

**REPUBLIC OF TURKEY  
ANKARA UNIVERSITY  
GRADUATE SCHOOL OF SOCIAL SCIENCES**

**DEPARTMENT OF INTELLECTUAL PROPERTY,  
TECHNOLOGY POLICIES AND INNOVATION MANAGEMENT**

**COMPULSORY PATENT LICENSING AND ACCESS TO  
MEDICINES:  
ORPHAN DRUGS**

**Master's Thesis**

**Elif İlayda İLERİ**

**Ankara,2022**

**REPUBLIC OF TURKEY**  
**ANKARA UNIVERSITY**  
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MASTER OF LAWS (LL.M.) in INTELLECTUAL PROPERTY

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## **DECLARATION**

**REPUBLIC OF TURKEY**

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**To the Directorship of Graduate School of Social Sciences**

I hereby, declare that all information in my master's thesis named "Compulsory Patent Licensing and Access to Medicines: Orphan Drugs (Ankara, 2022)" which has been prepared under the supervision of Assist. Prof. Dr. Selin ÖZDEN MERHACI has been gathered and submitted in compliance with academic rules and ethical conduct principles and as required by these rules and principles, I have fully indicated and cited all sources that are not original to this work. I also declare that, I have acted according to scientific research and ethical rules during the study process and if it is proven otherwise, I will accept all legal consequences.

Date: 25.04.2022

Elif İlayda İLERİ

## TABLE OF CONTENTS

|                                    |             |
|------------------------------------|-------------|
| <i>LIST OF ABBREVIATIONS</i> ..... | <i>V</i>    |
| <i>LIST OF TABLES</i> .....        | <i>VIII</i> |
| <i>INTRODUCTION</i> .....          | <i>1</i>    |

### CHAPTER ONE

#### **RARE DISEASES AND ORPHAN DRUGS IN GENERAL, GENERAL VIEW OF THE HUMAN RIGHTS FRAMEWORK, AND THE CORRELATION BETWEEN HUMAN RIGHTS AND PATENTS**

|                                                                                                                           |           |
|---------------------------------------------------------------------------------------------------------------------------|-----------|
| <b>I. Rare Diseases and Orphan Drugs in General</b> .....                                                                 | <b>5</b>  |
| A. Rare Diseases in General .....                                                                                         | 5         |
| B. Orphan Diseases .....                                                                                                  | 10        |
| C. Neglected Diseases .....                                                                                               | 11        |
| D. Orphan Drugs in General .....                                                                                          | 12        |
| <b>II. The Overview of Human Rights Framework</b> .....                                                                   | <b>15</b> |
| A. The Human Right to Health .....                                                                                        | 15        |
| B. The Right to Access to Essential Medicine .....                                                                        | 17        |
| <b>III. The Correlation Between the Human Rights and Patents</b> .....                                                    | <b>22</b> |
| A. General Conflicts Between the Human Rights and Patents .....                                                           | 22        |
| B. Opinions of the Commission on Intellectual Property, Innovation and Public<br>Health (CIPHI) .....                     | 24        |
| C. Opinions of the Intergovernmental Working Group on Public Health, Innovation<br>and Intellectual Property (IGWG) ..... | 26        |

### CHAPTER TWO

#### **LEGAL FRAMEWORK OF COMPULSORY LICENSE IN INTERNATIONAL REGULATIONS AND HISTORICAL PROCESS**

|                                                              |           |
|--------------------------------------------------------------|-----------|
| <b>I. Compulsory License in the Historical Process</b> ..... | <b>28</b> |
|--------------------------------------------------------------|-----------|

|                                                                                                              |           |
|--------------------------------------------------------------------------------------------------------------|-----------|
| <b>II. International Regulations and Legal Framework .....</b>                                               | <b>29</b> |
| A. Paris Convention for the Protection of Industrial Property .....                                          | 29        |
| 1. General Framework .....                                                                                   | 29        |
| 2. Related Regulations on Compulsory License.....                                                            | 31        |
| B. Agreement on Trade Related Aspects of Intellectual Property Rights .....                                  | 34        |
| 1. Establishment of TRIPS Agreement .....                                                                    | 34        |
| 2. General Framework.....                                                                                    | 35        |
| 3. Related Regulations.....                                                                                  | 36        |
| C. The Doha Declaration on the TRIPS Agreement and Public Health.....                                        | 40        |
| 1. Legal Nature of the Doha Declaration.....                                                                 | 40        |
| 2. General Structure.....                                                                                    | 42        |
| D. Implementation of Paragraph 6 of the Doha Declaration: "30 August Decision"<br>and the Article 31bis..... | 47        |

### **CHAPTER THREE**

#### **THE CONCEPT AND SCOPE OF COMPULSORY LICENSE, GENERAL PRINCIPLES AND GROUNDS, RECENT CASES**

|                                                                               |           |
|-------------------------------------------------------------------------------|-----------|
| <b>I. Scope, Components and Function of Compulsory License.....</b>           | <b>52</b> |
| A. Definition of Compulsory License.....                                      | 52        |
| B. Components and Principles of Compulsory License.....                       | 55        |
| 1. Principle of Case-to-Case Basis Evaluation.....                            | 57        |
| 2. Prior Negotiation Principle.....                                           | 58        |
| 3. Principle of Scope, Duration and Termination.....                          | 59        |
| 4. Non-Exclusivity and Non-Transferability Principle .....                    | 60        |
| 5. Domestic Market Use Principle.....                                         | 61        |
| 6. Adequate Remuneration Principle.....                                       | 62        |
| 7. Principle of Judicial Review.....                                          | 63        |
| <b>II. Grounds for Issue of Compulsory License.....</b>                       | <b>64</b> |
| A. Public Non-Commercial Use - Government Use.....                            | 66        |
| B. Control of Anti-Competitive Practices - Refusal to Deal.....               | 70        |
| C. Ensuring of the Public Interest.....                                       | 71        |
| D. Emergency and Other Situations of Extreme Urgency.....                     | 72        |
| <b>III. Recent Prominent Cases of Compulsory Licensing Implementation....</b> | <b>73</b> |

|                                                           |    |
|-----------------------------------------------------------|----|
| A. Thailand: Government Use License.....                  | 73 |
| B. India: Judicial Review.....                            | 77 |
| C. Rwanda-Apotex Case: Waiver Mechanism.....              | 79 |
| D. Brazil-'Threat Mechanism:' Government Use License..... | 82 |

## **CHAPTER FOUR**

### **THE EVALUATION OF COMPULSORY LICENSES IN TERMS OF DEVELOPING AND DEVELOPED COUNTRIES AND THE IMPACT OF COMPULSORY LICENSES ON R&D ACTIVITIES AND ORPHAN DRUGS**

|                                                                                                       |            |
|-------------------------------------------------------------------------------------------------------|------------|
| <b>I. Evaluation of Compulsory License Instrument: PROs and CONs.....</b>                             | <b>85</b>  |
| A. General Evaluation.....                                                                            | 85         |
| B. Developing Countries and the Advantages of Comprehensive Compulsory<br>Licensing.....              | 87         |
| C. Challenges and Controversies of Comprehensive Compulsory Licensing for<br>Developed Countries..... | 93         |
| <b>II. The Impact of the Compulsory License within the Scope of R&amp;D and<br/>Innovation.....</b>   | <b>97</b>  |
| <b>III. Evaluation of the Effect of Compulsory License Implementation on Orphan<br/>Drugs.....</b>    | <b>101</b> |

## **CHAPTER FIVE**

### **ANALYSIS OF ALTERNATIVE MECHANISMS TO COMPULSORY LICENSE IMPLEMENTATION IN PROVIDING ACCESS TO MEDICINES**

|                                                                                               |            |
|-----------------------------------------------------------------------------------------------|------------|
| <b>I. Alternative Ways Instead of Compulsory Licenses: Push and Pull<br/>Mechanisms .....</b> | <b>107</b> |
| A. General Framework .....                                                                    | 107        |
| B. Evaluation of Input-Oriented Systems: Push Mechanisms .....                                | 110        |
| 1. Patent Pool Mechanism .....                                                                | 110        |
| a) The Medicine Patent Pool .....                                                             | 111        |
| b) The Pool for Open Innovation Against Neglected Tropical<br>Diseases (POINT) .....          | 113        |

|                                                                      |                |
|----------------------------------------------------------------------|----------------|
| 2. The System of Research Grant .....                                | 115            |
| C. Evaluation of Output-Oriented Systems: Pull Mechanisms .....      | 116            |
| 1. Differential Pricing Mechanism .....                              | 116            |
| 2. Prizes: Public Incentives .....                                   | 120            |
| a) Medical Innovation Prize Fund: "De-Linkage"<br>Based.....         | 121            |
| b) The Approach of Health Impact Fund .....                          | 122            |
| 3. The System of Advanced Market Commitment .....                    | 124            |
| D. Integration of Push and Pull Mechanisms: Orphan Drug Schemes..... | 126            |
| <b>II. Evaluation of Alternative Mechanisms .....</b>                | <b>129</b>     |
| <br><i>CONCLUSION</i> .....                                          | <br><i>131</i> |
| <i>ABSTRACT</i> .....                                                | <i>134</i>     |
| <i>ÖZET</i> .....                                                    | <i>135</i>     |
| <i>BIBLIOGRAPHY</i> .....                                            | <i>136</i>     |

## **LIST OF ABBREVIATIONS**

|                         |                                                                                             |
|-------------------------|---------------------------------------------------------------------------------------------|
| <b>AIDS</b>             | : Acquired Immune Deficiency Syndrome                                                       |
| <b>ARV</b>              | : Antiretroviral                                                                            |
| <b>CAMR</b>             | : Canadian Access to Medicines Regime                                                       |
| <b>CIPHI</b>            | : Commission on Intellectual Property,<br>Innovation and Public Health                      |
| <b>CML</b>              | : Chronic Myeloid Leukemia                                                                  |
| <b>Doha Declaration</b> | : WTO Declaration on TRIPS and Public Health                                                |
| <b>EC</b>               | : European Community                                                                        |
| <b>EML</b>              | : Essential Medicines List                                                                  |
| <b>EU</b>               | : European Union                                                                            |
| <b>EURORDIS</b>         | : European Organization for Rare Diseases                                                   |
| <b>FDA</b>              | : Food and Drug Administration                                                              |
| <b>FDI</b>              | : Foreign Direct Investment                                                                 |
| <b>GSK</b>              | : GlaxoSmithKline                                                                           |
| <b>HIF</b>              | : The Health Impact Fund                                                                    |
| <b>HIV</b>              | : Human Immunodeficiency Virus                                                              |
| <b>ICESCR</b>           | : International Convention on Economic, Social<br>and Cultural Rights                       |
| <b>IGWG</b>             | : Intergovernmental Working Group on Public<br>Health, Innovation and Intellectual Property |
| <b>IP</b>               | : Intellectual Property                                                                     |
| <b>IPAB</b>             | : Intellectual Property Appellate Board (India)                                             |
| <b>IPRs</b>             | : Intellectual Property Rights                                                              |
| <b>KIPO</b>             | : Korean Intellectual Property Office                                                       |

|                |                                                                               |
|----------------|-------------------------------------------------------------------------------|
| <b>LDC</b>     | : Least-Developed Country                                                     |
| <b>LMICs</b>   | : Low and Middle-Income Countries                                             |
| <b>MPP</b>     | : The Medicine Patent Pool                                                    |
| <b>NCD</b>     | : Non-Communicable Diseases                                                   |
| <b>NGO</b>     | : Non-Governmental Organization                                               |
| <b>OECD</b>    | : Organization for Economic Cooperation and<br>Development                    |
| <b>OHCHR</b>   | : Office of the United Nations High<br>Commissioner for Human Rights          |
| <b>POINT</b>   | : The Pool for Open Innovation against Neglected<br>Tropical Diseases         |
| <b>R&amp;D</b> | : Research and Development                                                    |
| <b>TIPC</b>    | : Turkish Industrial Property Code No. 6769                                   |
| <b>TRIPS</b>   | : Agreement on Trade-Related Aspects of<br>Intellectual Property Rights       |
| <b>UDHR</b>    | : Universal Declaration of Human Rights                                       |
| <b>UK</b>      | : United Kingdom                                                              |
| <b>UN</b>      | : United Nations                                                              |
| <b>UNITAID</b> | : Organization cooperating with WHO and others<br>on the WHO millennium goals |
| <b>US</b>      | : United States                                                               |
| <b>USC</b>     | : United States Code                                                          |
| <b>WHA</b>     | : World Health Assembly                                                       |
| <b>WHO</b>     | : World Health Organization                                                   |
| <b>WIPO</b>    | : World Intellectual Property Organization                                    |
| <b>WTO</b>     | : World Trade Organization                                                    |

|              |                                       |
|--------------|---------------------------------------|
| <b>ibid.</b> | : ibidem, in the same place           |
| <b>i.e.</b>  | : <i>id est</i> , that is             |
| <b>e.g.</b>  | : <i>exempli gratia</i> , for example |
| <b>n.d.</b>  | : no date                             |
| <b>Art.</b>  | : article                             |
| <b>No.</b>   | : number                              |



## LIST OF TABLES

**Table 1:** Rare Disease Definitions by Member States of European Union ("EU").....7

**Table 2:** Rare Disease Definitions by the Rest of the World.....8

**Table 3:** Definitions of Orphan Drug According to the EU and Some Countries.....14



## INTRODUCTION

The most fundamental privileges of being human is the right to health and the right to access to essential drugs. Every individual has the right to fully, equally enjoy these rights regardless of their country, economic situation, race or gender. These rights are among the main rights that must be provided in order for a person to continue his/her life fully and to benefit from other rights and freedoms, within the scope of all human-based principles. However, from past to present, discrimination has been made in terms of the development level of countries and emerging diseases in these rights, and these have not been applied equally.

The lack of "medicine" and "access to medicine", which are the basis of the fundamental rights, showed itself especially regarding to diseases that people of least-developed countries ("LDC") or developing countries suffer from; and such diseases have been ignored by developed countries and big pharmaceutical companies, and no essential medicine has been produced. Especially since the past, medicines for rare diseases, which is uncommon in a society and therefore concern a segment that can be described as a minority, are not produced by pharmaceutical companies as they are not considered profitable; or the medicines produced are offered to the market at very high prices. Likewise, for diseases such as "*Human Immunodeficiency Virus*" ("HIV")/"*Acquired Immune Deficiency Syndrome*" ("AIDS"), "*tuberculosis*" and "*malaria*", which are not rare and very common in developing countries, adequate medicines have not been produced or produced medicines have been offered to the market at very high costs, due to the low prevalence in developed countries.

The fact that the produced medicines are offered to the market at prices much higher than the production cost is based on the aim of meeting the Research&Development ("R&D) and investment costs for the production in question and profit maximization. This aim is based on the patent protection and the rights derived from it. With the patent, which is a document given to the right owner for the protection of inventions, the patent owner acquires a monopoly right on his invention. Thanks to this right, he will be able to apply the pricing policy he wants to his invention and prevent third parties from exercising, making, or marketing it for a specific time frame.

Various flexibility has been put forward to enable access to medicines by reducing high medicine prices and increasing medicine production, the most prominent of which is compulsory licensing. The compulsory license, basically, is the right of another party to have a license on a patented innovation, with the decision of a public authority, as a result of the fulfillment of certain conditions. With this license, the invention is used in line with the needs of the society. With the license, it is aimed to decrease drug prices and increase access to drugs by producing generics of drugs that cannot be used by another party for a specific term due to the protection of patent, especially within the scope of drug patents.

The objective of this research is to analyze the effects of compulsory licensing within the scope of orphan drugs particularly in the right to health and right to access to drugs, particularly regarding to LDCs and developing countries.

In the first part, diseases that are rare will be defined in general according to their prevalence and classification in countries. Subsequently, the rights of the individual and the effects of these rights will be examined light of the right to health and the right to

access to medicines, finally, the correlation between these rights and patent rights will be evaluated.

In the second part, the compulsory license instrument, which is the main subject of this study, will be examined in terms of its historical and legal framework within the scope of three main international agreements, and the development process of the compulsory license will be emphasized.

In the third part, the general rules and conditions regarding the compulsory license instrument within the scope of international agreements will be emphasized, and then in which situations and under which conditions a compulsory license will be granted will be examined. The explanations in this section have been prepared on the basis of internationally accepted legal regulations and are valid for all compulsory license applications. In addition, this section will focus on the prominent events that took place within the scope of the reasons for compulsory licensing.

In the fourth part, the positive and negative aspects of the compulsory license application in terms of various actors and perspectives, especially in developing and developed nations, will be discussed. Afterwards, the impact of compulsory licensing on pharmaceutical R&D and investment activities will be evaluated by considering the positive and negative features, and finally, the applicability of the compulsory license on orphan drugs will be analyzed based on general information about the compulsory license and case studies.

Finally, in the fifth part, alternative mechanisms against the compulsory license instrument and the applicability of these mechanisms will be analyzed to increase access to drugs, specifically in the framework of rare and neglected diseases, and at last, alternative mechanisms will be generally evaluated.



## **CHAPTER ONE**

### **RARE DISEASES AND ORPHAN DRUGS IN GENERAL, GENERAL VIEW OF THE HUMAN RIGHTS FRAMEWORK, AND THE CORRELATION BETWEEN HUMAN RIGHTS AND PATENTS**

#### **I. Rare Diseases and Orphan Drugs in General**

##### **A. Rare Diseases in General**

In medical terms, rare diseases are defined as special types of diseases that heterogenic, intertwined with mental and physical disorders, have high complexity, life-limiting and even life-threatening<sup>1</sup> effects, generally affect more than one system, chronically debilitating, and visibly lowering the quality of life.

While 80% of rare diseases are genetic, 20% are thought to be caused by environmental or idiopathic reasons<sup>2</sup>.

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<sup>1</sup> **Sibel Atalay**, "Recent Issues on Accessibility to Orphan Drugs and Policy Implications in Turkey", (Unpublished Master Thesis, Yeditepe University, 2020), accessed May 03, 2021,

[https://tez.yok.gov.tr/UlusalTezMerkezi/tezDetay.jsp?id=v\\_tvBsAOiVswJmFUdWC6g&no=OUEO8xaOinoCTBlR8DoYzQ](https://tez.yok.gov.tr/UlusalTezMerkezi/tezDetay.jsp?id=v_tvBsAOiVswJmFUdWC6g&no=OUEO8xaOinoCTBlR8DoYzQ).

<sup>2</sup> **Duygu Ürek and Sevilay Karaman**, "Önemli Bir Halk Sağlığı Sorunu Olarak Nadir Hastalıklar ve Yetim İlaçlar", *Hacettepe Sağlık İdaresi Dergisi* 22, no.4 (2019): 863-878, accessed May 03, 2021,

[https://www.researchgate.net/publication/338178116\\_Onemli\\_Bir\\_Halk\\_Sagligi\\_Sorun](https://www.researchgate.net/publication/338178116_Onemli_Bir_Halk_Sagligi_Sorun)

In 2001, it was determined that there were approximately 5000 rare diseases worldwide and this number constitutes 10% of all disease types<sup>3</sup>. This number is raising day after day, and data of the *World Health Organization* ("WHO") stated that there are between 5000-8000 known rare diseases and new conditions today. In addition to this, roughly 250 new rare diseases are identified each year<sup>4</sup>.

Rare diseases include many genetic forms of disease as well as some cancers, autoimmune diseases, degenerative diseases and hereditary disabilities. Some of these diseases are; "*cystic fibrosis*", "*muscular dystrophy*", "*haemophilia*" and "*spina bifida*"<sup>5</sup>.

With the increasing number of diseases and emerging new conditions day by day, rare diseases have attracted the attention of both governments and societies, and have become a substantial public health issue with unique challenges, in many countries.

---

[u Olarak Nadir Hastalıklar ve Yetim İlaçlar Rare Diseases And Orphan Drugs A s An Important Public Health Problem](#)

<sup>3</sup> **Buket Aksu**, "Rare Disease and Orphan Drug Situations in Turkey and around the World", *Aurum Journal of Health Sciences*. 1, no.2 (2019): 95-109, accessed May 03, 2021, <https://dergipark.org.tr/tr/pub/ajhs/issue/47098/592398>,

<sup>4</sup> **Ece Doğuç**, "Yetim İlaçların (Orphan Drugs-Nadir Hastalıklarda Kullanılan İlaçlar) Türkiye'de ve Dünyadaki Durumu", *Sağlık Akademisyenleri Dergisi*, 4, no.3 (2017): 196-201, accessed May 03, 2021, <https://dergipark.org.tr/tr/pub/sagakaderg/issue/46725/586029>

<sup>5</sup> **Government of Western Australia**, Department of Health. *Rare Diseases*, n.d., accessed May 05, 2021, [https://www.healthywa.wa.gov.au/Articles/N\\_R/Rare-diseases](https://www.healthywa.wa.gov.au/Articles/N_R/Rare-diseases)

There are many definitions of rare diseases in the literature. However, apart from the medical definition of rare diseases, there is no single, harmonious and internationally accepted definition<sup>6</sup>. Each region or country has defined rare diseases as framed in their own laws and regulations.

