESS IN FRANCE

§ 1 – In General -

§ 2 – The Competent Authority: The ANSM -

§ 3 – The French National Procedure -