**Table 1:** Rare Disease Definitions by Member States of European Union ("EU")<sup>7</sup>

|         |                                                                                                                                                                                                                                                                                    |
|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EU      | Diseases or disorders that are mostly genetic, have a low prevalence (less than 1 per 2000), threatening life, or are chronically debilitating, resulting in significant morbidity or neonatal and premature deaths, and that cause major reductions in the person's life quality. |
| Belgium | Persistently weakening or life-threatening diseases that affect less than 1 in 2000 individuals.                                                                                                                                                                                   |
| Denmark | Rare disease does not have an official definition. However, rare diseases are defined by health authorities as diseases that affect no more than 500-1000 people in the Danish population.                                                                                         |
| Estonia | Rare disease does not have an official definition. Estonia accepted the definition of EU.                                                                                                                                                                                          |
| Finland | Severe and debilitating diseases that do not affect more than 1 person in 2000 people.                                                                                                                                                                                             |

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<sup>6</sup> **Domenica Taruscio, Fiorentino Capozzoli and Claudio Frank** "Rare Diseases and Orphan Drugs", *Annali dell'Istituto superiore di sanita*, 47, no.1 (2011): 83-93, accessed May 03, 2021, [https://doi.org/10.4415/ANN\\_11\\_01\\_17](https://doi.org/10.4415/ANN_11_01_17)

<sup>7</sup> **European Commission**, *Implementation report on the Commission Communication on Rare Diseases: Europe's challenges [COM (2008) 679 final] and Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02)*, 2014, accessed May 04, 2021, [https://ec.europa.eu/health/sites/default/files/rare\\_diseases/docs/2014\\_rarediseases\\_implementationreport\\_en.pdf](https://ec.europa.eu/health/sites/default/files/rare_diseases/docs/2014_rarediseases_implementationreport_en.pdf)

|        |                                                                                                             |
|--------|-------------------------------------------------------------------------------------------------------------|
| Sweden | Illnesses or conditions that affect less than 100 individuals per million and cause significant disability. |
|--------|-------------------------------------------------------------------------------------------------------------|

**Table 2: Rare Disease Definitions by the Rest of the World<sup>8</sup>**

|                      |                                                                                                                                                           |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Argentina            | Low prevalence diseases affecting less than 1 in 2000 people, as in the EU's description of rare disease.                                                 |
| Australia            | Diseases that occur in less than 2000 patients in the population, which is corresponding to 1.2 per 10,000.                                               |
| Japan                | According to the Japanese Medicine Act, conditions or diseases for which the number of people affected is no more than 50.000.                            |
| Singapore            | Life-threatening and staidly debilitating illnesses that affect no more than 20.000 people.                                                               |
| Turkey               | Rare diseases have no official explanation. As in the EU definition of rare diseases, it is accepted as diseases that affect 1 person in 2000 people.     |
| United States ("US") | According to the Food & Drug Administration ("FDA"), diseases that affect less than 200.000 people, which are equivalent to about 6.5 patients in 10.000. |

The WHO defines diseases in which the number of people impacted by the disease or the frequency of symptoms are below 0.1% as rare diseases<sup>9</sup>. Likewise, rare diseases are diseases that affect 6.5 people in 10,000 people.

<sup>8</sup> Ibid.

<sup>9</sup> **Arif Köken, Mustafa Hayırlıdağ, and Nüket Büken**, "Sağlık Hakkı Bağlamında Nadir Hastalıklar ve Yetim İlaçlar-Rare Diseases and Orphan Drugs in the Context of Right to Health", *Türkiye Klinikleri J Med Ethics Law Hist-Special Topics* 4, no.1 (2018): 91-8, accessed May 04, 2021, [https://www.researchgate.net/publication/323445712\\_Saglik\\_Hakki\\_Baglaminda\\_Nadir\\_Hastaliklar\\_ve\\_Yetim\\_Ilaclar\\_Rare\\_Diseases\\_and\\_Orphan\\_Drugs\\_in\\_the\\_Context\\_of\\_Right\\_to\\_Health](https://www.researchgate.net/publication/323445712_Saglik_Hakki_Baglaminda_Nadir_Hastaliklar_ve_Yetim_Ilaclar_Rare_Diseases_and_Orphan_Drugs_in_the_Context_of_Right_to_Health)

As can be seen from the Table 1 and Table 2, these diseases are generally defined on the basis of their low prevalence and rarity in a particular population. In other words, to be accepted as rare, a disease should not affect more than a certain number of individuals in the total population.

The low prevalence of the disease, determined as the main criterion in the definition, varies between 1/10000 and 10/10000. The prevalence assessment in question is performed by the *European Organization for Rare Diseases* and *Orphanet* with the support of European Commission<sup>10</sup>.

As can be understood from the definitions, rare diseases are perceived as health problems impacting a minor number of individuals compared to common diseases in the general population. However, although it seems to affect a relatively small number of people, it affects approximately 6% to 10% of the total population<sup>11</sup>. This number corresponds to roughly 400 million people globally, which is a significant minority of the population. Variety of sources state that, 30 million individuals in Europe and 25 million in North America are affected with rare diseases<sup>12</sup>.

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<sup>10</sup> Aksu, "Rare Disease and Orphan Drug Situations in Turkey and around the World", 97.

<sup>11</sup> Warren Kaplan et al., *Priority Medicines for Europe and the World: 2013 Update Report*, (WHO, 2013), 148, accessed May 04, 2021, [https://www.researchgate.net/publication/249995018\\_Priority\\_Medicines\\_for\\_Europe\\_and\\_the\\_World\\_2013\\_Update\\_Report](https://www.researchgate.net/publication/249995018_Priority_Medicines_for_Europe_and_the_World_2013_Update_Report)

<sup>12</sup> Ibid.

Rare diseases can be seen less frequently in a certain region or ethnic group, while it can be seen more frequently in another region or ethnic group. In other words, rare diseases may vary according to time and geographic region. For instance; While cystic fibrosis, which is a genetic disease, is rare in Asian countries, it is more common in Europe<sup>13</sup>. "*Leprosy*" is a rare disease in France however widespread in Middle Africa<sup>14</sup>. Likewise, diseases such as typhoid, tuberculosis and dysentery, which were quite common in Turkey in the past, are now considered in the rare disease category.

The concepts of rare disease, orphan disease and neglected disease are not clearly defined in the literature and these concepts are often used interchangeably. This situation leads to misunderstanding and confusion about what each of these concepts means and what reality each of them reflects.

## **B. Orphan Diseases**

Orphan diseases, which are generally used instead of the term rare diseases, include both rare diseases and neglected diseases. The term orphan disease is used refer to two separate but related concepts: On the one hand, it is used to refer to general conditions such as Fabry Disease and Alveolar Echinococcosis that are neglected by physicians, on the other hand, it is more specifically used to describe to diseases that

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<sup>13</sup> **Atalay**, "Recent Issues on Accessibility to Orphan Drugs and Policy Implications in Turkey", 3.

<sup>14</sup> **Elizabeth Hernberg-Stahl and Miroslav Reljanovic**, "Characteristics of Rare Diseases", in *Orphan Drugs: Understanding the rare disease market and its dynamics*, (Woodhead Publishing, 2013), 60.

impact only a minority of population.<sup>15</sup> That is, orphan diseases do not only cover the term rare disease but also include diseases that are neglected by the health sector.

These diseases are called "orphans". Because the small market of a limited number of patient population provides only low financial support and encouragement for the production and development of new drugs and treatment<sup>16</sup>. In other saying, these diseases are not seen as profitable, so they are not "adopted" by the pharmaceutical industry.

### C. Neglected Diseases

The term neglected disease refers to common and infectious diseases that affect people, most of whom live in the financially insufficient and developing nations of the world<sup>17</sup>. Some tropical diseases and diseases that do not provide sufficient incentives to develop drugs are considered within this scope. These are "neglected" by pharmaceutical

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<sup>15</sup> **J.K. Aronson**, "Rare Diseases and Orphan Drugs," *British Journal of Clinical Pharmacology*, 61 (2006): 243-245, accessed May 05, 2021, <https://doi.org/10.1111/j.1365-2125.2006.02617.x>

<sup>16</sup> **James W. Dear, Pajaree Lilitkarntakul and David J. Webb**, "Are Rare Diseases Still Orphans or Happily Adopted? The Challenges of Developing and Using Orphan Medicinal Products," *British Journal of Clinical Pharmacology* 62, no.3 (2006): 264-271, accessed May 05, 2021, <https://doi.org/10.1111/j.1365-2125.2006.02654.x>

<sup>17</sup> **Marilyn J Field and Thomas F Boat, ed.**, *Rare Diseases and Orphan Products: Accelerating Research and Development*, (Washington, DC: National Academies Press, 2010), 37.

companies because they are not seen as profitable<sup>18</sup>. Therefore, neglected diseases are not rare diseases.

#### **D. Orphan Drugs in General**

Orphan drugs, which are pharmacological products for the cure of rare diseases, are pharmaceutical products that are intended to treat rare diseases, which pharmaceutical companies are reluctant to develop under ordinary market conditions due to the very long, expensive and uncertain process from the discovery of a new molecule to its marketing. Investing in research, development and marketing for orphan drug is not considered profitable by pharmaceutical companies due to the low number of target patient population affected by rare diseases. In a word, orphan drugs are drugs that are not developed by pharmaceutical companies for economic reasons but are important drugs for public health needs<sup>19</sup>.

The term "orphan drugs" has been introduced by the governments of developed countries to assist in the development and marketing of pharmacological products by the

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<sup>18</sup> **European Organization for Rare Diseases (EURORDIS)**, "Rare Diseases: Understanding this public health priority", November 2005, accessed May 05, 2021, <http://www.eurordis.org/publication/rare-diseases-understanding-public-health-priority>

<sup>19</sup> **ORPHANET**, "About Orphan Drugs", *The portal for Rare Diseases and Orphan Drugs* accessed May 06, 2021, [https://www.orpha.net/consor4.01/www/cgi-bin/Education\\_AboutOrphanDrugs.php?lng=EN](https://www.orpha.net/consor4.01/www/cgi-bin/Education_AboutOrphanDrugs.php?lng=EN)

pharmaceutical companies for patients suffering from rare diseases living in their countries<sup>20</sup>.

There are two basic criteria, epidemiological and economic, for a drug or product to be determined as "orphan". In order to meet the epidemiological criterion, the product must be developed to treat a rare or low prevalence disease. The economic criterion is that regardless of the disease prevalence for the product, there is no expectation to fully regain R&D and production costs with sales revenues in the country where the orphan status is given<sup>21</sup>. So that drugs that are used in the treatment of rare diseases and whose production costs cannot be amortized with the profit obtained from their sales are in the status of orphan drugs. In other words, the use of a drug only in the treatment of a rare disease is not the only condition for qualifying as an orphan drug.

As with the rare diseases, orphan drug definitions and conditions for obtaining orphan drug status vary also within the framework of laws and regulations of countries and regions.

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<sup>20</sup> **Christina N Kontoghiorghie et al.**, "World health dilemmas: Orphan and rare diseases, orphan drugs and orphan patients", *World Journal of Methodology* 4, no.3 (2014): 163-188, accessed May 06, 2021, <https://doi.org/10.5662/wjm.v4.i3.163>

<sup>21</sup> **Stefano Villa, Amelia Compagni and Michael R Reich**, "Orphan Drug Legislation: Lessons for Neglected Tropical Diseases", *The International Journal of Health Planning and Management* 24, no.1 (2009): 27-42, accessed May 07, 2021, <https://doi.org/10.1002/hpm.930>

**Table 3:** Definitions of Orphan Drug According to the EU and Some Countries<sup>22</sup>

|           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Australia | According to the Orphan Drug Policy, orphan drugs are drugs that are used in the cure of a rare disease or are not economically viable when used in the target patient population.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Argentina | According to the National Administration for Food, Drugs and Technology's Regulation, an orphan drug is described as a medicine with an elevated medicinal relevance and scientific feasibility that is not existing because of different causes or conditions to treat or enhance the health issues of patients.                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| EU        | <p>It is described as a pharmacological product that is developed for rare diseases, which is life-threatening or permanently debilitating, and has a low return on investment due to small market capacity.</p> <p>According to the EU Regulation (EC) No 141/2000, three basic criteria must be found together in order for a drug to be granted orphan status. These criteria are:</p> <ul style="list-style-type: none"><li>• It should be produced for a rare disease with low prevalence,</li><li>• The medicinal product should provide a significant benefit over existing diagnostic, preventive or therapeutic products for rare diseases,</li><li>• There should be no other satisfactory method of diagnosing, preventing or treating a rare disease.</li></ul> |

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<sup>22</sup> **Hernberg-Stahl and Reljanovic**, *Orphan drugs: Understanding the rare disease market and its dynamics*, 14.

|        |                                                                                                                                                                                                                              |
|--------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Turkey | Currently, there is no official definition of the term orphan drug and the regulation about orphan drugs. Generally, drugs used in the cure of rare disorders are defined as orphan drugs.                                   |
| US     | The Orphan Drug Act defines orphan drugs as medicine or biological products used for the cure of rare diseases or circumstances that affect a minority living in the United States (with a prevalence of less than 200.000). |

As can be understood from the definitions of different countries in Table 3, orphan drugs are drugs that have additional factors such as the absence of alternating treatments, will treat diseases below the limit determine for rare diseases, and have a scientific rationale for the treatment at any phase of this drug.

## II. The Overview of Human Rights Framework

### A. The Human Right to Health

The human right to health is mentioned in numerous sources. For instance; Article 25.1 of the Universal Declaration of Human Rights ("UDHR") states that *"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services"*<sup>23</sup>.

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<sup>23</sup> **The United Nations General Assembly**, *Universal Declaration of Human Rights*, 1948, accessed June 12, 2021, <https://www.un.org/en/about-us/universal-declaration-of-human-rights>

Article 12.1 of the International Covenant on Economic, Social and Cultural Rights ("ICESCR") acknowledges that everyone has the right to the enjoyment of the highest attainable standard of physical and mental health<sup>24</sup>.

According to the Declaration of Alma-Ata; *"health, which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector"*<sup>25</sup>.

As can be seen, this right, which is analogous to the right to life, acknowledged as a basic and standard right, which has been codified and well-founded differently in numerous major international treaties and national constitutions and has gained universal validity.

This right is about health and it means the individual's request from the state authority to protect and develop his/her health, to be treated in case of illness, and to benefit from the opportunities provided to the society. From this point of view, this right is a fundamental right that the government has to fulfill, and it includes many freedoms and obligations. In this context, the right to health is a positive right of the individual.

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<sup>24</sup> **The United Nations General Assembly**, *International Covenant on Economic, Social and Cultural Rights*, 1966, accessed June 12, 2021, <https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx>

<sup>25</sup> **International Conference on Primary Health Care**, "Declaration of Alma-Ata", *WHO Chronicle* 32, no.11 (1978), accessed June 12, 2021, [https://www.euro.who.int/\\_data/assets/pdf\\_file/0009/113877/E93944.pdf](https://www.euro.who.int/_data/assets/pdf_file/0009/113877/E93944.pdf)

This right is considered as an inclusive right that can be divided into specific sub-headings. Some of these sub-headings are the control, prevention and treatment of diseases within the scope of access to essential medicines<sup>26</sup>.

All states should ensure that this right as a whole is accessible to all individuals; must protect and support this right. There should be no discrimination at any level between any individual while carrying out these acts. This is stated in the Constitution of WHO (1946) as "*The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.*" That is to say, in the implementation of this right, equality of opportunity should be provided for every person, and an equal and non-discriminatory access should be created.

As it can be understood, non-discrimination and equality, which are the two most basic elements of human rights, are among the critical constituents at the center of this right.

## **B. The Right to Access to Essential Medicines**

This right, which stems from the right to health and is an indispensable and required part of it, is acknowledged as one of the basic and crucial parts.

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<sup>26</sup> **Burcu G. Özcan Büyüktanır, Görkem Birinci and Uğur Ömürgönülşen**, "Trips Sözleşmesi ve İlaç Firmalarının Sağlık Hakkına İlişkin Etik Sorumlulukları", *H.Ü. İktisadi ve İdari Bilimler Fakültesi Dergisi*, 30, no.2 (2012): 1-26, accessed June 14, 2021, <https://dergipark.org.tr/tr/download/article-file/88736>

It has been acknowledged by the United Nations ("UN"), in addition to WHO, as one of the initial marks in evaluating the level of the progressing achievement of the right to the greatest achievable standard of health. Also, countless court cases, as well as the UN and WHO approve that access to essential medicines is a basic part of the right to health and connected to other rights, like the right to life<sup>27</sup>.

According to WHO, essential drugs are drugs that meet the health requirements of the majority. These medicines should always be available in appropriate quantities and doses, at a price that individuals and communities always access<sup>28</sup>. In other words, essential medicines are life-saving medicines that are imperative for the preservation and continuity of the patient's life. The term essential medicines is nested in the right to health and life, especially in customary international law, and is derived from these rights.

Accessibility, affordability and availability, which are the three interrelated criteria for the application of the right to health, are also applied within the provision of essential medicines that are an important part of this right.

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<sup>27</sup> **Paul Hunt and Rajat Khosla**, *Human Rights Guidelines For Pharmaceutical Companies in Relation to Access to Medicines: The Sexual and Reproductive Health Context*, 2008, accessed June 28, 2021, <http://repository.essex.ac.uk/4425/1/human-rights-guidelines-pharmaceutical-companies-access-medicines.pdf>

<sup>28</sup> **Özcan Büyüktanır, Birinci and Ömürgönülşen**, 'Trips Sözleşmesi ve İlaç Firmalarının Sağlık Hakkına İlişkin Etik Sorumlulukları', 5.

Accessibility means that medicines should be accessible to every individual without discrimination of any nature<sup>29</sup>. Adequate accessibility for medicines is a main and primary step for the right to health. Accessibility contains economic accessibility, in other words, affordability. According to this term, medicines should be affordable to all based on equity.

Additively to being accessible, drugs must also be available in all parts of the nation. Drugs must be available without inequality on any of the forbidden grounds, such as race, ethnicity, socio-economic status and race. The WHO, countless court cases, verdicts of the Human Rights Council, and other international regulations confirm access to essential drugs should be available for all.

States have primary obligations for improving these three criteria. They need to make sure that available medicines are in enough quantities, affordable and accessible for every individual without any discrimination. In addition to the obligations of states, pharmaceutical companies and private providers should also take positive steps that help individuals and communities about the access to medicines<sup>30</sup>.

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<sup>29</sup> **Ines Lasić**, "Pharmaceutical Patents, Right to Health and Access to Essential Medicines: A Human Rights Critique", (Master Thesis, Lund University, 2013), 28, accessed July 06, 2021, <http://lup.lub.lu.se/luur/download?func=downloadFile&recordId=3955219&fileId=3955220>

<sup>30</sup> **Hunt and Khosla**, "Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines", 13.

Timely and proper implementation of the three criteria aforementioned above has a significant place in fulfilling the right to health. The difficulties in realizing these three criteria and the lack of access to adequate essential drugs became a global issue. This issue is mainly due to the unreasonably high costs of medicines and the existence of gross inequities in access to medicines<sup>31</sup>. High medicine costs and inequalities affect all countries, not just developing ones.

States are responsible to ensure that their people have access to medicines, whether by actually buying and procuring them or by other means like making sure the price of medicines makes them accessible<sup>32</sup>. While fulfilling these responsibilities, states should act in a nondiscriminatory and equal manner, and provide that all individuals and groups have equal, effective and transparent access to medicines.

Non-discrimination and equality principles further allude those states should acknowledge and ensure for the diversity and particular requirements of groups that usually confront specific health difficulties, such as greater mortality and morbidity rates or disease vulnerability<sup>33</sup>.

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<sup>31</sup> Ibid., 2.

<sup>32</sup> **Richard T. De George**, "Intellectual Property and Pharmaceutical Drugs: an Ethical Analysis", *Business Ethics Quarterly: The Journal of The Society for Business Ethics* 15, no. 4 (2005): 549-75, accessed June 07, 2021, <https://pubmed.ncbi.nlm.nih.gov/16358442/>

<sup>33</sup> **UN Office of the High Commissioner for Human Rights ("OHCHR")**, The Right to Health: Fact Sheet No. 31, June 2008, accessed June 11, 2021, <https://www.ohchr.org/sites/default/files/Documents/Publications/Factsheet31.pdf>

However, non-discrimination and equality do not always mean equal implementation of rights. In some cases, states must take on positive obligations to prioritize marginalized individuals and communities, like rare disease patients. For instance, rare disease patients who have high mortality and morbidity rates need particular attention as the most vulnerable and disadvantaged group in society, with no discrimination regarding their rights by governments, private providers and public sector. In other words, people with rare diseases are recognized as a separate community with very specific needs that must be met.

If individuals living with rare diseases are left behind and their needs are not met, the right to health can never be fully achieved and realized. Much remains to be done by states to provide that rare disease patients have equal access to rights to realize their full potential. However, the right to access medicines is one of the most solemn issues faced by rare disease patients, as most orphan drugs are not considered essential and, in addition, the price of medicines is unreasonably high<sup>34</sup>.

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<sup>34</sup> **Non-Governmental Organization ("NGO") Committee for Rare Diseases**, "The "Right to Health" in Rare Diseases: A Practical Contribution to Implementing and Achieving the Sustainable Development Goals", February 2018, accessed June 13, 2021, [https://www.ngocommitteerarediseases.org/wp-content/uploads/2018/05/NGO-CfRDs-Submission-The-Right-to-Health-in-Rare-Diseases\\_Feb-15-2018.pdf](https://www.ngocommitteerarediseases.org/wp-content/uploads/2018/05/NGO-CfRDs-Submission-The-Right-to-Health-in-Rare-Diseases_Feb-15-2018.pdf)

### **III. The Correlation Between the Human Rights and Patents**

#### **A. General Conflicts Between the Human Rights and Patents**

The right to health and the right to access drugs, are intertwined with the patent, one of the intellectual property rights. Especially in terms of providing access to necessary drugs as well as treatment, protection of patent and the rights obtained from this protection cause various conflicts, especially on the right of access to drugs, and a balance is sought between both rights.

In its narrow sense, a patent is a document that is given to the inventor by an official authority and protects the right to use the patented invention only for a certain period (20 years) by the inventor or the persons authorized by him. However, in a broad sense, a patent, besides being a document, gives its owner a monopoly right to prevent the production, use or import of the invention subject to the patent. Patents, although there are exceptions, cover all kinds of inventions, including the conditions that they are novel, contain an inventive step, and be applicable to the industry. That is, the product subject to the patent must not have been publicly disclosed, must not be obvious to an individual of ordinary competence in the related area, and must have a benefit for industrialization. Patent rights are limited in terms of place, time, and content and are not absolute rights.

There are two main reasons for protection of patent. One is the provision of fair compensation; the other is about incentives to support invention and investment activities<sup>35</sup>. In other words, the main reason for issuing a patent to the right holder is to

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<sup>35</sup> **Eniola Olufemi Adesola**, "Compulsory Patent Licensing and Access to Essential Medicines in Developing Countries After the Doha Declaration", (Doctoral Thesis,

pay a certain amount of compensation to the inventor. The patentee can then take advantage of the right to commercialize his product and prevent others from benefiting from his product.

Patents serve as an important incentive in the healthcare and pharmaceutical industries. Pharmaceutical manufacturers enjoy exclusive rights with patent protection that provides a monopoly for a specific duration. In this way, pharmaceutical companies have the freedom to determine the price of the medicine they produce. However, when the situation in question is evaluated in terms of access to drugs, it is seen that there are barriers to access to drugs due to the overpriced patented medicines. In other words, these basic rights are connected with the patent system. However, there is a fundamental distinction between a patent right and a right to access medicines. While patent rights are a temporary right issued by a government and subject to revocation by the government, the right to health as well as access to medicine is inalienable and indefinite.

At this point, when an evaluation is made as a result of international regulations regarding the correlation between patents and human rights, it is seen that a balance is sought between the interests of human rights and the interests of patent holders. It is argued that this balance will be achieved by taking a human rights-oriented approach and shaping patent rights within the framework of this fundamental right. The aim here should be to improve human welfare and dignity, to maximize economic benefit, while patent protection should be understood as a social tool rather than an economic end.

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University of South Africa, 2014), 40, accessed, June 13, 2021  
<http://hdl.handle.net/10500/18795>

However, although a human rights-based view is advocated, pharmaceutical companies that act to combat diseases and ensure the production of new medicines argue that patent protection and the rights provided by this protection and profit maximization are necessary for incentives in medicine production.

As a result, there will always be a particular conflict between companies dealing with pharmaceutical R&D and investment activities and ensuring the right of access to drugs, specifically for LDCs as well as developing countries that have difficulties in accessing medicines.

In this context, two main actors play a role in examining the correlation between IP, especially patents, and right to health within the scope of WHO's World Health Assembly ("WHA").

## **B. Opinions of the Commission on Intellectual Property, Innovation and Public Health ("CIPIH")**

CIPIH, which was established in 2003, has the task to overseeing existing R&D studies, examining the correlation between IP and the promotion of innovation, and promoting concrete recommendations to both public and private actors, particularly for diseases that affect developing countries disproportionately<sup>36</sup>. At this point, the

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<sup>36</sup> **Ellen't Hoen**, "Report of the Commission on Intellectual Property Rights, Innovation and Public Health: A Call to Governments", *Bulletin of the World Health Organization* 84, no.5 (2006): 421, accessed June 13, 2021, [https://www.researchgate.net/publication/317453165\\_Report\\_of\\_the\\_Commission\\_on\\_Intellectual\\_Property\\_Rights\\_Innovation\\_and\\_Public\\_Health\\_a\\_call\\_to\\_governments](https://www.researchgate.net/publication/317453165_Report_of_the_Commission_on_Intellectual_Property_Rights_Innovation_and_Public_Health_a_call_to_governments)

commission focuses on mechanisms that encourage various research and investment activities that are necessary for patients and provide access to innovations for the public, thereby access to medicines. In particular, the Commission tries to create a potential balance between compulsory licensing, the patent pool and various research exemptions and incentives, as well as intellectual property rules and access to medicines<sup>37</sup>.

The opinion<sup>38</sup> come forward as a result of the observation carried out by the Commission is that the preservation brought by IPRs and the innovation realized due to this protection benefits only if people have access to the product created as a result of this innovation. In other words, it is argued that the benefit of intellectual property on the human rights disappears if access to a new medicine produced cannot be provided due to high price policy.

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<sup>37</sup> Ibid.

<sup>38</sup> **Commission on Intellectual Property Rights, Innovation and Public Health**, "Public Health: Innovation and Intellectual Property Rights", *WHO* (Geneva, 2006): 196, accessed June 13, 2021, <https://iris.paho.org/bitstream/handle/10665.2/7606/CD47-20-e.pdf?sequence=1&isAllowed=y> (Intellectual property rights have an important role to play in stimulating innovation in health-care products in countries where financial and technological capacities exist, and in relation to products for which there are profitable markets. However, the fact that a patent can be obtained may contribute little or nothing to innovation if the market is too small or scientific and technological capability inadequate. Where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding)

At this point, the commission supports the compulsory licensing mechanism that ensuring access to affordable drugs in the struggle against all kinds of diseases, both communicable and non-communicable diseases ("NCD")<sup>39</sup>, and to increase competition by creating generic medicine production.

In other words, the Commission argues that R&D activities, which has an important part in ensuring access to drugs, should not be left to the monopoly of patent protection unlimitedly. It reveals that the high pricing brought by patent protection should be balanced with the right to access to drugs, through various mechanism.

### **C. Opinions of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property ("IGWG")**

Following the CIPIH report, the WHA constituted the IGWG to prepare a new framework for prioritizing and funding essential health R&D such as access to drugs and diagnostics in developing nations. The objective of the IGWG is to negotiate and enforce a global strategy as well as an action plan for setting priorities and financing primary health R&D<sup>40</sup>.

The strategy put forward by the IGWG proposes mechanisms such as patent pools, compulsory licensing to stimulate competition in the generic medicines market, the

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<sup>39</sup> **Hoehn**, "Report of the Commission on Intellectual Property Rights, Innovation and Public Health", 422.

<sup>40</sup> **Adesola**, "Compulsory Patent Licensing and Access to Essential Medicines", 248.

rejection of the use of TRIPS-plus measures in trade agreements, government-based awards and R&D incentives<sup>41</sup>.

In addition, with the Global Strategy, a fundamental change was tried to be achieved in two areas. Firstly, it recommends developing proposals for healthcare needs-focused research, including addressing the de-linking of R&D expenses and final prices for healthcare products, especially medicines. Secondly, it proposes intergovernmental negotiations on basic health and biomedical R&D agreements for the change of medical R&D rules <sup>42</sup>.

In this context, the IGWG and its Global Strategy are characterized as one of the prominent multilateral initiatives that provide better solutions to real health needs<sup>43</sup>, especially access to medicines, by changing the boundaries of intellectual property rules.

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<sup>41</sup> **Ellen't Hoen**, "The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health," *Open Society Foundations* (2009): 93, accessed June 13, 2021, [https://www.opensocietyfoundations.org/publications/global-politics-pharmaceutical-monopoly-power#publications\\_download](https://www.opensocietyfoundations.org/publications/global-politics-pharmaceutical-monopoly-power#publications_download)

<sup>42</sup> Ibid.

<sup>43</sup> Ibid.

## **CHAPTER TWO**

### **COMPULSORY LICENSE IN INTERNATIONAL REGULATIONS AND HISTORICAL PROCESS**

#### **I. Compulsory License in the Historical Process**

The term of compulsory licensing was first put forward in connection with the obligation to work domestically on a patented invention and various concessions introduced by the United Kingdom ("UK") Monopoly Statute in 1623 and recognized in many national patent laws throughout the 19th century<sup>44</sup>. This license, especially, emerged from the relationship of the patent with trade and became recognized by many national patent laws in the early 19th century in terms of not working the patented invention locally and not harming the trade<sup>45</sup>.

The first regulation on compulsory licensing came to the fore in the US Senate dated 1790. In the international arena, the term compulsory license was first accepted in the intellectual area under the name of "*strategic compromise*" at the patent law congress

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<sup>44</sup> **Carlos M. Correa**, "Intellectual Property Rights and The Use of Compulsory Licenses: Options for Developing Countries", *Trade-Related Agenda, Development and Equity Working Paper* 5, (South Centre, 1999) accessed June 22, 2021, [https://www.iatp.org/sites/default/files/Intellectual\\_Property\\_Rights\\_and\\_the\\_Use\\_of\\_Co.pdf](https://www.iatp.org/sites/default/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf)

<sup>45</sup> **Deli Yang**, "Compulsory Licensing: For Better or For Worse, the Done Deal Lies in the Balance", *Journal of Intellectual Property Rights* 17, no.1 (January 2012): 77, accessed June 22, 2021, <http://docs.manupatra.in/newslines/articles/Upload/76691AEF-0A18-46A4-9CA8-84E09668D815.pdf>

held at the Vienna World Exhibition in 1873<sup>46</sup>. Today, especially in terms of patents, regulations related to compulsory license have been accepted internationally with the Paris Convention for the Protection of Industrial Property and the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS").

In the subsequent duration, with the TRIPS Agreement, this instrument has become a concept that has become a widely accepted concept in many countries, especially in public health, non-working issues and unfair competition<sup>47</sup>. Since the TRIPS Agreement, compulsory licensing has to be part of the patent law provisions of WTO members<sup>48</sup>.

## **II. International Regulations and Legal Framework**

### **A. Paris Convention for the Protection of Industrial Property<sup>49</sup>**

#### **1. General Framework**

The Paris Convention, which covers the patent, utility model, industrial design, trademark, geographical products and the prevention of unfair competition, was signed

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<sup>46</sup> **Hakan Koçak**, "Patent Hukukunda Kullanmama Nedeniyle Zorunlu Lisans", (Master Thesis, Ankara University, 2019), 37, accessed June 22, 2021, <https://dspace.ankara.edu.tr/xmlui/bitstream/handle/20.500.12575/71684/538090.pdf?sequence=1&isAllowed=y>

<sup>47</sup> **Yang**, "Compulsory Licensing: For Better or For Worse", 77.

<sup>48</sup> Ibid.

<sup>49</sup> Hereinafter referred to as the "Paris Convention"

on March 20, 1883, in order to eliminate the differences that cause issues regarding the protection of industrial rights<sup>50</sup>.

The Paris Convention, which was periodically revised over the following years, was brought up to date with the minor changes in the Stockholm text dated 28 September 1979<sup>51</sup>. The Convention has today 177 contracting party and is administrated by the World Intellectual Property Organization ("WIPO")<sup>52</sup>.

The convention accommodates procedures to connect with the subject of priority, registration and licensing, and provides national treatment for foreign patent holders<sup>53</sup>. In other words, national arrangements for the preservation of IP of any national of the contracting nations are applicable to the nationals of other states signatory to the convention, however the person who wanted to protect his invention in other countries need to file for patent protection in each country which he wanted protection<sup>54</sup>. In this

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<sup>50</sup> **Rezan Saran**, "Fikri Mülkiyet Hukuku'nda Zorunlu Lisanslama" (Master Thesis, Istanbul University, 2019), accessed June 20, 2021, <http://nek.istanbul.edu.tr:4444/ekos/TEZ/ET001861.pdf>

<sup>51</sup> Ibid.

<sup>52</sup> **WIPO**, "WIPO-Administered Treaties", *WIPO Lex*, accessed June 20, 2021, [https://wipo.lex.wipo.int/en/treaties/ShowResults?search\\_what=C&treaty\\_id=2](https://wipo.lex.wipo.int/en/treaties/ShowResults?search_what=C&treaty_id=2)

<sup>53</sup> **Laurence R. Helfer**, "Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines", *Transnational Legal Orders* (2015): 311-339, accessed June 20, 2021, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2737170](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2737170)

<sup>54</sup> **Thomas F. Mullin**, "Aids, Anthrax, and Compulsory Licensing: Has the United States Learned Anything? A Comment on Recent Decisions on the International Intellectual

regard, one of the prominent multinational conventions assuring the preservation of IP, particularly patents, is the Paris Convention.

With the Paris Convention, a compulsory license instrument was proposed as a conciliatory solution within the scope of monopoly arising from patent rights and European countries concluded that compulsory license was the most appropriate solution to mitigate the effects of monopoly arising from patent rights<sup>55</sup>.

## 2. Related Regulations on Compulsory License

The first regulation regarding to the compulsory license is carried out with the La Hague amendment dated 1925<sup>56</sup>.

In the Paris Convention, the main cause about the acceptance of the compulsory license instrument is on the one side that to meet the requirement for the product or method that is the subject of the innovation within the borders of the nation, on the other side, is to subject the infringement of the patent right to more stringent conditions. In the Convention, the only regulation that is considered as an intervention in the national legal

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Property Rights of Pharmaceutical Patents," *ILSA Journal of International & Comparative Law* 9, no.1: (2002), accessed June 20, 2021, <https://core.ac.uk/download/pdf/51096569.pdf>

<sup>55</sup> **Nurşin Ayiter**, "Milletlerarası İhtira Hukukunun Bugünkü Durumu ve İktisaden Geri Kalmış Ülkelerde İhtira Hukuku Problemleri", *Ankara Üniversitesi Hukuk Fakültesi Dergisi* 3, no.5 (1968): 137-165.

<sup>56</sup> **Koçak**, "Patent Hukukunda Kullanmama Nedeniyle Zorunlu Lisans", 38.

orders among the regulations related to patent law and that necessitates sanctions in the situation of non-compliance is the compulsory license provisions<sup>57</sup>.

Issues regarding to the compulsory license is regulated in the Article 5/A in the convention. According to the Article 5A/1<sup>58</sup>, if a product protected by a patent in a Member State is imported from another Member State and offered for sale, the existing patent for the relevant product is not invalidated due to this importation.

According to the regulation in the Article 5A/2<sup>59</sup> of the Convention, it is regulated that compulsory licensing may be ordered in order to prevent the exclusive rights arising from the patent from being used by the right owner in a way that will be abused, and the case of failure to work is shown as an example for situations that can be considered as abuse. In other words, the case of failure to work in this article may be considered as one of the reasons for issuing a compulsory license by the Member States<sup>60</sup>. Although there is a broad range of contexts regarding the provision of compulsory license in the Convention such as public non-commercial use, anticompetitive practices, etc., the most common type of compelling precautions about compulsory license are actions to prevent

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<sup>57</sup> Ibid.

<sup>58</sup> Article 5A/1 of the Paris Convention; *"Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent."*

<sup>59</sup> Article 5A/2 of the Paris Convention; *"Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."*

<sup>60</sup> **Koçak**, "Patent Hukukunda Kullanmama Nedeniyle Zorunlu Lisans", 41.

abuses caused by the patent owner within the scope of failure to work. In this regard, there is no limitation or restriction in the Convention as to which situations will be grounds for compulsory licensing, except for the instance of failure to work. But this article does not impose an obligation to the Member States to make arrangements regarding compulsory licenses, but it is foreseen that they can make arrangements in this direction.

To briefly mention the other provisions regarding the compulsory license in the Convention, another situation is related to the duration. Article 5A/4 <sup>61</sup> in the Convention stipulates that four years from the filing of the patent application or three years from the granting of the patent in order to demand a compulsory license on the reason of failure to work.

Within the scope of the Article 5A/4, there are other issues regulated besides the duration requirement in terms of compulsory license. In this sense, the other issue regulated in the relevant article is that the compulsory licensing request of the patent right holder should be rejected if justified reasons have existed regarding failure to work. The last point in the article regarding compulsory licensing is that the compulsory license

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<sup>61</sup> Article 5A/4 of the Paris Convention; *"A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license."*

should be non-exclusive, should not be transferred or sublicensed except for the transfer of the enterprise where the said license is used and benefited.

It should be mentioned that all of these provisions for compulsory licenses in Article 5A/4 are specifically applicable to compulsory licenses on the reasons of failure to work<sup>62</sup>. They are not feasible to the other kind of compulsory licenses that the national law is free to ensure.

In addition to the above-mentioned article, compulsory licenses may also be issued on the public benefit grounds in cases where the patent owner does not abuse his exclusive rights, for instance in the areas of public health. In this area, compulsory licenses can be categorized under the heading of compulsory licenses in the public interest. National laws do not hinder the granting of such compulsory licenses by the Paris Convention and they are not subject to the limitations stated in article 5A<sup>63</sup>. In other words, compulsory licenses for the public benefit can be issued without waiting for the expiry of the duration specified in the scope of compulsory licensing related to failure to work.

## **B. Agreement on Trade Related Aspects of Intellectual Property Rights**

### **1. Establishment of TRIPS Agreement**

In the early 1980s, developing countries demanded the reformation of the Paris Convention and the establishment of a new financial scheme to facilitate access to technology. As a result of these demands, the 1986 and 1994 Uruguay Rounds were held

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<sup>62</sup> **WIPO**, *Intellectual Property Handbook*, 247.

<sup>63</sup> *Ibid.*, 248.

and the TRIPS Agreement was accepted as the Annex 1C text of the Marrakesh Agreement Establishing the World Trade Organization ("WTO"), in Marrakesh on 15.04.1994. The Agreement came into force on 1 January 1995. Since the Agreement is an annex to the WTO Agreement, all WTO members are parties to this agreement.

## 2. General Framework

The TRIPS Agreement contains an extensive variety of subjects such as copyright, trademarks, industrial designs, geographical indications, trade secrets and patent is considered as a most exhaustive and effective multinational agreement. The Agreement deals and governs with the intellectual and industrial property rights in terms of commercial and economic ways, and also from the perspective of their relations with the international industrial impact<sup>64</sup>.

The primary aim of this agreement center on how members of the WTO can cushion obstacles and distortions to international trade, how they can support effectual and sufficient preservation of IPRs, how they can provide that internal preservation precautions do not become trade barriers. The agreement states that the preservation of IP will advantage practically others as well as its creators by conducting to the lucratively transfer and spread of innovation and inventive activity<sup>65</sup>. The WTO created the TRIPS

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<sup>64</sup> **Ali Pash**, *Uluslararası Antlaşmaların Türk Marka Hukukunun Esasına İlişkin Etkileri*, (İstanbul: Vedat Kitapçılık, 2014), 73-74.

<sup>65</sup> **Chang-Sik Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries" (Doctoral Thesis, Georgetown University Law Center, 2014), 9, accessed June 26, 2021,

Agreement to establish an equilibrium between protecting patent holders and ensuring public access to inventions.

### 3. Related Regulations

TRIPS Agreement supports international intellectual property protection standards at a minimum level by reducing the differentiation between national intellectual property policies and obliges WTO member states to adhere with these standards. This put forth international rules for national intellectual property protection system. The principle of minimum standards adopted by the agreement is guaranteed by the provision of Article 1/1<sup>66</sup> of the TRIPS Agreement. According to this provision, the principle of minimum standards introduced by the agreement points out that a state that is a party to the agreement has to accept at least minimum standards; however, states can ensure more comprehensive preservation than is essential under the agreement and that any bilateral or multilateral agreement can set a greater standard<sup>67</sup>. In other words, member states of

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[https://repository.library.georgetown.edu/bitstream/handle/10822/1047832/Change-sik%20Min%20dissertation\\_opt.pdf?sequence=8&isAllowed=y](https://repository.library.georgetown.edu/bitstream/handle/10822/1047832/Change-sik%20Min%20dissertation_opt.pdf?sequence=8&isAllowed=y)

<sup>66</sup> Article 1/1 of the TRIPS Agreement; *"Members shall give effect to the provisions of this Agreement. Members may, but not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."*

<sup>67</sup> **Peter Drahos**, "Expanding Intellectual Property's Empire: The Role of FTAs" January 2003, accessed June 26, 2021,

WTO are free to constitute and implement stronger IP protection. The provisions that provide more stringent intellectual property protection are called "*TRIPS-Plus*" provisions.

In the provision of Article 7<sup>68</sup>, which regulates the purpose of the agreement, it is emphasized that a balance should be struck between the mutual benefits of those who develop technological innovations and those who use them during the protection and implementation of IPRs

The provision of Article 8<sup>69</sup>, which regulates the principles of the agreement, indicates that necessary measures can be considered with the provisions of this agreement

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[https://www.researchgate.net/publication/268001027\\_Expanding\\_Intellectual\\_Property's\\_Empire\\_The\\_Role\\_of\\_FTAs](https://www.researchgate.net/publication/268001027_Expanding_Intellectual_Property's_Empire_The_Role_of_FTAs)

<sup>68</sup> Article 7 of the TRIPS Agreement; *"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."*

<sup>69</sup> Article 8/1 of the TRIPS Agreement; *"Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."* Article 8/2 of the TRIPS Agreement; *"Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort*

in order to provide public interest in sectors that are important for the protection of nutrition, socio-economic and technological development, and specifically public health. Pursuant to this article, the measures in question may be such as to prohibit the misuse of IPRs by patent owners or to protect them from practices that unnecessarily hinder trade or negatively impact the international transmission of technology. These measures consist of TRIPS flexibilities, especially the compulsory license instrument protected and placed on legal ground by the agreement.

Before expressing the compulsory license instrument and the provisions about this instrument, which will be examined in detail in the title below, it is necessary to state the patent protection and the TRIPS flexibilities regarding this protection in general terms.

The fifth section of the second part of the TRIPS Agreement includes the regulation on patents and TRIPS flexibilities. Article 30 is about the exceptions to the rights issued to the patent owner, and Article 31 is about the exercise of the patent without the permission of the right owner, including compulsory licensing.

According to the TRIPS Agreement, a patent protects all kinds of innovations and technologies, including products and processes, within the framework of Article 27/1<sup>70</sup>

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*to practices which unreasonably restrain trade or adversely affect the international transfer or technology."*

<sup>70</sup> Article 27/1 of the TRIPS Agreement; *" Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable*

of the Agreement. With this Article, the extent of patentable subject matter was increased importantly. For instance; prior to this Article medicines and their manufacturing processes had not been patentable in some developing and even developed countries. However, with the TRIPS Agreement the extent of the protection has expanded. In order for an invention to be evaluated within the scope of patent protection, it must be novel, contain an inventive step and have industrial applicability. Patent protection gives the patentee 20 years of the exclusive right which includes preventing the third parties from making, exercising, marketing, or importing the innovation without the patentee's consent. In other words, third parties have no authorization on the patented invention without permission from the inventor.

While the TRIPS Agreement provides an effective and global patent protection, it also ensures some ways that restrict the harsh impacts of patent rights on public health, public welfare and competitive environment. These mechanisms are called "*TRIPS-Flexibilities*". TRIPS-Flexibilities basically aim to balance the private interests of intellectual property creators/inventors arising from IPRs and the interests of the public enjoying these rights. In other words, these flexibility mechanisms function as exceptional provisions that serve to make a balance between the benefits of the public and the benefits of the inventor by eliminating the negative effects of patent protection. The main point is that the provisions in question must be compatible and coherent with the TRIPS Agreement<sup>71</sup>.

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*without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."*

<sup>71</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries", 13.

TRIPS-Flexibilities generally consist of parallel importation, exceptions to exclusive rights ("Bolar Exception"), government use as well as compulsory licenses. The most important and prominent instrument in the field of public health, where these flexibilities are frequently used, is a compulsory license, and only the problems arising from compulsory license will be discussed in this thesis.

Members of the WTO may exercise any of the aforementioned flexibilities to avoid misuse of exclusive rights granted to the right owner by the Agreement. TRIPS flexibilities, and in particular compulsory licensing, are important tools that can assist countries accomplish their fundamental obligations to ensure access to essential and affordable drug<sup>72</sup>. The usage of such flexibilities will facilitate global access to essential drugs for all, create and maintain general competition, actively reduce the medicine prices. In this sense, among other IP tools, these flexibilities are policy areas for countries to reduce the negative impact of patents (e.g. overpriced patented medicines) and achieve the goal of public health.

### **C. The Doha Declaration on the TRIPS Agreement and Public Health<sup>73</sup>**

#### **1. Legal Nature of the Doha Declaration**

The Doha Declaration adopted by the WTO member states in Doha, Qatar on 14 November 2001 at the 4th WTO Ministerial Meeting is essentially a declaration that

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<sup>72</sup> **Başak Özkök Gökmen**, *Patent Hakkının Sınırları ve İstisnaları: Kamu Sağlığı Gerekçesi Özelinde İncelenmesi*, (Ankara: Adalet Yayınevi, 2020), 280.

<sup>73</sup> Hereinafter referred to as to "Doha Declaration"

confirms the concerns about access to medicines under the TRIPS Agreement, public health and various exceptions, particularly the compulsory license<sup>74</sup>.

The Doha Declaration includes and promotes the interpretation and implementation of specific provisions of the TRIPS Agreement by the member states within the scope of ensuring adequacy, accessibility and affordability of medicines for all, especially the preservation of public health<sup>75</sup>. In other words, the Declaration aims to clarify the balance between the IPRs which are preserved within the TRIPS Agreement and the politics of public health. The Declaration creates this balance by bringing a public health perspective to the purpose and relevant provisions of the TRIPS Agreement. In this respect, the Declaration states that the fields of public health and the IPRs cannot be isolated from each other. Within this scope, the Doha Declaration is the first historical document that exclusively address the correlation between the IPRs and the public health since the establishment of multinational trading system.

The Declaration is considered as a proper interpretation tool, which broadly interprets and executes the provisions of the TRIPS Agreement, especially TRIPS flexibilities and access to drugs, within the framework of public health, clarifies the

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<sup>74</sup> **South Centre**, "The Doha Declaration TRIPS and Public Health Ten Years Later: The State of Implementation" *Policy Brief* 7, no.1 (November 2011), accessed June 28, 2021 [https://www.southcentre.int/wp-content/uploads/2013/06/PB7\\_-Doha-Declaration-on-TRIPS-and-Health\\_-EN.pdf](https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf)

<sup>75</sup> **Shimrit Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, Intellectual Property Rights and Compulsory Licenses." (Master Thesis, Tilburg University, 2012), 30, accessed June 28, 2021 <http://arno.uvt.nl/show.cgi?fid=127476>

existing provisions without changing them, and introduces new provisions<sup>76</sup>. In other words, the Doha Declaration affirms and strengthens the rights to public health in the TRIPS Agreement, and guides how the agreement should be interpreted nationally and internationally. This interpretation also includes facilitating access to pharmaceutical patents, ie., compulsory licensing, which is a type of flexibility, especially in terms of providing access to essential medicines related to epidemics, infectious or other types of diseases requiring precautions<sup>77</sup>.

## 2. General Structure

The Doha Declaration consists of seven paragraphs. The first three of these are of an introductory nature to the declaration and its purpose. In this sense, paragraphs 1 to 3 summarize the concerns of both developing and developed countries regarding intellectual property protection for public health, while recognizing that a balance must be made between inventor's rights and public welfare benefits. Paragraphs 4 to 7, on the other hand, address various perspectives of the TRIPS Agreement, such as the right to issue compulsory licenses, the right to specify the reasons for which licenses are issued, the right to specify what the national emergency is and the conditions of extreme urgency,

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<sup>76</sup> **Aleksandar Ristanić**, "Using Compulsory Licenses to Facilitate Access to Medicines: The Indian Experience" (Master Thesis, Lund University, 2016), 29, accessed June 29, 2021, <https://lup.lub.lu.se/student-papers/search/publication/8894039>

<sup>77</sup> **İpek Çimen Bulut**, "Avrupa Birliği Rekabet ve Fikri Mülkiyet Kuralları Çerçevesinde Hakim Durumun Kötüye Kullanılmasının Bir Sonucu Olarak Zorunlu Lisanslama" (Master Thesis, Dokuz Eylül University, 2014), 99, accessed June 29, 2021, [https://tez.yok.gov.tr/UlusalTezMerkezi/tezDetay.jsp?id=yvNywyDvu-e\\_7lZ1cSuwsA&no=unE6jtfpz9XjJXii25ne5g](https://tez.yok.gov.tr/UlusalTezMerkezi/tezDetay.jsp?id=yvNywyDvu-e_7lZ1cSuwsA&no=unE6jtfpz9XjJXii25ne5g)

the freedom to determine the system of extinction of IPRs, and how it should be interpreted and applied. In this sense, the first three paragraphs are considered as the preamble of the Declaration, and the other paragraphs as the implementing provisions<sup>78</sup>. Because of the subject of the thesis, only paragraphs 1 to 6 of the declaration will be explained in general terms.

In paragraph 1, epidemic diseases such as as "*tuberculosis*" , "*HIV/AIDS*", and "*malaria*" are shown as examples of diseases that require urgent action, and the seriousness and importance of public health problems arising from these diseases and affecting developing or LDCs have been accepted by the WTO countries. It should be emphasized that the reason why some diseases are exclusively listed in the provision is the intention to give elucidatory examples of public health problems affecting many developing and LDCs<sup>79</sup>. With the spread of diseases such as diabetes and cancer in other countries, which are frequently encountered in high-income countries, the approach of not limiting diseases within the framework of the declaration has become more important and any public health problem is included in the scope of this provision.

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<sup>78</sup> **Frederick M. Abbott**, "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO" *Journal of International Economic Law*, 5 (2002): 490, accessed June 29, 2021, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1493725](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1493725)

<sup>79</sup> **Kevin Outterson**, "Disease-Based Limitations on Compulsory Licenses Under Articles 31 and 31bis" *Boston University School of Law Working Paper* 09, no.26 (2009): 7, accessed June 29, 2021, [https://scholarship.law.bu.edu/cgi/viewcontent.cgi?article=1852&context=faculty\\_scholarship](https://scholarship.law.bu.edu/cgi/viewcontent.cgi?article=1852&context=faculty_scholarship)

Paragraph 2 points out that the TRIPS Agreement should be a part of comprehensive national and international action to address the issues raised in the declaration, in particular public health. This paragraph affirmed that IPRs are one of the factors affecting public health, but also stated that it is not the only factor.

With the provision of Paragraph 3, the declaration expresses the concerns about the significance of intellectual property protection in the new medicine development, as well as the impacts of such protection on prices of medicines. In this regard, the Declaration pioneered the ability of countries with insufficient production capacity and low economic competence to access costly medicines at affordable prices.

With the provision of Paragraph 4, the member states declare that they acknowledge that the TRIPS Agreement "*does not and should not prevent member states from taking the necessary measures to protect public health*<sup>80</sup>." In this context, while reaffirming their adherence to the TRIPS Agreement, they appointed that the Agreement "*can and should be interpreted and implemented in a way that supports the right of WTO members to protect public health and, in particular, to promote access to medicines for all.*<sup>81</sup>" Paragraph 4 refers to two parts; interpretation and fulfillment of the Agreement. This provision provided a valid basis for the Member States to introduce flexibilities to preservation of patent in their domestic legislation to preserve public health and encourage access to drugs. The provision consolidates the clear meaning of Article 8 of the TRIPS Agreement, which enables members to take the necessary precautions to

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<sup>80</sup> **WTO**, "Declaration on the TRIPS Agreement and Public Health", (November 2001), accessed July 1, 2021 [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)

<sup>81</sup> Ibid.

preserve public health. In this sense, it is a regulation that can be used as an important interpretation tool that the measures taken regarding public health in line with the Agreement, especially at the points where the text of the Agreement is ambiguous. In other words, any prevention that is essential to preserve public health cannot be opposed to the provision of TRIPS Agreement<sup>82</sup>. On the other hand, exclusive importance was attached to the issue of "*access to drugs for all*" in the provision. It was stated that the implementation of this objective should be given importance when interpreting the obligations of the Agreement. In this implementation, it has an important role that not only the developing and LDCs take the necessary measures for the preservation of public health, but also that the developed countries do not hinder the measures taken by the developing or less developed countries<sup>83</sup>.

Although the 5th paragraph is divided into various titles, the first 3 titles will be briefly explained due to their relevance to our thesis. In this context, first of all, the 5/1-a provision states that each provision of the TRIPS Agreement should be interpreted in line with the purposes and principles determined in the Articles 7 and 8 of the Agreement, and that the customary interpretation rules should be implemented in the light of these purposes and principles.

Paragraph 5/1-b has reaffirmed many primary flexibilities in the TRIPS Agreement, especially compulsory licensing, which concerns public health. In the continuation of the provision, it is stated that each member country has the right to issue compulsory licenses and also has the freedom to specify the reasons for issuing these licenses. In other words, with the aforementioned provision, the grounds for issuing

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<sup>82</sup> **South Centre**, *The Doha Declaration TRIPS and Public Health Ten Years Later*, 4.

<sup>83</sup> *Ibid.*, 4.

compulsory licenses are given directly to the national discretion<sup>84</sup>. Member states have full freedom to rely on various grounds such as public interest, public health, non-working, etc. for the issuance of compulsory licenses<sup>85</sup>. There are various examples in the literature regarding the possibilities of implementing for a compulsory license, especially for the preservation of public health. These are high medicine prices and barriers to access to medicines, anticompetitive practices of pharmaceutical companies, inability of pharmaceutical patent right holders to meet medicine needs, and public health emergencies<sup>86</sup>.

With the provision 5/1-c, the terms "*national emergency or state of extreme urgency*", which are vaguely included in the TRIPS Agreement, have been clarified. With this provision, national discretion was granted in the scope of public health crises by first giving each member state the right to specify which situations and conditions constitute a national emergency or state of extreme urgency<sup>87</sup>. With this discretion, it has been clarified that the issues of compulsory licensing within the principles of the Agreement and exemption from prior negotiations with the right owner for obtaining a voluntary license, establishing various exceptions and taking other measures allowed under the Agreement<sup>88</sup>.

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<sup>84</sup> **Özkök Gökmen**, "Patent Hakkının Sınırları ve İstisnaları", 335.

<sup>85</sup> **South Centre**, "The Doha Declaration TRIPS and Public Health Ten Years Later", 4.

<sup>86</sup> **Özkök Gökmen**, *Patent Hakkının Sınırları ve İstisnaları*, 336.

<sup>87</sup> **Abbott**, "Lighting a Dark Corner at the WTO", 494.

<sup>88</sup> **Carlos M. Correa**, "Implications of the Doha Declaration on the TRIPS Agreement and Public Health", *WHO Document*, (2002): 16, accessed July 1, 2021, [https://www.who.int/medicines/areas/policy/WHO\\_EDM\\_PAR\\_2002.3.pdf](https://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf).

It further declares that public health crises, including those related to "*HIV/AIDS*", "*tuberculosis*", "*malaria*" and other epidemics, can constitute a national emergency or state of extreme urgency. Although the diseases especially listed in this provision are considered exemplary, they ensured help to narrow the extent, meaning that the concept of urgency can be used in long-term or short-term public health crises. In other words, the licenses or measures to be taken under the provision will be maintained as long as the national emergency or state of extreme urgency in question exists<sup>89</sup>. Besides, it is important to state that, these licenses may be used in "normal times" for public health necessities. Consequently, with this provision, the Declaration reconfirms the right of WTO Members to take full advantage of TRIPS flexibilities for the aim of preserving public health and ensuring access to medicines. The Declaration is effective for any public health crisis and epidemic.

#### **D. Implementation of Paragraph 6 of the Doha Declaration: "30 August Decision" and the Article 31bis**

A key necessity to take benefit of TRIPS flexibilities regarding public health, especially compulsory licensing, is the existence of the capacity to produce required and essential medicines locally. In that regard, a substantial restriction for many developing countries and LDCs is the lack of adequate manufacture capacity of pharmaceuticals<sup>90</sup>. This meant that, within the TRIPS Agreement, a country that does not have the capacity for manufacturing generics in their area, could not use compulsory licenses.

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<sup>89</sup> **South Centre**, "The Doha Declaration TRIPS and Public Health Ten Years Later", 5.

<sup>90</sup> *Ibid.*

With the 6th paragraph of the Declaration; It was stated that WTO member countries, which do not have sufficient or no production capacity in terms of the pharmaceutical industry and therefore cannot produce the essential medicines they need, may encounter difficulties in effectively benefiting from the compulsory license instrument in line with the TRIPS Agreement. However, the TRIPS Council was instructed to get a swift remedy to the problem and report to the WTO General Council by the end of 2002<sup>91</sup>.

The provision in question aims to come through the shortcomings of Article 31/(f)<sup>92</sup> of the TRIPS Agreement. Therefore, the provision empowered countries that do not have the capacity to manufacture generics for expensive patented medicines under locally granted compulsory licenses to establish a legal mechanism to acquire imports from countries willing and capable to help them, without interferences from the related right owners<sup>93</sup>. With this solution, in addition to domestic needs, a compulsory license is provided for the export of generics to countries that do not have a production capacity. In this context, it was decided that the 31/(f) provision of the TRIPS Agreement, should be changed only in terms of pharmaceutical products and, various proposals were offered by the WTO member countries during the taking of this decision. When the aforementioned proposals were examined under three headings in general, firstly, two basic proposals were made by the European Community ("EC"). These proposals are 1) making an

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<sup>91</sup> **Özkök Gökmen**, *Patent Hakkının Sınırları ve İstisnaları*, 339.

<sup>92</sup> Article 31/(f) of the TRIPS Agreement; *"Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."*

<sup>93</sup> **Jerome H. Reichmen**, "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options", *Journal of Law, Medicine and Ethics* 37, no.2 (2009): 247-263, accessed July 1, 2021, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2893582/>

exception to Article 31/(f) of the TRIPS Agreement to ensure that compulsory licenses are granted for the export of products needed to struggle with public health problems, under specific circumstances and guarantees; and 2) interpreting the limited exceptions provision in Article 30 to struggle critical public health problems and to allow manufacturing for export to certain countries within this scope<sup>94</sup>. Secondly, the US stated that compulsory licenses should be restricted to "severe" or "urgent" public health issues such as "*malaria*", "*tuberculosis*", and "*HIV/AIDS*" and that importing countries within the scope of the proposal are limited to developing and LDCs. Also, the US expressed that the license should be applied to only non-commercial and public sectors Thirdly, a set of proposals has been offered by African countries and other developing countries. In this proposal, an amendment of Article 31/(f) or an authorized interpretation of Article 30 has been proposed to allow the manufacturing of medicine without the consent of the right owner<sup>95</sup>.

The compromise resulting from these proposals recognized the problem that countries with little or no production capacity would be unable to effectively implement compulsory licensing. Upon the said compromise, the "Waiver Decision", as known as Paragraph 6 system, dated 30 August 2003 within the scope of the Declaration has been added to TRIPS with the Protocol Amending the TRIPS Agreement. It should be noted that this decision is the first to amend TRIPS Agreement.

Pursuant to the Decision, the country that wants to import a medicine through the compulsory license must notify the WTO Secretariat regarding the name of the medicine it needs and the qualifications of this medicine; that it does not have sufficient capacity

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<sup>94</sup> **South Centre**, *The Doha Declaration TRIPS and Public Health Ten Years Later*, 5.

<sup>95</sup> **South Centre**, "The Doha Declaration TRIPS and Public Health Ten Years Later", 5.

to manufacture this medicine; and if there is a patented medicine in its country, it shall notify that a compulsory license has been issued or will be granted in line with the provisions of TRIPS Article 31 and the Decision. In case of the importation of medicines through compulsory licensing a country in need, remuneration will be paid to the importing country in accordance with TRIPS Article 31<sup>96</sup>. In addition, under these situations, the patent holder will be remunerated by the exporting country, not the importing one. However, this remuneration is quite minor due to the Waiver Decision. Although the Waiver Decision has a temporary quality, it has been the subject of various positive and negative opinions. Some of the positive opinions are, for instance, that this decision is more successful than the alternative trade negotiation systems, that the extent of diseases is not restricted, and that preventing the return of cheaper medicines from developing countries to developed countries<sup>97</sup>. Some of the negative opinions, also called constraints are that just a limited number of countries have adopted legislation in order to implement the said decision as an exporting country, the system in the decision is used in limited situations and the system is quite long, complex and inconvenient for developing countries and less developed countries<sup>98</sup>. For example, the first and only LDC to use the system in question is Rwanda. The system, which is thought to have complex requirements, was used for the importation of 21000 "HIV/AIDS" medicines between Rwanda, the importing country, and Apotex, the Canadian generic medicine company, which is the supplier<sup>99</sup>.

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<sup>96</sup> **Başak Bak**, "İlaçta Zorunlu Patent Lisansı", *Ankara Barosu Dergisi*, 3 (2011): 119, accessed July 2, 2021, <https://dergipark.org.tr/tr/download/article-file/397858>

<sup>97</sup> **Özkök Gökmen**, *Patent Hakkının Sınırları ve İstisnaları*, 361.

<sup>98</sup> **South Centre**, "The Doha Declaration TRIPS and Public Health Ten Years Later", 8.

<sup>99</sup> *Ibid.*

The paragraph 6 decision of 30 August 2003, in other words the Waiver Decision, was accepted as a temporary solution and it was decided to make a permanent change to the provision of TRIPS Agreement Article 31/(f) in line with the provisions of this decision. Accordingly, the WTO members came to an agreement named The Ministerial Declaration on 18 December 2005 amending the Article 31 of the TRIPS Agreement and making the Waiver Decision permanent<sup>100</sup>. This situation is explained in the Ministerial Declaration as follow:

*"We reaffirm the importance we attach to the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and to an amendment to the TRIPS Agreement replacing its provisions. In this regard, we welcome the work that has taken place in the Council for TRIPS and the Decision of the General Council of 6 December 2005 on an Amendment of the TRIPS Agreement<sup>101</sup>."*

Within the scope of this permanent decision, Article 31*bis* has been added to the TRIPS Agreement, and various changes were made, such as allowing the export of pharmaceuticals manufactured within compulsory licensing under the said article to countries that do not have the capacity to manufacture the product, and the prevention of the patent owner from being remunerated twice<sup>102</sup>.

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<sup>100</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health", 31.

<sup>101</sup> **WTO**, "The Ministerial Declaration", 22 December 2005, accessed July 5, 2021, [https://www.wto.org/english/thewto\\_e/minist\\_e/min05\\_e/final\\_text\\_e.htm#public\\_health](https://www.wto.org/english/thewto_e/minist_e/min05_e/final_text_e.htm#public_health)

<sup>102</sup> **Saran**, "Fikri Mülkiyet Hukuku'nda Zorunlu Lisanslama", 106.

As a result, in general, the Doha Declaration and the Waiver Decision enabled nations which are used compulsory licensing to import generics from other nations.

### **CHAPTER THREE**

#### **THE CONCEPT AND SCOPE OF COMPULSORY LICENSE, GENERAL PRINCIPLES AND LEGAL FRAMEWORK**

##### **I. Scope, Components and Function of Compulsory License**

###### **A. Definition of Compulsory License**

Compulsory licensing or non-voluntary licensing is generally defined as a mechanism whereby the state authority authorizes a government or another party without or against the right holder's consent for the exploitation of a patented product<sup>103</sup>. In other words, a compulsory license is considered an involuntary contract granted by a government to another party to exercise, sell or import a patented innovation, without the right holder's permission.

The provisions regarding TRIPS flexibilities, including compulsory license, are contained in Articles 30 and 31 of the TRIPS Agreement. First, in Article 30, the exceptions regarding the rights arising from the patent were mentioned, and in addition, the compulsory license mechanism, albeit implicitly, was stated with the expression "*other use without the authorization of the right holder*" in Article 31.

Although the concept of the compulsory license is not clearly stated in Article 31, a detailed regulation regarding this concept is included in this article, and the delicate

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<sup>103</sup> **Correa**, "Intellectual Property Rights and The Use of Compulsory Licenses", 3.

balance between enabling third parties to benefit from existing inventions and encouraging new inventions and creativity is tried to be maintained<sup>104</sup>.

In this context, the compulsory licensing mechanism, which is also highlighted in the Doha Declaration, was essentially regulated with Article 31 in a more pointed way and was described as one of the key TRIPS flexibilities.

The legal nature of the compulsory license instrument is controversial in the doctrine. In one opinion, compulsory license is a type of license agreement and is an example of an obligation to enter into a contract<sup>105</sup>. However, compulsory licensing is subject to some limitations and is realized by "pressure of the public authority"<sup>106</sup>. On the other hand, another opinion does not consider a compulsory license as a contract, since a consent transaction is not established between the parties<sup>107</sup>. Those who support this opinion do not make an assessment of the legal nature of the compulsory license, they

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<sup>104</sup> **Çimen Bulut**, "Avrupa Birliği Rekabet ve Fikri Mülkiyet Kuralları Çerçevesinde Hakim Durumun Kötüye Kullanılmasının Bir Sonucu Olarak Zorunlu Lisanslama", 94.

<sup>105</sup> **Rafael V. Baca**, "Compulsory Patent Licensing in Mexico in the 1990s: The Aftermath of NAFTA and the 1991 Industrial Property Law", *IDEA: The Journal of Law and Technology* 35, no.2 (1994): 34, accessed July 9, 2021, <https://scholarlycommons.pacific.edu/cgi/viewcontent.cgi?article=1427&context=globe>

<sup>106</sup> **Madhavi "Mira" Chopra**, "Of the Big Daddy, the Underdog, the Mother Hen, and the Scapegoats: Balancing Pharmaceutical Innovation and Access to Healthcare in the Enforcement of Compulsory Patent Licensing in India, its Compliance with TRIPS, and Bayer v. Natco", *Santa Clara Journal of International Law* 13, no.2 (2015): 345, accessed July 9, 2021, <https://digitalcommons.law.scu.edu/scujil/vol13/iss2/2/>

<sup>107</sup> **Ali Necip Ortan**, *Patent Lisans Sözleşmesi*, (Ankara: Doğan Basımevi, 1979), 155.

generally only include the definition of the compulsory license. Another opinion defines compulsory licenses as administrative contracts managed by a government agency<sup>108</sup>, in other words *ex lege*<sup>109</sup> licenses.

In our opinion, the compulsory license does not have the nature of a contract since it is carried out without the consent of a party and its conditions are determined by the public authorities. The compulsory licensing mechanism can be considered as a limit or exception to the rights arising from patent protection<sup>110</sup>.

The compulsory licensing mechanism, which will be examined in detail within the scope of the thesis, aims to support the right to health and the right to access to medicines, by spreading technology to the public and ensures the wide utilization of inventions under patent protection at affordable and reasonable prices<sup>111</sup>.

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<sup>108</sup> **Enrico Bonadio**, "Compulsory Licensing of Patents: The Bayer/Natco Case", *European Union Intellectual Property Review*, no.10 (2012): 720, accessed July 9, 2021, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2157477](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2157477)

<sup>109</sup> Derived from the legal rights and obligations; by virtue of law.

<sup>110</sup> **Hakan Koçak**, "TRIPS Anlaşması'nda İlaç Patentlerinin Zorunlu Lisansı", *Türkiye Adalet Akademisi Dergisi*, no.41 (2020): 282, accessed July 9, 2021, <https://dergipark.org.tr/tr/download/article-file/1500621>

<sup>111</sup> **Patel Nishidh**, "Compulsory Licenses 'A Two-Edged Sword'", (September 4, 2011): 7, accessed July 9, 2021, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1922292](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1922292)

## B. Components and Principles of Compulsory License

The compulsory license instrument, which is one of the most substantial and key elements of the TRIPS Agreement, is regulated in Articles 30 and 31. Article 31 of the agreement focuses directly on the compulsory license instrument compared to the title of "exceptions to rights conferred" in Article 30, and considers this instrument as an exception to infringement of a patent, instead of a dispensation from patentability under the title of *"other use without the authorization of the right holder"*<sup>112</sup>.

In that regard, Article 31 contains an exhaustive list of various procedural requirements. Member states must comply and assist with the fulfillment of eleven of the twelve requirements on this list. Eleven requirements in question impose significant restrictions on the implementation of the compulsory license instrument and are considered to provide a strict safeguard<sup>113</sup>.

Article 31 of the TRIPS Agreement, which will be examined in detail below, contains the minimum and undetailed principles for the issue of compulsory license. The principles regarding the establishment process of the compulsory license are regulated in

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<sup>112</sup> **Neil George Cherian**, "Using Compulsory Licenses to Access Pharmaceuticals: A Cross Case Analysis on Outcomes", (Master Thesis, University of Oslo, 2016), 12, accessed July 12, 2021, [https://www.duo.uio.no/bitstream/handle/10852/54054/1/Cherian\\_Thesis\\_Nov2016.pdf](https://www.duo.uio.no/bitstream/handle/10852/54054/1/Cherian_Thesis_Nov2016.pdf)

<sup>113</sup> **Jerome H. Reichman and Catherine Hasenzahl**, "Non-voluntary Licensing of Patented Inventions", *Intellectual Property Rights and Sustainable Development*, no.5 (June 2003): 14, accessed July 12, 2021 [https://unctad.org/system/files/official-document/ictsd2003ipd5\\_en.pdf](https://unctad.org/system/files/official-document/ictsd2003ipd5_en.pdf)

the Article 31/(a,b,c,h). According to the provision of 31/a, public authorities authorized to issue compulsory licenses should evaluate each compulsory license request according to the characteristics of the concrete case. In other words, member states should decide by examining whether each compulsory license request meets the compulsory license requirements determined in the legislation, instead of granting a universally valid compulsory license authorization for patents in certain areas<sup>114</sup>. 31/b provision states that before the compulsory license decision, the party requesting the compulsory license should make a plausible effort to establish a license agreement with the right holder with admissible commercial conditions. According to the 31/c provision, the scope and duration of compulsory licensing should be determined by considering the objective of issuing the compulsory license. 31/h consists the provision that a compulsory license must be established in consideration of a sufficient compensation according to the conditions in the compulsory license decision, considering the financial value of the license.

The principles regarding the implementation of the compulsory license are regulated in the provisions of Article 31/(f,g,i,j). According to the provision of 31/f, the products manufactured under the compulsory license must be supplied to the local market of the country where the compulsory license is decided. Provision of 31/(i,j) states that the compulsory license decision should be able to be audited by a different higher authority or a jurisdiction than the authority that made the decision. Lastly, Article 31/g regulates the termination of compulsory license. Accordingly, a person with a legal interest should be able to request the termination of the compulsory license if the reasons for granting the compulsory license disappear and there is no possibility of reoccurrence.

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<sup>114</sup> **Koçak**, "TRIPS Anlaşması'nda İlaç Patentlerinin Zorunlu Lisansı", 283.

The principles regarding the qualification of the compulsory license are regulated in Article 31/(d,e). According to these regulations, compulsory licenses cannot be exclusive and, as a rule, non-transferable.

The principles, among other things, required for the issuance of compulsory license in Article 31 are gathered under the provisions of:

- Assessment on a case-to-case basis (Art. 31/(a))
- Prior negotiation with the patentee (Art. 31/(b))
- Restricted scope and duration (Art. 31/(c))
- Non-exclusivity (Art. 31/(d))
- Non-transferability (Art. 31/(e))
- Use for domestic market (Art. 31/(f))
- Termination of the license (Art. 31/(g))
- Adequate remuneration (Art. 31/(h))
- Judicial review (Art.31/(i,j))

### **1. Principle of Case-to-Case Basis Evaluation:**

According to the provision of the article, a WTO member state cannot automatically subject an entire class of medicines, e.g., essential medicines, or classes that can be licensed, such as technology and food, to a pre-established compulsory license mechanism<sup>115</sup>.

The compulsory license should be given as a result of an evaluation carried out on individual merits, taking into account the characteristics and purpose of the concrete case

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<sup>115</sup> **Reichman**, "Compulsory Licensing of Patented Pharmaceutical Inventions", 10.

for which the license is requested. In that regard, the compulsory license must be given after the case-to-case assessment. In other words, states should not enact laws that automatically grant a compulsory license in particular areas or vis-a-vis certain patent holders<sup>116</sup>.

## **2. Prior Negotiation Principle**

Pursuant to Article 31/b of the TRIPS Agreement, the license seeker must make an effort to negotiate with the patent owner to acquire a voluntary license under acceptable commercial conditions and within a admissible duration before applying for a compulsory license. In this context, a prior negotiation is a prerequisite for requesting a compulsory license, and it strengthens the position of the patent owner and plays a role that provides predictability<sup>117</sup>. In other words, it is not possible to request a compulsory license without prior negotiation for a voluntary license.

Seeking the acceptable commercial terms criterion in the license proposal is intended to protect the interests of the patent owner. Because it is possible for a license proposal with admissible commercial conditions to be accepted by the patent owner. Likewise, the interests of both the applicant and the right holder are protected by seeking the continuation of the prior negotiations for a reasonable duration.

If the voluntary license cannot be obtained within an acceptable time and is arbitrarily refused<sup>118</sup> by the patent owner, the license seeker has the right to request a

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<sup>116</sup> **Bonadio**, "Compulsory Licensing of Patents", 724.

<sup>117</sup> **Ristanić**, "Using Compulsory Licenses to Facilitate Access to Medicines", 27.

<sup>118</sup> **Bonadio**, "Compulsory Licensing of Patents", 725.

compulsory license. However, it is worth noting that the necessity of prior negotiation can only be waived in situations of national emergency, other extreme urgency or public non-commercial use.

### 3. Principle of Scope, Duration and Termination

Article 31/(c) of the TRIPS Agreement lays down a limit on the scope and duration of the compulsory license. According to this provision, the conditions in the compulsory license decision should be determined on the basis of the duration and scope related to that purpose, in accordance with the purpose of issuing the license. That is, the scope and duration of the compulsory license should be proportional to the objective of issuing the license in question. In that regard, the compulsory license may be issued for the invention subject to the license in order to provide the needs of a certain class of the community. In such a case, the licensee's authority should only be limited to the needs of the class in question. For instance, the compulsory license granted for a pharmaceutical patent due to the public health crisis should have a functional and necessary scope for the remedy of this health problem, and the compulsory license duration should be determined accordingly<sup>119</sup>. Or, it may be possible to issue a compulsory license in a certain area such as the defense sector with certain patent claims that are valid only for a certain territory<sup>120</sup>.

In addition to the provision of this article, it is stated in the provision of TRIPS 31/(g) that the competent authority can be terminated compulsory license if the conditions for granting a compulsory license are no longer valid or there is no probability of

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<sup>119</sup> **Koçak**, "TRIPS Anlaşması'nda İlaç Patentlerinin Zorunlu Lisansı", 283.

<sup>120</sup> **Bonadio**, "Compulsory Licensing of Patents", 725.

recurrence<sup>121</sup>. This provision states that the compulsory license cannot be granted automatically to the invention subject to the patent during the entire protection duration<sup>122</sup>. Therefore, if the conditions for granting the license are no longer met, a termination can be requested by those with an interest. Also, it is emphasized in subparagraph 31/(k) that the competent authority may reject the request for the termination of the compulsory license if there is a possibility of recurrence of anti-competitive practices in compulsory licenses granted due to disruption of the competition order<sup>123</sup>.

#### 4. Non-exclusivity and Non-transferability Principle

According to the provision of Article 31/(d) compulsory license cannot be exclusive. In other words, the patent right holder, i.e. the licensor, may grant more than one voluntary or compulsory license for the invention subject to the license. He also may himself have the right to enter the market by continuing to the exploitation of the invention in question and may compete with the other license seekers and competitors<sup>124</sup>. With this article, it is aimed not to prevent the patent owner from benefiting from his invention without completely severing his relationship with patent<sup>125</sup>.

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<sup>121</sup> **Koçak**, "Patent Hukukunda Kullanmama Nedeniyle Zorunlu Lisans", 52.

<sup>122</sup> **Bonadio**, "Compulsory Licensing of Patents", 726.

<sup>123</sup> **Koçak**, "Patent Hukukunda Kullanmama Nedeniyle Zorunlu Lisans", 54.

<sup>124</sup> **Bonadio**, "Compulsory Licensing of Patents", 725.

<sup>125</sup> **Özkök Gökmen**, *Patent Hakkının Sınırları ve İstisnaları*, 162.

In subparagraph (g) of the same article, it is stated that the compulsory license cannot be transferred as a rule. This provision aims to prevent the development of the market for compulsory licenses, which are tools of independent value<sup>126</sup>.

However, there are exceptions to this rule. According to these exceptions, firstly, the transfer of the rights derived from the compulsory license separately from an enterprise that enjoys the license is invalid. However, if the license is related to only a part of the enterprise, the said license can be transferred only with that part. Secondly, in case the license is granted for dependent patents, the dependent patent can be transferred<sup>127</sup>. These exceptions are intended to ensure the continuity of investments made for compulsory licensing and to meet the public's need for invention.

In short, with the non-exclusive and non-transferable character of the compulsory license, conspicuous abuses of the license are tried to be prevented.

## **5. Domestic Market Use Principle**

The licensee within the scope of Article 31/(f) must predominantly supply the products manufactured under compulsory license to the local market of the country where the compulsory license has been granted<sup>128</sup>. In other words, the principle of national use is in question in terms of compulsory license. With this provision, licenses are mostly valid for selling products in the country where the non-voluntary license is issued.

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<sup>126</sup> **Bonadio**, "Compulsory Licensing of Patents", 725.

<sup>127</sup> Article 31/(l) of the TRIPS Agreement; "[...] *the use authorized in respect of the first patent shall be non-assignable except with the assignment of second patent.*"

<sup>128</sup> **Koçak**, "Patent Hukukunda Kullanmama Nedeniyle Zorunlu Lisans", 52.

Although this is the general rule, sales abroad are permitted in exceptional and limited circumstances<sup>129</sup>.

The principle of national use and its exceptions, which will be examined in detail, are of great importance, especially in terms of whether the licensee has the right to export.

## **6. Adequate Remuneration Principle**

In the cases of compulsory license, an adequate remuneration should be made to the right holder, considering the financial value of the license and the characteristics of the circumstances, even if a license is issued against the consent of the right holder. This remuneration is usually in the form of royalty<sup>130</sup>.

When determining an adequate remuneration, the criteria set in Article 1 of the TRIPS Agreement should be considered. The TRIPS Agreement mentions that member states are free to specify the suitable procedure to implement the provisions of this Agreement within their legal system and practice, and indicates that member states may set criteria in their national legislation to determine what an adequate remuneration is. In other words, regarding royalties, it should be noted that there is no internationally accepted criterion for determining the remuneration to be paid<sup>131</sup>. The lack of adequate

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<sup>129</sup> **Bonadio**, "Compulsory Licensing of Patents", 726.

<sup>130</sup> **Eniola Olufemi Adesola**, "Compulsory Patent Licensing and Access to Essential Medicines", 93.

<sup>131</sup> **WHO Mission**, "Improving Access to Medicines in Thailand: The Use of TRIPS Flexibilities", (Bangkok, 2008): 24, accessed July 15, 2021, <https://www.keionline.org/misc-docs/thaimissionreportfeb08.doc>;

remuneration definition in the TRIPS Agreement has led to results of arbitrary royalties depending on the license type and application.

In that regard, some countries envisage different maximum rates for compulsory license royalties. For instance, in the compulsory license regarding an ulcer medicine patent, the royalty was determined by UK is 45%, by the Philippines is 2.5%, and 3.5% by Japan. Canada usually sets a rate of 4% for compulsory license royalties. The USA generally adopted the rate of 6%, although it has changed over the years. Malaysia determined 4%, Mozambique 2%, Zambia 2.5% and Indonesia 0.5% royalty for HIV/AIDS drug patents. In practice, it is claimed that the compulsory license royalties for patents in the pharmaceutical industry are between 2% and 10%<sup>132</sup>.

## **7. Principle of Judicial Review**

According to Article 31/(i) of the TRIPS Agreement, decisions of compulsory license can be appealed and decisions can be requested to be review. In addition, it is stated in Article 31/(j) that the compulsory license remunerations may also be the subject of appeal. With the provision of 31/(j), the possibility of appeal to the compulsory license remuneration is not introduced as a new feature, but the existence of the possibility of appeal expressed in Article 31/(i) is emphasized once again<sup>133</sup>. According to these regulations, member states are obliged to provide the opportunity to appeal against compulsory license decisions and license royalties.

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<sup>132</sup>**Adesola**, "Compulsory Patent Licensing and Access to Essential Medicines", 122.

<sup>133</sup>**Koçak**, "Patent Hukukunda Kullanmama Nedeniyle Zorunlu Lisans", 53.

Under the above-mentioned regulations, the appeal authority may be a judicial authority or an administrative authority. However, the authority that will examine the objection must have a different and higher qualification than the public authority that grants the license, and the examination must also be carried out independently<sup>134</sup>.

In this context, the fact that the compulsory license authority is subject to judicial review ensures the patent owner the right to some degree of legal action<sup>135</sup>.

## II. Grounds for Issue of Compulsory License

The TRIPS Agreement does not specify or restrict the admissible reasons for the compulsory licensing<sup>136</sup>. That is, the agreement does not contain a limited and particular list regarding to reasons.

From the Article 31 of the Agreement, it is understood that with the other imperative conditions, the WTO member states are free to specify the reasons for compulsory licensing and states can be granted compulsory license for almost any

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<sup>134</sup> Ibid., 54.

<sup>135</sup> **Pier DeRoo**, "Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs", *Michigan Journal of International Law* 32, no.2 (2011): 383, accessed July 15, 2021, <https://repository.law.umich.edu/mjil/vol32/iss2/3>

<sup>136</sup> Although Article 31/(c) of the TRIPS Agreement regulates that compulsory licenses can only be granted due to public interest issues and activities that harm competition, this restriction has been introduced for integrated circuit topographies and is not binding in terms of patent right.

reasonable purpose by giving wide national discretion. This approach also supported by the Article 5/(b) of the Doha Declaration, which stressed that "*each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted*"<sup>137</sup>."

Within the scope of the agreement, some common and possible grounds have been determined by various national laws for the issuance of compulsory license, although there is no certain and binding list of grounds. Some of these grounds for granting compulsory licenses are; (1) Public Non-Commercial Use/Government Use, (2) Anti-Competitive Practices, (3) Refusal to Deal, (3) Public Interest (4) Emergency and Extreme Urgency, (5) Lack of Working<sup>138</sup>, (6) Dependent Patents.

In this context, with the granting of such a patent license, it is aimed to fulfill several purposes such as mass and generic manufacture of patented products to cure diseases, anti-trust act to allow fair competition between companies, and non-commercial use by the government for the public interest<sup>139</sup>. With the public interest ground, the use of compulsory license has been relatively extended to comprise other public health issues, such as the wider access to pharmaceutical products by decreasing their prices, playing the role health crisis like "*HIV/AIDS*", "*malaria*", "*tuberculosis*"<sup>140</sup>.

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<sup>137</sup> **Ristanić**, "Using Compulsory Licenses to Facilitate Access to Medicines", 25.

<sup>138</sup> Which means failing to "work" the patent by making the product commercially available, or only making it commercially available at prices that are unaffordable by the public.

<sup>139</sup> **Yang**, "Compulsory Licensing: For Better or For Worse", 76.

<sup>140</sup> **Dianne Nicol and Olasupo Owoeye**, "Using TRIPS Flexibilities to Facilitate Access to Medicines", *Bulletin of the World Health Organisation* 91, no.7 (2013): 534, accessed

## A. Public Non-Commercial Use - Government Use

A government can authorize itself to use the patented invention. This specific type of compulsory license is named government use or public non-commercial use. According to the general opinion in the doctrine, the term of public non-commercial use also comprises the government use authorization of the patented invention<sup>141</sup>.

Describing public non-commercial use is very difficult due to its lack of standard meaning and vagueness in patent laws, and no WTO panel or TRIPS articles have a definition for this use.

The definition of public non-commercial use may be found in the procedures of the purpose of the use of the patent. Based on the procedures' nature, non-commercial use can be understood as non-profit use, while in terms of the objective of the use, non-commercial use may refer to the supply of public entities which are not functioning as commercial institutions<sup>142</sup>. Likewise, even private entities tasked with using a patented invention for the public benefit, with regard to the objective of the usage, may fall within the scope of "public non-commercial use". Also, the fact that the license is used to promote a public healthcare program can be considered as an adequate rationale.

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July 18, 2021,  
[https://www.researchgate.net/publication/245030067\\_Using\\_TRIPS\\_flexibilities\\_to\\_facilitate\\_access\\_to\\_medicines](https://www.researchgate.net/publication/245030067_Using_TRIPS_flexibilities_to_facilitate_access_to_medicines)

<sup>141</sup> **DeRoo**, "Public Non-Commercial Use", 374.

<sup>142</sup> **WHO Mission**, "Improving Access to Medicines in Thailand", 22.

The government can grant a compulsory license in the type of government use or public non-commercial use for a number of purposes and grounds. In other words, there is no limitation on the reasons for granting compulsory licenses in these types, as in the case for compulsory licensing in general. In this context, various countries have added various purposes and reasons to their national laws, such as difficulty in accessing drugs due to high drug prices, preservation of public health and the health of groups that constitute a certain segment of the population, in order to issue compulsory licenses within the framework of government use. For instance, French law in this context allows compulsory licensing of medicines "*only when they are made available to the public in inadequate quantity or quality, or at significantly high prices*<sup>143</sup>." A government use license can also be utilized by the government to authorize another party to carry out particular actions, such as purchasing and supplying medicines, in a manner that does not constitute patent infringement<sup>144</sup>. Similarly, a government may issue compulsory licenses to distribute generically manufactured medicines to its citizens, often through its own healthcare program. This is also considered in the extent of public non-commercial use, as the government will generally provide medicines to the public free or non-profit with this license.

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<sup>143</sup> Article L613-16 of the French Intellectual Property Code ("CPI"); "*[...] only when these products, or products resulting from these processes, or these methods are made available to the public in an insufficient quantity or quality, or at abnormally high prices [...]*"

<sup>144</sup> **Ellen't Hoen**, "Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines", (2016): 51, accessed July 22, 2021, <https://haiweb.org/wp-content/uploads/2016/07/Private-Patents-Public-Health.pdf>

In the situation of government use or public non-commercial use, contrary to the general compulsory license rule, there is no requirement for prior negotiation with the right holder to grant a voluntary license. In other words, where a patent is used by the government for public benefits, the necessity for prior negotiations to grant a voluntary license with the right owner is waived. This waiver allows a speedy process with fewer bureaucratic hurdles, especially when there is an urgent need for life-saving medicines<sup>145</sup>. Because of this waiver, this type of compulsory licenses is preferred by most governments. However, according to article 31/(b)<sup>146</sup> of the TRIPS Agreement, in public non-commercial use cases, the government has an important obligation to urgently notify the patent owner. The Agreement does not have any explanatory or restrictive provision regarding the content of this notification. Nevertheless, considering the practices in certain countries regarding the compulsory license and the notifications made to the patent owners, the content of the notification should mainly include<sup>147</sup>:

- \* The compulsory license decision and the grounds for the decision,
- \* The number of products to be produced under the license,

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<sup>145</sup> **Cecilia Oh**, "Compulsory Licenses: Recent Experiences in Developing Countries", *International Journal of Intellectual Property Management* 1, no. 1/2 (2006): 25, accessed July 22, 2021, [https://www.researchgate.net/publication/247835566\\_Compulsory\\_licences\\_Recent\\_experiences\\_in\\_developing\\_countries](https://www.researchgate.net/publication/247835566_Compulsory_licences_Recent_experiences_in_developing_countries)

<sup>146</sup> Article 31/(b) of the TRIPS Agreement "[...]In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;"

<sup>147</sup> **Koçak**, "TRIPS Anlaşması'nda İlaç Patentlerinin Zorunlu Lisansı", 292.

- \* The countries to which the products produced under the license will be exported,
- \* The remuneration to be paid and the type of payment,
- \* The term of the license,
- \* The law to be applied in disputes.

Basically, the public non-commercial use/government use license is divided into two different systems as the US system and the UK system. In this context, under 28 United States Code ("USC") 1498, the US system provides a wide example of how patents can be comprehensively framed for public use where the US government can use the patents or authorize another party to use the patents for various public purposes<sup>148</sup>. According to this system, The US government does not have to negotiate or seek for a voluntary license for the use of a patent. The government is only responsible for paying reasonable remuneration to the patent owner<sup>149</sup>. In that regard, the right holder has a right to reasonable and entire remuneration but may not have appeal to interim injunction to inhibit the use of the patent by the government or the delegated contractor, who would act on government's behalf<sup>150</sup>.

Another type of government use is in the UK system. This system is called "Crown Use" according to the 1883 Crown Act, and the patent is used in "Crown Services" without the prior consent or negotiation with the patent owner<sup>151</sup>. The license can be used by the Crown itself or by an authorized third party. The use of the license by the Crown in the

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<sup>148</sup> **Oh**, "Compulsory Licenses", 25.

<sup>149</sup> **Correa**, "Intellectual Property Rights and The Use of Compulsory Licenses", 18.

<sup>150</sup> **Oh**, "Compulsory Licenses", 25.

<sup>151</sup> **Correa**, "Intellectual Property Rights and The Use of Compulsory Licenses", 17.

produce or supply of medicines or defense means against a certain remuneration is not considered a patent infringement.

## **B. Control of Anti-Competitive Practices - Refusal to Deal**

A widely acknowledged principle of IP law is that patent holders are not under an obligation to license a patented product to others. However, compulsory license sanction is in question in case the patent holder abuses his dominant position in the market arising from intellectual property rights<sup>152</sup>. In this context, compulsory licensing plays a role as a remedy in basic competition activities such as ensuring the balance of competition in the market, providing consumers with access to primary services such as pharmaceuticals, and encouraging innovation. With this role, the compulsory license provides a balance between competition law and intellectual property law.

The patent holder should not engage in activities that prevent, distort or restrict competition while exercising his/her monopoly right. In the correlation between the intellectual property rights ("IPR") and the competition law, anti-competitive applications may occur in the cases of unfair refusal of the deal and anti-competitive activities of IPRs by the right holder. As a result of these practices, a compulsory license is granted for a certain remuneration to protect the competitive area.

Many national laws, such as the patent laws of China, Argentina, Israel<sup>153</sup>, and the Andean Group countries consider the anti-competitive practices and essentially "refusal to deal" as a reason for the compulsory licensing.

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<sup>152</sup> **Özkök Gökmen**, *Patent Hakkının Sınırları ve İstisnaları*, 156.

<sup>153</sup> **Correa**, *"Intellectual Property Rights and The Use of Compulsory Licenses"*, 11.

For instance, in the UK and other countries that model UK legislation, a "refusal to deal" may result in compulsory licensing if an export market is not supplied, a major contribution is blocked or prohibited, the development of industrial activities is hindered or prohibited<sup>154</sup>.

### **C. Ensuring of the Public Interest**

Another way in which an invention can be subject to compulsory licensing is the public benefit. Public benefit is accepted as a reason for compulsory licensing in many countries' laws. However, there is no definite and one definition of the term public interest accepted by the countries. The term and scope of public interest differ from nation to nation and from time to time. It is the duty of the courts and administrative authorities to evaluate which situations are in the scope of the public interest.

In this context, for instance, what should be understood from the public interest in Turkish law is exemplified in Article 132/(1) of the Turkish Industrial Property Code No. 6769<sup>155</sup> ("TIPC"). In the doctrine, the increase in exports due to invention, establishment of new business areas, the prevention of an economic crises, the reduction of imports, the

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<sup>154</sup> Ibid.

<sup>155</sup> Article 132/(1) of the IP Law No. 6769; *"If use of the invention forming the subject of patent, increase of its use, dissemination of it in general, improvement of it for a beneficial use have a great importance by the reason of public health or national security issues or if non-use of the invention forming the subject of patent or its insufficient usage in terms of either quality or quantity shall cause serious damages in terms of the economic or technological development of the country [...]"* a compulsory license for the public interest is granted.

treatment of new diseases is shown as examples of situations where the public interest is accepted<sup>156</sup>.

In many jurisdictions such as the US, insufficient work, dependent patents, or obtaining a patented product by the consumer obtains a patented product at the lowest price is not considered sufficient grounds for the public interest. However, the US granted a compulsory license on the reason of public benefit in situations where the public interest was at stake, such as the 1973 energy crisis<sup>157</sup>.

Likewise, Germany grants the compulsory license due to the public interest in the presence of an indispensable situation for the public interest. In addition, the laws of developing countries such as Argentina and the Andean Group, public interest is among the grounds for compulsory licenses<sup>158</sup>.

#### **D. Emergency and Other Situations of Extreme Urgency**

In emergencies or other extreme emergencies, prior negotiation is not necessary to obtain a voluntary license. Similar to the ground of public interest, countries do not have a precise and single definition of emergency/other circumstances of extreme urgency. As indicated in Article 5/(a)<sup>159</sup> of the Doha Declaration, each country has the

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<sup>156</sup> **Özkok Gökmen**, '2*Patent Hakkının Sınırları ve İstisnaları*', 151.

<sup>157</sup> **Correa**, "Intellectual Property Rights and The Use of Compulsory Licenses", 13.

<sup>158</sup> *Ibid.*, 14.

<sup>159</sup> Article 5/(a) of the Doha Declaration; *"In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall*

authority to specify which situations and cases will fall under the scope of emergency, according to its own legal rules. As a result of this freedom, the requirement for compulsory licensing due to the ground of emergency differs from country to country and from time to time. An example of this emergency situation is to provide access to drugs in diseases such as epidemics<sup>160</sup>, "*HIV/AIDS*", "*malaria*", "*tuberculosis*", and to issue compulsory licenses for generic drug manufacture.

Since the negotiation for a voluntary license is not mandatory in case of emergency, and a compulsory license is granted directly in return for a certain remuneration, the process of granting a compulsory license based on this ground is faster and easier<sup>161</sup>.

### **III. Recent Prominent Cases of Compulsory Licensing Implementations**

#### **A. Thailand: Government Use License**

As a result of increased medicine prices due to patent protection, and difficulties in accessing medicines, the compulsory license for public non-commercial use/government-use was granted for three patented drugs in 2006 and 2007 by the Thai Government. These drugs are respectively Merck's anti-HIV/AIDS medicine "*Efavirenz*", branded "*Stocrin*"; anti-retroviral ("ARV") drug "*lopinavir/ritonavir*", branded "*Kaletra*"

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*be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."*

<sup>160</sup> **DeRoo**, "Public Non-Commercial Use", 354.

<sup>161</sup> **Hoen**, "Private Patents and Public Health", 51.

from Abbott Laboratories; The heart disease drug "*Plavix*", owned by Sanofi-Aventis and BMS, is "*clopidogrel*"<sup>162</sup>.

It has been stated by the Thai Ministry of Public Health that only 20,000 infected people in the total population have access to the necessary medicine treatment within the scope of HIV/AIDS, one of the diseases with the highest mortality rate in Thailand<sup>163</sup>.

The Thai government argues that the main reason for the low rate of access to the drugs and the insufficiency to ensure health insurance for the medicine in question is due to the excessively high medicine prices. For instance, it was stated that expenditures on public health constituted 9.5% of aggregate public expenditures in 2007, and this ratio was approximately 4,373 million baht, or 112 million dollars<sup>164</sup>. In the given year, it was pointed out by the government that one-fifth of the approximately 500,000 Thai citizens living with "*HIV/AIDS*" could ensure medicine at a price equal to the cost of producing the medicine<sup>165</sup>. In that regard, in order to increase the access of more people to the medicine by reaching a price that is equivalent to the manufacture expenses, the government first issued for a compulsory license within the scope of "*HIV/AIDS*".

At this point, Thailand ruled over compulsory licensing to manufacture generics of the "*HIV/AIDS*" drug "*Efavirenz*" from 2006 to 2011, as well as to import generic

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<sup>162</sup> **Jakkrit Kuanpoth**, "Compulsory Licences: Law and Practice in Thailand", *MPI Studies on Intellectual Property and Competition Law* 22, (2015): 64, accessed August 02, 2021, [https://link.springer.com/chapter/10.1007/978-3-642-54704-1\\_4#citeas](https://link.springer.com/chapter/10.1007/978-3-642-54704-1_4#citeas)

<sup>163</sup> Ibid.

<sup>164</sup> Ibid.

<sup>165</sup> Ibid.

versions from India until domestic production capacity is ready. However, although it was stated by one of the original medicine manufacturer Merck that the license in question was "in line with TRIPS"<sup>166</sup>, it was stated that the Thai government did not adequately negotiate access to more affordable medicines before the compulsory license decision. As a result of this decision, Thailand's compulsory license decision and the validity of the license were questioned by the US Government, and pressure was put on the Thai government to withdraw the licenses and negotiate with Merck<sup>167</sup>.

The Thai government was not affected by the pressures and ruled for compulsory licenses for the ARV drug "*Kaletra*" and the heart medicine "*Plavix*", respectively. The fact that patients who needed ARV medicine could not be covered by health insurance due to high medicine prices and limited public budget prevented the fulfillment of the "*principle of universal access to all treatments*" promised by the government, and as a result, access to medicines could not be achieved.<sup>168</sup> At this point, the Thai Government, arguing that the prices of ARV medicines are too high, ruled for the compulsory license that will increase access to medicines by providing local production of generic versions and importing generic medicines from other countries. As a result of this license, generic medicine named "*GPO-vir*" with a lower price, costing 31 dollars per patient per month,

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<sup>166</sup> **Vanessa Bradford Kerry and Kelley Lee**, "TRIPS, the Doha Declaration and Paragraph 6 Decision: What Are the Remaining Steps For Protecting Access to Medicines", *Globalization and health* 3, no.3 (2007): 4 accessed August 02, 2021 <https://globalizationandhealth.biomedcentral.com/track/pdf/10.1186/1744-8603-3-3.pdf>

<sup>167</sup> Ibid.

<sup>168</sup> **Kuanpoth**, "Compulsory Licences: Law and Practice in Thailand", 65.

were produced by the government-affiliated Government Pharmaceutical Organization and generic versions were authorized to be imported from other countries<sup>169</sup>.

Due to the heart disease that approximately 200,000 Thai patients suffer from and the high price of the necessary medicine for this condition<sup>170</sup>, the Thai government has ruled for a compulsory license for the heart medicine called "*Plavix*". As a result of this license decision, Abbot, one of the medicine owners, stated that it would not import new medicines to the Thai market and claimed that the Thai government wanted to damage the patent system with the compulsory license instrument<sup>171</sup>.

As a result of the compulsory license decisions given by the Thai government, the availability of the local production capacity in generic medicine research and production has come to the fore, especially in increasing access to medicines in the long term. However, there have been many criticisms by politicians, pharmaceutical companies and the media that compulsory licensing violates TRIPS provisions. In particular, there have been many criticisms and controversies about the lack of adequate prior negotiations with right holders before the compulsory license decision, the failure to declare an emergency before the license decision, the very low remuneration rate of 0.5%<sup>172</sup>.

The TRIPS rules regarding the compulsory license terms and conditions were referred to by the Thai government regarding the criticism and controversies in question and it was stated that they had been negotiating with the patent holders for more than 2

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<sup>169</sup> Ibid.

<sup>170</sup> **Kerry and Lee**, "TRIPS, the Doha Declaration and Paragraph 6 Decision", 64.

<sup>171</sup> **Adesola**, "Compulsory Patent Licensing and Access to Essential Medicines", 115.

<sup>172</sup> **Kerry and Lee**, "TRIPS, the Doha Declaration and Paragraph 6 Decision", 66.

years but could not come to a conclusion<sup>173</sup>. As a result of the Thai government's refusal to reverse its compulsory licensing decision, the Thai government was listed in Special 301 Reports Priority Watch list by the US, and it was argued by the US that stricter conditions regarding compulsory licensing should be enforced<sup>174</sup>.

## **B. India: Judicial Review License**

The first compulsory license in India was granted by the Indian Patent Office on March 9, 2012 to the Indian generic medicine producer Natco Pharma for the production and sale of the generic of Bayer's patented medicine called Sorafenib, branded "*Nexavar*", which is beneficial in the treatment of liver and kidney cancer<sup>175</sup>.

Although Bayer, the original medicine owner, obtained a license to import the medicine *Nexavar* into the Indian market in 2008, it was stated by the Patent Office that *Nexavar* was never imported by Bayer in 2008, and was only imported in certain and small quantities in 2009 and 2010<sup>176</sup>. That is, Bayer was not making the medicine in question accessible and to Indian patients. This situation is considered failure to work of

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<sup>173</sup> Ibid.

<sup>174</sup> Ibid., 67.

<sup>175</sup> **Bonadio**, "Compulsory Licensing of Patents", 720.

<sup>176</sup> **Maura Nuno**, "A Fair Return Approach to Pharmaceutical Compulsory Licensing", Case Western Reserve Journal of International Law 48, no.1 (2016): 403, accessed August 05, 2021,

<https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=2251&context=jil>

a patent under the Indian Intellectual Property Law<sup>177</sup>, and constitutes one of the reasons for compulsory licensing in India.

The Patent Office also found that the price Bayer set for *Nexavar* was not accessible and therefore unreasonable for Indian consumers in the Indian market, which is known to have a fairly low average income level. Indeed, the cost of Bayer's treatment involving the medicine *Nexavar* was stated as INR 280.000 (around \$5,404) a month and INR 3.365,136 (around \$64,947) a year<sup>178</sup>. This will prevent patients from accessing the medicine they need or push them further into poverty. At this point, the generic medicine manufacturer Natco, which claimed that the same medicine would reduce the monthly treatment cost to an average of \$167, requested a voluntary license from Bayer, the owner of the original medicine, as well as the request was rejected by Bayer<sup>179</sup>. Upon rejection, Natco applied to the Indian Patent Office requesting a compulsory license for *Nexavar*. During voluntary licensing negotiations before compulsory licensing, Bayer requested a royalty payment of 15 percent of net earnings, taking into account R&D costs and production costs<sup>180</sup>, but the negotiations were unsuccessful. In the end, the request for compulsory licensing was granted with a royalty rate of 6% on net sales payable quarterly to Bayer, provided it was produced for local sales only<sup>181</sup>.

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<sup>177</sup> Ibid.

<sup>178</sup> **Bonadio**, "Compulsory Licensing of Patents", 721.

<sup>179</sup> **Çimen Bulut**, "Avrupa Birliği Rekabet ve Fikri Mülkiyet Kuralları Çerçevesinde Hakim Durumun Kötüye Kullanılmasının Bir Sonucu Olarak Zorunlu Lisanslama", 101.

<sup>180</sup> **Bonadio**, "Compulsory Licensing of Patents", 721.

<sup>181</sup> **Nuno**, "A Fair Return Approach", 403

Bayer objected to the decision of the compulsory license to the Intellectual Property Appellate Board ("IPAB"), who upheld the licensing decision but raised the rate of royalty to 7%<sup>182</sup>. Upon this objection, it was rejected by the board, stating that Bayer's drug costs and expenses were not a criterion and that this remuneration amount did not have the quality to compensate for the said expenses<sup>183</sup>. Subsequently, Bayer appealed against the said decision at the Mumbai High Court, and this appeal was dismissed by the Court, stating that the IPAB's decision was convenient.

As a result, the fact that medicine prices are kept extremely high by the original medicine owner, differential price policies are not applied in different markets, and a sufficient amount of medicines are not imported to the needed market creates an obstacle in accessing the medicines. This situation leads to the issuance of compulsory licenses in accordance with the principle of protecting public health as a priority and prioritizing the interests of the public.

### **C. Rwanda-Apotex Case: Waiver Mechanism**

Granting of the compulsory license instrument for export purposes (Paragraph 6 method) was implemented one time only. Rwanda, one of the developing countries, did not have a local production capacity and needed assistance for access to medicines. In this context, on 17 July 2007, Rwanda acquainted the WTO that it aimed to import 260,000 packages of a fixed-dose compound "*HIV/AIDS*" containing "*zidovudine*",

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<sup>182</sup> Ibid.

<sup>183</sup> Ibid.

"*lamivudine*", and "*nevirapine*", manufactured by Canadian-based Apotex Inc. under the brand name "*TriAvir*", during two years<sup>184</sup>.

In the medicine in question, the existence of nine different patents and three different patent holders<sup>185</sup> with these patents created obstacles to medicine production and export. In this context, first of all, a voluntary license was requested from other patent holders by Apotex, taking into account the rules of the Canadian Patent Law<sup>186</sup>. Apotex has requested a royalty-free license, stating that it demands to market and export 15.6 million tablets for \$0.405 each. However, patent holders rejected the voluntary license<sup>187</sup>.

Following this situation, on September 19, 2007, Apotex applied for a compulsory license for export within the Canadian Access to Medicines Regime ("CAMR") to manufacture and export medicines to Rwanda under the Paragraph 6 mechanism<sup>188</sup>. As a result of the application, the two-year compulsory license was issued, which allowed and

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<sup>184</sup> **Hoen**, "Private Patents and Public Health", 45.

<sup>185</sup> **Beatrice Stirner and Harry Thangaraj**, "Learning from Practice: Compulsory Licensing Cases and Access to Medicines", *Pharmaceutical Patent Analyst* 2, 2 (2013): 198, accessed August 07, 2021, <https://pubmed.ncbi.nlm.nih.gov/24237026/>

<sup>186</sup> **Adesola**, "Compulsory Patent Licensing and Access to Essential Medicines", 117.

<sup>187</sup> **Holger P. Hestermeyer**, "Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines", *American Society of International Law* 11, no.28 (2007), accessed August 07, 2021, <https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and>

<sup>188</sup> *Ibid.*, 118.

authorized Rwanda to export the medicine containing nine patents, and Canada notified the TRIPS Council of this compulsory license on October 4, 2007<sup>189</sup>.

However, although compulsory licensing was granted, there was a substantial delay in this process. Especially, the mechanism's first implementation demonstrates that it is too inefficient to be useful. In particular, *TriAvir* was shipped to Rwanda about 4 years after the start of activities such as the manufacture of drugs by Apotex and the fulfillment of CAMR terms and conditions<sup>190</sup>. However, the delay here is due not only to the drug procedure, but also to WTO provisions Canadian legislation, and other patent holders' refusal to approve the voluntary license, as it is a combination drug<sup>191</sup>. In addition, this situation caused great financial losses for Apotex due to manufacture expenses, transaction expenses, legal expenses, and also royalties paid to the patent owner. This situation revealed a negative feature in the face of the necessity for compulsory licensing to be granted quickly, especially as a result of emergency medical assistance.

In this context, Apotex stated that the mechanism in question should be changed in order to work effectively. It has been concluded that it is not economical and encouraging to produce for only one importing country when their investment and R&D activities are compared, and also it is difficult to persuade countries to declare the import needs to the WTO<sup>192</sup>.

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<sup>189</sup> **Nishid**, "Compulsory Licenses 'A Two-Edged Sword'", 24.

<sup>190</sup> **Stirner and Thangaraj**, "Learning from Practice", 198.

<sup>191</sup> **Adesola**, "Compulsory Patent Licensing and Access to Essential Medicines", 118.

<sup>192</sup> **Hestermeyer**, "Canadian-made Drugs for Rwanda"

However, although there is a long and costly procedure, Apotex's willingness to be included in the R&D process and export the medicine combination in question is based on humanitarian grounds<sup>193</sup>. Moreover, the Apotex case is the only completed practice of exporting medicines to a third country with the compulsory license instrument.

#### **D. Brazil-"Threat Mechanism": Government Use License**

Brazil has efficiently used compulsory licensing as a threat to enable the production of local generic medicines and lower medicine prices<sup>194</sup>. The first implementation of the compulsory license as a threat in Brazil was seen in 2001. In this context, the Brazilian government threatened to issue compulsory licenses for the ARV drugs *Efavirenz*, *Lopinavir/Ritonavir* and *Nelfinavir* patents in 2001 and started negotiations with the patent owners<sup>195</sup>. In March 2001, an agreement was reached with Merck, one of the owners of *Efavirenz*, to obtain price reductions in exchange for not ruling on a compulsory license.

Subsequently, in August 2001, it was stated that compulsory licensing used by the Brazilian government to the Brazilian pharmaceutical company Far Manguinhos <sup>196</sup> for

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<sup>193</sup> **Stirner and Thangaraj**, "Learning from Practice", 198.

<sup>194</sup> **Adesola**, "Compulsory Patent Licensing and Access to Essential Medicines", 114.

<sup>195</sup> **Nathan Ford et al.**, "Sustaining Access to Antiretroviral Therapy in the Less-Developed World: Lessons from Brazil and Thailand", *AIDS* 21, no.4 (2007): 25, accessed August 09, 2021, [https://journals.lww.com/aidsonline/Fulltext/2007/07004/Sustaining\\_access\\_to\\_antiretroviral\\_therapy\\_in\\_the.4.aspx](https://journals.lww.com/aidsonline/Fulltext/2007/07004/Sustaining_access_to_antiretroviral_therapy_in_the.4.aspx)

<sup>196</sup> Ibid.

the generic production of Nelfinavir, produced under the brand name of *Viracept* belonging to Roche, and the parties started negotiations. Consequently, the compulsory license proposal put forward by the government, the price of the medicine was reduced by 40% by the owner of the medicine, Roche, in return for the Brazilian government not deciding on the compulsory license<sup>197</sup>.

As a result of these compulsory licensing threats, the Brazilian Government has come under pressure from the US government and various international pharmaceutical companies. At this point, the US complained that Brazil's article 68<sup>198</sup> of the IP Law directly violated the TRIPS agreement<sup>199</sup>. In the face of the complaint in question, various health activists and non-governmental organizations supported the Brazilian government to impose a compulsory license, and the complaint was withdrawn by the US under great pressure. In this way, the Brazilian government provided massive price reductions for high-cost ARV medicines<sup>200</sup>.

Until 2005, the average cost of treatment per patient rose from US\$1000 to US\$2616 per year and the cost of lopinavir/ritonavir, one of the most expensive ARV

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<sup>197</sup> **James Packard Love**, "Recent Examples of the Use of Compulsory Licenses on Patents", *Knowledge Ecology International*, (2007), accessed August 09, 2021, [https://www.keionline.org/misc-docs/recent\\_cls\\_8mar07.pdf](https://www.keionline.org/misc-docs/recent_cls_8mar07.pdf)

<sup>198</sup> Article 68 allows for compulsory licensing if the patent holder does not manufacture a product domestically within three years from the date of issuing the patent.

<sup>199</sup> **Adesola**, "Compulsory Patent Licensing and Access to Essential Medicines", 114.

<sup>200</sup> *Ibid.*

medicines, costing US\$3241 per patient per year, hinders access to the medicines<sup>201</sup>. This situation has led to compulsory licensing by the Brazilian Government.

In this context, in June 2005, the Brazilian government threatened with compulsory licensing for the local production and sale of *Kaletra* branded "*lopinavir/ritonavir*" drug, on the reasons of public benefit. At the same time, the government negotiated prices with patent holder Abbott and agreed on \$1380 per patient per year. However, the agreed amount was much higher than the best price offered by Abbott to other countries (\$500 per patient per year), and the manufacturing expenditure estimate published by the WTO (\$338 per patient per year)<sup>202</sup>.

Compulsory licensing was granted by the Brazilian government in May 2007, after negotiations with Merck, one of the medicine owners, for the manufacture and sale of *Efavirenz* were interrupted due to a low-price reduction (only 2% off the current price) claimed by Merck. It has been argued that with this license, 30 million dollars were saved from the medicine in question in 2007 alone<sup>203</sup>.

In the end, the use of compulsory licenses as a threat tool has been seen by the Brazilian government as an effective way to lower medicine prices, thereby providing less costly and faster medicines.

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<sup>201</sup> **Ford et al.**, "Sustaining Access to Antiretroviral Therapy", 25.

<sup>202</sup> **Ford et al.**, "Sustaining Access to Antiretroviral Therapy", 26.

<sup>203</sup> **Bonadio**, "Compulsory Licensing of Patents", 727.

## **CHAPTER FOUR**

### **THE EVALUATION OF COMPULSORY LICENSES IN TERMS OF DEVELOPING AND DEVELOPED COUNTRIES AND THE IMPACT OF COMPULSORY LICENSES ON R&D ACTIVITIES AND ORPHAN DRUGS**

#### **I. Evaluation of Compulsory License Instrument: PROs and CONs**

##### **A. General Evaluation**

The compulsory license instrument has different effects for different actors such as developing countries, developed countries, pharmaceutical companies, governments and patients.

In general, compulsory licensing is framed around two opposing headings. These opposite headings arise from the impact of compulsory licensing on developed and developing nations and their perspectives. The former argues that patent protection is substantial for the new drug development; the latter argues that patent protection may harm right to health and access to drugs, so TRIPS safeguards like compulsory licensing is beneficial for these situations. In this chapter, the advantages and disadvantages of the compulsory license system in terms of developing countries and developed countries will be analyzed.

Compulsory licensing is often encouraged as a way to refrain from the potential negative effect of patents on access to drugs. For instance, after a comprehensive literature review on how to increase access to drugs within the IPRs system established

under the TRIPS Agreement, compulsory licensing appears to be the most recommended TRIPS protection to improve access to drugs <sup>204</sup>.

Although difficulties in accessing medicines is often correlated with low and middle-income countries ("LMIC"), compulsory licensing of overpriced medicines is also part of the agenda of high-income countries<sup>205</sup>. However, the compulsory license instrument is evaluated differently in terms of various factors, especially the economic situation and social welfare of the countries.

According to Hunt, large pharmaceutical companies carry out their investment and production activities mainly for diseases with high market and demand value. Diseases such as malaria and tuberculosis, which are now rare in developed countries but still among the fatal diseases in many countries of the world, tropical diseases seen only in certain countries or the production of medicines for orphan diseases that are rarer than the general population, have not been taken into account because they do not have a market value and do not provide profit<sup>206</sup>. For this reason, especially by developing

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<sup>204</sup> **Eduardo Urias and Shyama V. Ramani**, "Access to Medicines After TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence", *Journal of International Policy* 3, no.4 (2020): 369, accessed July 25, 2021, [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7468182/pdf/42214\\_2020\\_Article\\_68.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7468182/pdf/42214_2020_Article_68.pdf)

<sup>205</sup> Ibid.

<sup>206</sup> **Hatice Ersöz Seer and Sevgi ar**, "İlata Ptent ve Saėlıėa Eriřim Hakkı", *Journal of Faculty of Pharmacy of Ankara University* 43, no.3 (2019): 280, accessed July 25, 2021, [https://dergipark.org.tr/tr/pub/jfpanu/issue/48575/545266#article\\_cite](https://dergipark.org.tr/tr/pub/jfpanu/issue/48575/545266#article_cite)

countries, the patent is tried to be reconciled with the right to health by applying compulsory license so that the patent does not affect this right. However, the emergence of the same diseases in developing countries and developed countries makes the compulsory license instrument considered for developed countries as well.

## **B. Developing Countries and the Advantages of Comprehensive Compulsory Licensing**

In general, according to developing countries and governments, patent holder rights should not exceed people's access to life-saving medicines<sup>207</sup>. However, these countries and NGOs express apprehension that strict patent law will hinder access to essential drugs; and one of the leeways from these difficulties is the compulsory licensing. According to them, compulsory licensing serves to strike a balance between human life and profit.

While compulsory licensing has generally positive effects for developing countries, patients and NGOs, it also has negative effects at some points. As patterns of diseases in developed and developing countries become similar, protection of patents strengthens in developing countries, and health problems increase and become more challenging, the compulsory license, a tool to increase access to patented drugs, is gaining rapid attention<sup>208</sup>. Developing nations governments need the identical patented medicines marketed in developed nations, but have few resources to access these high-priced drugs. Under these circumstances and within restricted budgets, compulsory licensing is considered an advantageous alternative to increase access to drugs.

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<sup>207</sup> **Mullin**, "Aids, Anthrax, and Compulsory Licensing", 194.

<sup>208</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries, 52.

For developing countries and patients, one of the most prominent positive effects of the compulsory license is that the prices of high-priced medicines have decreased significantly because of patent protection. With the issuance of a compulsory license, developing countries with a high burden of life-threatening diseases such as "*HIV/AIDS*" will have a better opportunity to access and afford life-saving medicines for the treatment of diseases that constitute health emergencies<sup>209</sup>. This opportunity is provided by encouraging efficient price negotiation with right holders and making possible local manufacture, importing and distributing patented drugs at accessible prices. With this cost-cutting and access-assuring feature of the compulsory license, the obstacle in front of patients who cannot access high-cost medicines is removed. For instance, in Malaysia, the "*HIV/AIDS*" drug, which consisted of three substances and was 363 dollars per month in 2001, was reduced to 115 dollars per month by the Malaysian government in 2003 by giving a compulsory license to two of these substances<sup>210</sup>.

Another positive feature of compulsory licensing is ensuring the manufacture and import generic versions of drugs. In that regard, the impact of compulsory licensing on medicine prices is prompt <sup>211</sup> and effective, especially when affordable generics are accessible in other countries. By taking a part in the development of the local industrial sector related to generic medicine production in developing countries, it reduces unemployment by increasing manufacturing capacity and thus employment.

Compulsory licensing ensures that remuneration is paid for the patent owner's right to the invention, prevents intellectual property rights abuses such as monopoly and

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<sup>209</sup> **Ibid.**, 232.

<sup>210</sup> **Ibid.**, 49.

<sup>211</sup> **Ibid.**, 48.

cartel<sup>212</sup>, and enables governments to establish a control mechanism over dominant companies. According to the developing countries, in this way, the compulsory license creates an environment of free competition.

In general, developing countries argue that compulsory licensing has an immediate effect on social justice<sup>213</sup>. Especially in the face of the fact that access to medicines is significant for life and health, a social justice perspective should be considered when deciding on compulsory license. With this perspective, the benefit of the compulsory license instrument in terms of public welfare emerges increasing public welfare with compulsory licensing is realized by creating market competition and ensuring small/middle-sized pharmaceutical companies have good opportunities like sources of new or generic medicines<sup>214</sup>.

Another advantageous feature of the compulsory license for developing countries is that it can be used as a threat tool. With the compulsory licensing instrument directed by developing countries to developed countries and large pharmaceutical companies, the willingness to issue a voluntary license under acceptable circumstances<sup>215</sup> and the possibility of negotiation in reducing medicines prices increase.

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<sup>212</sup> **Muhammad Zaheer Abbas**, "Pros and Cons of Compulsory Licensing: An Analysis of Arguments", *International Journal of Social Science and Humanity* 3, no.3 (2013): 255, accessed July 24, 2021, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2368116](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2368116)

<sup>213</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries, 234.

<sup>214</sup> **Ibid.**, 56.

<sup>215</sup> **Correa**, "Intellectual Property Rights and The Use of Compulsory Licenses", 23.

At this point, compulsory licensing enables companies to price their drugs at a lower level to enable individuals to buy them instead of losing their monopoly with the compulsory licensing instrument. This argument is seen by its supporters as the use of compulsory licensing as a commercial incentive tool<sup>216</sup>. In the doctrine, the threat of compulsory license is considered advantageous for developing countries. In the doctrine, there are those who argue that the threat of compulsory license is advantageous for developing countries, especially in the issue of voluntary licenses<sup>217</sup>. For instance, in South Africa and Brazil, the compulsory license is used as a threat tool in various cases and forces companies to decrease the prices of medicines or to settle on reasonable terms<sup>218</sup>.

In that regard, according to developing countries facing various health problems, the economic damage complained by pharmaceutical companies in developed countries should have nothing to do with the right to access adequate medicine. For these countries, compulsory licenses should be accessible for any health problem if there is a medicine

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<sup>216</sup> **Rivka Shaindla Ajzentel**, "Compulsory License: Analysis of the Effectiveness in Providing Access to Medicines" (Master Thesis, Tilburg University, 2018), 22, accessed July 25, 2021, <http://arno.uvt.nl/show.cgi?fid=145698>

<sup>217</sup> **Stephen P Ladas**, *"Patents, Trademarks and Related Rights: National and International Protection"* (Cambridge, Mass: Harvard University Press, 1975), 427 (The practical value of the compulsory license provisions in the Patent Law is that the threat of it usually induces the grant of contractual licenses on reasonable terms.).

<sup>218</sup> **Adesola**, "Compulsory Patent Licensing and Access to Essential Medicines", 240.

that can cure or delay the disease<sup>219</sup>. The rationale for the developing countries' point of view derives from the exceptions stated in Article 27/(2)<sup>220</sup> of TRIPS.

Compulsory license, besides its various advantages, is necessary in terms of protecting human health and removing the barriers in access to medicines, in terms of general improvement of health and preventing abuses of monopoly right. For this reason, the compulsory license institution has been supported by developing countries, NGOs, various scholars and jurists since its creation. This support for compulsory licensing has been strengthened by the fact that the interests of the patent owner are protected around certain principles, on the one hand, and on the other hand, the society's need for patented medicines is met<sup>221</sup>.

Altogether, the overall advantage and impact of compulsory license instrument according to developing countries and NGOs is to increase access to patented medicines through manufacture or import in developing countries.

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<sup>219</sup> **Sara M. Ford**, "Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents", *American University International Law Review* 15, no.4 (2000): 964, accessed July 25, 2021 <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1278&context=auilr&httpsredir=1&referer=>

<sup>220</sup> Article 27/2 of the TRIPS Agreement; "*Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*"

<sup>221</sup> **Koçak**, "TRIPS Anlaşması'nda İlaç Patentlerinin Zorunlu Lisansı", 279.

Although the compulsory license instrument generally has positive effects for developing countries, it also has various negative effects. An important negative effect regarding compulsory licensing is the emergence of trade friction and trade retaliation between the countries that grant the compulsory license and the countries that produce patented medicines<sup>222</sup>.

The threat of trade retaliation by patent-holder governments, which can severely damage the economy of licensing countries<sup>223</sup>, is often a major concern for many developing countries, influencing considerations as to whether or not compulsory licensing increases access to drugs. The extent of these retaliations is not restricted to certain products or industries that impacted straightly by compulsory licenses issued by developing nations. These nations are especially vulnerable to such a threat, particularly when their local industries are undeveloped or depend heavily on international commerce. Due to the fear of sanctions and retaliation from developed countries, the compulsory license instrument has not been used effectively by developing countries. For instance, after compulsory licenses were issued by the Thai Government in 2007 to increase access to several patented medicines, the US added Thailand to its annual Special 301 Reports Priority Watch list. In particular, they cited the Thai Government's compulsory licenses as proof of the detriment of rights resulting from patent protection. The European Union Trade Commissioner also warned the Thai Government not to take any further steps to reduce medicine prices<sup>224</sup>.

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<sup>222</sup> **Abbas**, *"Pros and Cons of Compulsory Licensing"*, 255.

<sup>223</sup> **Reichman**, *"Compulsory Licensing of Patented Pharmaceutical Inventions"*, 13.

<sup>224</sup> **Min**, *"Compulsory Licensing of Pharmaceutical Patents in Developing Countries"*, 57.

Another disadvantage of compulsory licensing for developing countries is that the process of obtaining a license is very detailed, costly, complex and lengthy. In addition to their positive effects, many countries trying to avoid these licenses due to these important obstacles brought by compulsory licenses<sup>225</sup>.

### **C. Challenges and Controversies of Comprehensive Compulsory Licensing for Developed Countries**

Developed countries and pharmaceutical companies believe that intellectual property protection has significant importance for new medicine R&D. According to them, compulsory licensing instrument violates international IP law prescribed, protected under the TRIPS Agreement.

The government of both developed and developing countries may face significant hurdles in granting a compulsory license.

The most common negative feature of the compulsory license for developed countries and pharmaceutical companies is that thanks to patent protection, the profit maximization to be obtained from the invention is largely prevented and this situation causes a decrease in the incentive for innovation. According to large pharmaceutical companies, compulsory licensing prevents income and profits from the production and renewal of medicines necessary for human health. Remunerations determined by the government which grants compulsory licenses do not provide an inducement for further research and in no way cover the possible profit that the patentee can benefit exclusively

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<sup>225</sup> Mullin, "Aids, Anthrax, and Compulsory Licensing", 191.

from<sup>226</sup>. At this point, compulsory licenses at marginal expenses will diminish the ability to generate and exploit the significant profits needed to offset the fixed research costs. In some cases, this loss of profit will delay new drugs and result in the renunciation of unprofitable developments<sup>227</sup>. These losses will be effective in every nation, not just in nations that implement compulsory licenses. The impact will be particularly disadvantageous and large for medicines targeting orphan diseases, which are most prevalent in countries that advocate compulsory licensing.

Contrary to the social welfare arguments of developing countries, developed countries and pharmaceutical companies argue that widespread use of compulsory licensing will allow inefficient producers to enter the market and therefore may have a negative effect on public welfare<sup>228</sup>. This effect may occur under the threat of producing and presenting poor quality and counterfeit medicines to the public by inadequate manufacturers.

Compulsory licenses also decrease the market exclusivity and monopoly on which patent holders depend<sup>229</sup>. This situation acts as a disincentive for R&D-based developed country companies. Pharmaceutical companies and multinational patent holders argue that compulsory licensing threatens their patent security and their R&D activities suffer. At this point, compulsory license reduces the expected return of patent holders from R&D investments<sup>230</sup> and therefore access to health services.

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<sup>226</sup> **Abbas**, "Pros and Cons of Compulsory Licensing", 254.

<sup>227</sup> **Nishid**, "Compulsory Licenses 'A Two-Edged Sword'", 21.

<sup>228</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries, 55.

<sup>229</sup> **DeRoo**, "Public Non-Commercial Use", 348.

<sup>230</sup> **Ibid**.

Another challenge that acts as a deterrent to R&D investments stems from the unpredictability of the compulsory license. In this context, the production and sale of a patent-protected product, which has become uncertain due to the compulsory license, and concerns about compensation and innovation may prevent the production of new medicines, especially needed by third world countries<sup>231</sup>. The lack of a legal business-friendly commercial environment drives right holder companies to venture in countries where there are no compulsory license provisions and have strong patent protection<sup>232</sup>. Regarding this situation, compulsory license decisions made by developing countries and some emerging economies lead to a loss of FDI in these countries. Foreign investors generally want to invest in markets with strong patent protection in a more business-friendly legal environment<sup>233</sup>. In addition, compulsory licensing may adversely affect the transfer of technology from developed to developing nations. Most developed nations argue that strict patent protection is an important prerequisite for the transfer of their technology to developing nations<sup>234</sup>.

Another controversy put forward by developed countries and pharmaceutical companies is that patients in developed countries are mostly liable for the R&D costs of new medicines due to compulsory licensing. This results in a lower and disproportionate economic burden-sharing for patients in developing countries that grant compulsory licensing<sup>235</sup>. In other words, the requirement of compulsory license in one country

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<sup>231</sup> **Yang**, "Compulsory Licensing: For Better or For Worse", 78.

<sup>232</sup> **Abbas**, "Pros and Cons of Compulsory Licensing", 255.

<sup>233</sup> **Reichman**, "Compulsory Licensing of Patented Pharmaceutical Inventions", 12.

<sup>234</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries, 62.

<sup>235</sup> *Ibid.*, 56.

necessarily forces individuals in other countries to endure all these fixed R&D costs<sup>236</sup>. This creates unfair and negative consequences for consumers outside the country of compulsory license.

Developed countries find it risky to implement the compulsory licensing instrument in a way that developing countries can interpret minor health problems as urgent<sup>237</sup>. Because developing countries considering using compulsory licensing are under significant economic pressure, pharmaceutical companies and developed countries argue that compulsory licensing creates a culture of abuse and disrespect for patent rights in these countries<sup>238</sup>. At that point, granting a compulsory license will adversely affect the profits of the pharmaceutical industry and possibly harm their ability to innovate, research and develop new medicines. Moreover, pharmaceutical companies argued that compulsory licensing, which only targets patent costs and cannot eliminate the real problem of production costs, distribution and timely administration of medicines, cannot be a definitive solution<sup>239</sup>. According to them, it is clear that other problems not concerned with patent law, such as infrastructure, insurance, and transportation, are also responsible for the difficulties in accessing life-saving drugs.

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<sup>236</sup> **Nishid**, "Compulsory Licenses 'A Two-Edged Sword'", 21.

<sup>237</sup> **Ford**, "Compulsory Licensing Provisions Under the TRIPs Agreement", 966.

<sup>238</sup> **Rojina Thapa**, "Waiver Solution in Public Health and Pharmaceutical Domain under TRIPS Agreement", *Journal of Intellectual Property Rights* 16, (2011): 472, accessed July 26 2021, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2088705](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2088705)

<sup>239</sup> **Ristanić**, "Using Compulsory Licenses to Facilitate Access to Medicines", 57.

## **II. The Impact of the Compulsory License within the Scope of R&D and Innovation**

The most important challenge and controversy regarding the use of compulsory licenses arises regarding their impact on R&D. According to the developed countries and pharmaceutical companies, the compulsory license instrument has significant negative impacts on innovation, R&D, foreign direct investment ("FDI") and technology transfers<sup>240</sup>. They argue that the pharmaceutical industry cannot be developed or exist without patent protection for medicines. In this context, the compulsory license that improves access to patented drugs will cause R&D investment for new medicines to be abandoned and have negative effects on the incentive to innovate. Especially in areas with high financial risk and less profit, such as orphan, neglected or tropical diseases, research and incentives for innovation are not considered possible in the presence of a compulsory license. In other words, the compulsory license is accepted as a potential deterrent for R&D activities. This argument is particularly supported by the fact that many drugs do not enter the market because of regulatory issues or even because they are unprofitable, and compulsory licensing is likely to hinder profitable drugs and incentives for innovation<sup>241</sup>.

Although it is argued by developed countries and pharmaceutical companies that compulsory licensing harms R&D investments while trying to access patented medicines and causes obstacles in medicine production, developing countries that support compulsory licensing argues that compulsory licensing does not have a substantial impact

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<sup>240</sup> Ibid., 61.

<sup>241</sup> Ajzentel, "Compulsory License: Analysis of the Effectiveness", 25.

on innovation, R&D and FDI<sup>242</sup>. These countries argue that investment activities related to innovations in pharmaceutical products, especially medicines, are not affected by whether a nation issues compulsory licenses or not, on the contrary, they are affected by different factors such as tax advantages, market demands and diffusion of technology. In other words, compulsory licensing is unrelated with the economic and technological improvement. Moreover, they argue that by enabling the dissemination of technical knowledge through compulsory licensing, it will support and encourage technical development, R&D and innovation in developing countries in the long run<sup>243</sup>. At this point, supporters of compulsory licensing also state that this licensing activity does not hinder research and development, because the expenses for research are covered by the sale of patented products in developed countries with strict patent protection<sup>244</sup>. This argument, which is especially defended by developing countries, is also supported by empirical studies. For example, Scherer's work related to anti-trust compulsory licensing did not find a significant difference in R&D expenditure between companies with and without a compulsory license<sup>245</sup>. In this study, Scherer and Weisburst analyzed compulsory licensing cases in the US specifically to examine the amount spent on R&D, and they found no exact evidence to point to a reduction in cost<sup>246</sup>. Also, according to the Chien<sup>247</sup>, compulsory licenses do not always lead to a decline in innovation. For instance,

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<sup>242</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries, 62.

<sup>243</sup> *Ibid.*, 63.

<sup>244</sup> **Abbas**, "Pros and Cons of Compulsory Licensing", 255.

<sup>245</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries, 63.

<sup>246</sup> **Ajzenal**, "Compulsory License: Analysis of the Effectiveness" 26.

<sup>247</sup> **Colleen Chien**, "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?", *Berkeley Technology Law Journal* 18,

it is seen that compulsory licensing in Canada did not appear to greatly hinder innovation and R&D from 1969 to 1983. During this time, about 20 compulsory licenses have been issued by the Canadian government each year. Likewise, in 2013, Moser demonstrated that the loss of intellectual property essentially spurs innovation, as companies want to stay competitive<sup>248</sup>. Moser made a staggering finding that contrary to the cases that would dissuasion in innovation, compulsory licenses can boost innovation locally in licensing countries<sup>249</sup>.

Along the same lines, there are those who argue that these studies show that compulsory licensing has no real impact on the cost of innovation and R&D. In particular, there is a report by the WHO confirming this situation for developing and least developed countries<sup>250</sup>.

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no.1 (2004): 25, accessed July 25, 2021,  
[https://www.researchgate.net/publication/228171202\\_Cheap\\_Drugs\\_at\\_What\\_Price\\_to\\_Innovation\\_Does\\_the\\_Compulsory\\_Licensing\\_of\\_Pharmaceuticals\\_Hurt\\_Innovation](https://www.researchgate.net/publication/228171202_Cheap_Drugs_at_What_Price_to_Innovation_Does_the_Compulsory_Licensing_of_Pharmaceuticals_Hurt_Innovation)

<sup>248</sup> **Petra Moser**, "Patents and Innovation: Evidence from Economic History", *Journal of Economic Perspectives* 27, no.1 (2013): 18, Accessed July 26, 2021,  
[https://www.researchgate.net/publication/262094944\\_Patents\\_and\\_Innovation\\_Evidence\\_from\\_Economic\\_History](https://www.researchgate.net/publication/262094944_Patents_and_Innovation_Evidence_from_Economic_History)

<sup>249</sup> Ibid., 16.

<sup>250</sup> **Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH)**, "Public Health, Innovation and Intellectual Property Rights", *WHO*, (2006): 84, accessed July 26, 2021,  
<https://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf?ua=1>

However, compulsory licenses in major markets are thought to have a major impact on innovation. This idea is generally related to the types of diseases and related medicines. As a whole, it is advocated that there are basically two groups of diseases and the existence of medicines created to cure them. The first concerns diseases common to both developed and developing countries, and medicines for these diseases have proven beneficial for both groups of countries. Such medicines are usually those for diabetes, heart disease, various types of cancer, and AIDS. The second is country-specific diseases such as malaria, tuberculosis or certain types of HIV found in less developed or developing countries, for example some African countries<sup>251</sup>.

Regarding the first group, it has been claimed that compulsory licenses for pharmaceutical patents, which primarily play a role in developed country markets, do not have much effect on R&D and innovation activities in developing countries. As long as patent holders' exclusive rights arising from their inventions are protected in developed country markets where they can cover their costs and profits, it generally does not have a negative impact on innovation<sup>252</sup>. Also, compulsory licensing has an attractive role in improving access to overpriced drugs in developed nations, as it does in developing nations, with increasing costs and regulations<sup>253</sup>.

Therewithal, the fact that the medicines produced for orphan, tropical, neglected or poverty-related diseases are not seen profitable by the pharmaceutical companies<sup>254</sup> and therefore, sufficient R&D and investment activities are not carried out, leading to the

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<sup>251</sup> **Ristanić**, "Using Compulsory Licenses to Facilitate Access to Medicines", 51.

<sup>252</sup> *Ibid.*

<sup>253</sup> **DeRoo**, "Public Non-Commercial Use", 374.

<sup>254</sup> **Ristanić**, "Using Compulsory Licenses to Facilitate Access to Medicines", 52.

inability to implement compulsory licensing activities. It is argued that the possibility of the compulsory license, especially in medicines connected to these diseases, will harm R&D activities and incentives, which are already very rare.

### **III. Evaluation of the Effect of Compulsory License Implementation on Orphan Drugs**

Compulsory licensing is required for any disease that is contagious, chronic, tropical, neglected, or rare. In general, although the three main diseases targeted by compulsory licensing cases are "*HIV/AIDS*", cancer, and cardiovascular diseases, there is no restriction on issuing compulsory licensing for other types of diseases.

In the text of Article 31 of the TRIPS Agreement, it is also seen that the compulsory license instrument is not restricted to a specific disease type or disease group, and it is supported that any disease can be subject to compulsory licensing in order to protect public health<sup>255</sup>.

From a public health perspective, limiting compulsory licensing to certain diseases can be dangerous and impact access to medicine, particularly as the global burden of diseases shifts in developed and developing countries for different types of diseases, including NCDs, such as heart diseases and cancer<sup>256</sup>.

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<sup>255</sup> **Outterson**, "Disease-Based Limitations on Compulsory Licenses" 9.

<sup>256</sup> *Ibid.*

At this point, governments should be free to use the compulsory licensing instrument to fully protect public health, regardless of disease type, and harmonize it with health systems so that access to medicine can be guaranteed<sup>257</sup>.

The compulsory license decision given by the governments for any disease group leads to the emergence of the effects of the principle of social justice. Especially in the case of a compulsory license application for the remedy of any disease that poses a important threat to health and life, the criteria to be determined will be examined within the scope of this principle.

Various principles are adopted by governments at the point of ruling on compulsory license. These principles, although there are no limitations, focus on what kind of diseases and under which criteria the compulsory license can be granted. When these principles are considered in terms of rare diseases and essential orphan drugs required for these diseases, three different principles regarding the compulsory licensing of orphan drugs come to the fore.

As explained earlier, orphan drug is a drug developed for a rare disease. Whether a drug can be considered as an orphan drug and whether it can be subject to compulsory licensing differs from country to country. However, there is only one thing common to all countries. That is, patients with rare diseases have a much lower quality of life, not only in physical and psychological aspects, but also because of the socio-economic

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<sup>257</sup> **Kyung-Bok Son**, "Importance of the Intellectual Property System in Attempting Compulsory Licensing of Pharmaceuticals: A Cross-Sectional Analysis", *Globalization and Health* 15, no.42 (2019): 7, accessed August 12, 2021 <https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-019-0485-7>

inequality. It is the duty of governments to eliminate this discrimination and ensure that rare disease patients have access to essential medicines for them.

In that regard, governments that adopt the principle of utilitarianism argue that it is more profitable and cost-effective to fund the development of a drug that will benefit the greater majority of society. In other words, the utilitarian approach expresses the compulsory licensing of medicines that will be needed by the majority of a society when the conditions for two different types of diseases are equal, and it finds the compulsory license to a medicine that will be used by the minority contrary to the idea of benefit underlying the principle<sup>258</sup>. With this principle, the aim is to maximize the total of the benefits of the individuals affected by the license.

The social contract, which is another principle, argues that the right of rare disease patients, who can be defined as a minority in a society, to access health and medicine cannot be ignored for the financial advantage of the majority of the society<sup>259</sup>. At this point, it is thought that the compulsory license institution, which can only be applied in certain and exceptional cases, will be a greater difficulty and burden for the minority suffering from rare diseases rather than common diseases affecting the majority, and will prevent access to medicine. With this principle, it is stated that making a compulsory license application for an orphan drug should not be considered as a sufficient reason for rejection, especially when considering patients suffering from rare diseases.

Finally, the principle of human functioning states that every person deserves the preservation of his life and health, as well as the functioning of a normal life. According

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<sup>258</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries, 191.

<sup>259</sup> *Ibid.*, 192.

to this principle, individuals should not be behaved unfairly just because their diseases are rare and they remain a minority in society<sup>260</sup>. For this reason, it would be inadmissible from an aspect of social justice for rare disease patients not to have access to essential medicine, or access it too expensively. Within the scope of this principle, the fact that a compulsory license application has been made for only an orphan drug cannot be a reason to reject such an application. Governments embracing this principle must take into account how requisite such a medicine will be for patients who need to maintain their life skills. That is, governments should not only establish policies that provide the presence of orphan drugs at accessible prices but also examine how rare diseases and essential medicines for these diseases limit or enhance human functional abilities<sup>261</sup>. In addition, according to this principle, governments have a responsibility to provide various types of support for the development of new orphan drugs.

At this point, developed countries and pharmaceutical companies argue that R&D and investment costs in orphan drugs for rare diseases that affect the minority in a society are very high and that research activities on these drugs should be carried out through state-financed institutions. Because, according to them, the profit rate to be obtained from an orphan drug produced for a rare disease that impacts a minority of people is very low, and it does not seem possible to cover the research and production costs<sup>262</sup>.

Indeed, governments are hesitant to decide which medicines should be primarily developed and supplied with limited resources. Herein, if governments only considered the cost-effectiveness aspect of their R&D activities, the R&D of orphan drugs needed

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<sup>260</sup> Ibid.

<sup>261</sup> Ibid., 193.

<sup>262</sup> Nuno, "A Fair Return Approach", 407.

by the minority would remain in the background. This situation, on the other hand, will mean that the interests of the majority are prioritized over the interests of the minority, and this will not be accepted within the scope of the principle of social justice. Although it is thought that the profit return is low for developed countries and pharmaceutical companies, the R&D of orphan drugs that the minority suffering from rare diseases need should be considered in accordance with the principle of social justice. In that regard, the fact that only a minority of people in a society need the drug in question should not be seen as an important factor in compulsory licensing activities for orphan drug patents. What is important here is to prioritize the factors such as how an orphan drug, subject to R&D activities and subsequent compulsory license application, affects the vital functions of people suffering from a rare disease, and what the medicine is necessary for in the treatment of which disease. In other words, a compulsory license application for a medicine necessary for human life should not be rejected on the grounds that the disease is rare, alternative treatment methods are available, or that the medicine in question is not included in the WHO Essential Medicines List ("EML")<sup>263</sup>.

The important thing here is to provide a balance between the criteria for compulsory license decisions by governments and human health and life, and this balance should be achieved within the framework of the social justice principle, which includes the principle of human functioning and the principle of social contract.

The case of Gleevec is shown as an example in terms of whether orphan drugs can be subject to compulsory licensing. Novartis's Gleevec is an essential medicine for the cure of rare "*Chronic Myeloid Leukemia*" ("CML")<sup>264</sup>. At this point, Gleevec is requisite

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<sup>263</sup> Min, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries, 190.

<sup>264</sup> Ibid.

for the treatment of CML patients and accordingly may be subject to the compulsory licensing for the public benefit.

Due to its usage in the remedy of rare diseases, the drug is not included in the WHO's EML, which is prepared on the basis of cost-effectiveness. The reason why it is not included in the list is that it is used in the treatment of a rare disease and for this reason, it is not seen "essential" and needed by the majority of the society. However, although it is not considered necessary by the majority, it is considered an essential medicine for people suffering from this rare disease.

The low demand for the medicine in question has a negative impact on the development and supply of the medicine. At this point, medicine manufacturers will give up developing orphan drugs with the belief that the profit return will be low due to low demand, and will invest in this medicine with a government support and sell it at the highest price in order to maximize their profit. As a result of this situation, people suffering from rare diseases will be able to access medicines with very extremely high costs or they will not be able to access medicines at all.

The first compulsory license application for Gleevec was rejected by the Korean IP Office ("KIPO") on the grounds that the disease for which the medicine is used was not a contagious or urgent disease, did not involve any national or social risk, and did not meet a sufficient public need<sup>265</sup>. This rejection arose as a result of the utilitarian theory. However, contrary to this theory, whether compulsory licensing will be issued to increase access to drugs should be evaluated by taking into account the criteria that how essential the patented medicine is to maintain fundamental human functions, whether this drug is

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<sup>265</sup> Ibid., 191.

particularly required for the cure of rare diseases, whether this drug is specifically requisite to preserve the life or health of people who are disadvantaged, and whether there are other treatments that can replace this medicines economically<sup>266</sup>.

## **CHAPTER FIVE**

### **ANALYSIS OF ALTERNATIVE MECHANISMS TO COMPULSORY LICENSE IMPLEMENTATION IN PROVIDING ACCESS TO MEDICINES**

#### **I. Alternative Ways Instead of Compulsory License: Push and Pull Mechanisms**

##### **A. General Framework:**

Although the idea of providing access to medicines with the compulsory licensing, especially in developing countries, is largely supported, many countries hesitate to apply to compulsory license institutions due to the problems they will encounter in practice and look for different alternatives. So, in the face of various advantageous and disadvantageous features of the compulsory license instrument, various different mechanisms have argued to maintain the balance between the right to health and IPRs. At this point, it was necessary to determine alternative ways to compulsory licensing by evaluating different strategies to ensure access to drugs, specifically for developing nations, and to encourage and increase investment in the production of pharmaceuticals in developed nations.

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<sup>266</sup> Ibid., 202.

The most comprehensive mechanisms aiming to increase access to medicines are basically classified as "push" and "pull" programs in the literature<sup>267</sup>.

Push mechanisms aim to decrease the risks that may occur in the research process and the initial costs of the developers engaged in R&D activities<sup>268</sup>. In this way, it increases the investment in innovation and research by reducing the barriers to entry to areas where it is needed but where there is not much incentive due to the low-profit return. It encourages innovation in areas that are not attractive to the private sector by reducing industry costs, especially during R&D activities, and provides opportunities to access public funding<sup>269</sup>. Unlike push mechanisms, pull mechanisms aim to create a suitable market for the medicines to be produced as a result of R&D activities and to increase the participation of the private sector by securing this market. In this way, the probability of returning the investments made by those engaged in R&D activities is increased. After the completion of the activities for the medicine developed as a consequence of the R&D activity, the reward is guaranteed for this development, and R&D activities and investments are encouraged<sup>270</sup>.

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<sup>267</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 46.

<sup>268</sup> **Shiwei Gong and Si Jin**, "Current Progress in the Management of Rare Diseases and Orphan Drugs in China", *Intractable & Rare Disease Research* 1, no.2 (2012): 46, accessed July 28, 2021, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4204559/>

<sup>269</sup> **Organisation for Economic Co-operation and Development (OECD)**, "Pharmaceutical Innovation and Access to Medicines: Executive Summary" *OECD Health Policy Studies*, (2018): 9, accessed July 28, 2021, <https://www.oecd.org/health/health-systems/Pharmaceutical-Innovation-and-Access-to-Medicines-Executive-Summary-ENGLISH.pdf>

<sup>270</sup> Ibid.

That is, while the "push" mechanisms include grants and subsidies for research expenses in innovation and R&D activities, which are the first stage, and focus on the effort given; the "pull" mechanisms focus on the outputs obtained as a result of R&D activities, the process after the research<sup>271</sup>.

Both mechanisms aim to make R&D investments for medicine production in disease areas with low sales and profit volumes, especially tropical, neglected and rare diseases, and seek to provide effective access to available medicines by de-linking the connection between R&D costs and final prices of medicines<sup>272</sup>. In this context, there are reports<sup>273</sup> and decisions<sup>274</sup> advocating that de-linking the connection between the R&D costs and final prices of medicines should be implemented.

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<sup>271</sup> **Cheri Grace and Margeret Kyle**, "Comperative Advantages of Push and Pull Incentives for Technology Development: Lessons for Neglected Disease Technology Development", *Global Forum Update on Reseaech For Health* 6, (2009): 147, accessed July 28, 2021, <http://www.margaretkyle.net/PushPull.pdf>

<sup>272</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 46.

<sup>273</sup> **WHO**, "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property", (2011): 15, accessed July 28 2021, [https://www.who.int/phi/publications/Global\\_Strategy\\_Plan\\_Action.pdf](https://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf) (Explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the delinkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries...)

<sup>274</sup> **Council of the European Union**, "Council Conclusions on the EU Role in Global Health: 3011th Foreign Affairs Council Meeting", (May 2010): 5, accessed July 28, 2021

To encourage access to medicines, there are various mechanisms under push and pull programs. The most prominent mechanisms are; (1) Patent Pools, (2) Differential Pricing, (3) Prizes, (4) Orphan-Drug Schemes, (5) Advanced Market Commitment, (6) Research Grant.

## **B. Evaluation of Input-Oriented Systems: Push Mechanisms**

### **1. Patent Pool Mechanism**

Under the WHO's Global Strategy and Plan of Action, fostering innovation and improving access to drugs in developing nations are suggested<sup>275</sup>. One of the propositions that emerged under this action plan is patent pools.

A patent pool is a licensing arrangement, a consortium<sup>276</sup>, in which at least two holders of patents for a particular invention accept to share their intellectual property with each other and/or another parties<sup>277</sup>. Patent pools often encompass complicated new technologies with interconnected patents that can hinder product development. In other

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[https://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/foraff/114352.pdf](https://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/foraff/114352.pdf)

(Exploring models that dissociate the cost of Research and Development and the prices of medicines... including the opportunities for EU technology transfer to developing countries)

<sup>275</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 47.

<sup>276</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries", 43.

<sup>277</sup> **Hoen**, "Private Patents and Public Health", 73.

words, the patent pool is a collective structure that includes different patents to facilitate the usability and accessibility of new technologies<sup>278</sup>.

The purpose of this mechanism is to create a regulation on licensing by creating a stack of patents that allows multiple licenses of patented products to be parallel purchased at once in order to provide access to technology that requires high investment and capital, such as pharmaceuticals, and thus to make the conditions for new and fundamental technologies more effective<sup>279</sup>.

In the field of pharmaceutical products, there are two main pools designed to share patents about pharmaceuticals. These are the Medicine Patent Pool ("MPP") and the Pool for Open Innovation against Neglected Tropical Diseases ("POINT")<sup>280</sup>.

#### **a) The Medicine Patent Pool**

In 2010, The Medicine Patent Pool was established the under UNITAID's financing, to ensure the manufacture and availability of medicines for diseases such as "HIV/AIDS", "tuberculosis" through voluntary licensing for developing nations<sup>281</sup>. This patent pool arose out of the need to find an effective response to the challenges faced by developing countries in accessing medicines in an evolving intellectual property environment.

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<sup>278</sup> **Ellen't Hoen**, "The Medicines Patent Pool", *Health Action International*, (2012), accessed July 29, 2021, <https://haiweb.org/encyclopaedia/medicines-patent-pool/>

<sup>279</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 48.

<sup>280</sup> Ibid.

<sup>281</sup> Ibid.

The main purpose of the MPP, which emerged due to the view that patent protection would prevent the production of affordable drugs, is to increase the production of generic medicines and reduce current prices in developing countries, as well as by encouraging R&D for the new medicine production<sup>282</sup>.

The patent pool has a “one-stop shop” function in terms of licenses<sup>283</sup>. This function has several advantages. Especially, thanks to the patent pool, it is much easier for generics manufacturers to collect and benefit from licenses under a single pool<sup>284</sup>. This plays an important role in enabling generics manufacturers to produce drugs faster and more cost-effectively without the need to wait for patent expiration, thus increasing the accessibility of drugs to developing countries. It also ensures a reference for other agents to negotiate with the right owner within public health norms or seek other resolutions to improve access to drugs, as well as determines new standards for voluntary licensing with predictability and transparency.<sup>285</sup>

There are also several challenges and restraints with the MPP. The prominent challenge is that participation in the patent pool is voluntary, not mandatory<sup>286</sup>. That is, the effectiveness of a patent pool will basically depend on the willingness of patent holders to license through the pool and generic drug manufacturers to utilize this pool. At this point, it is not possible for the patent pool to strain unwilling patent holders to negotiate or impose binding terms and conditions. This situation greatly limits the

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<sup>282</sup> Ibid., 49.

<sup>283</sup> Hoen, "The Medicines Patent Pool", 4.

<sup>284</sup> Shahaf (Segev), "The Complex Relationship Between the Right to Health, " 49.

<sup>285</sup> Hoen, "Private Patents and Public Health", 76.

<sup>286</sup> Ibid.

effectiveness of the patent pool. Another challenge arises in the effective and sustained funding of the patent pool and licensing activities, which are also implemented in different countries for various disease types and levels<sup>287</sup>. Lastly, another of the challenges of patent pools is that they require extensive, long-term and complex activities such as patent searches, remuneration negotiations, licensing and distribution<sup>288</sup>.

The first contribution to the MPP was made by the US National Institute of Health in 2009, by licensing the patent for the molecule "*darunavir*" for antiretrovirals<sup>289</sup>. Gilead Sciences, which licensed the patent rights of various products used in the cure of HIV and hepatitis B to the pool in 2011, was the first corporation to negotiate with the MPP<sup>290</sup>.

#### **b) The Pool for Open Innovation against Neglected Tropical Diseases ("POINT")**

Another prominent patent pool for medicines is POINT, which was established in 2009, by *GlaxoSmithKline* ("GSK") and adopted within WIPO Re:search Framework<sup>291</sup>. The primary purpose of POINT is to develop and promote new and effective drugs and treatments by providing third parties access to technical information such as patents,

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<sup>287</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries", 44.

<sup>288</sup> *Ibid.*, 45.

<sup>289</sup> **Hoen**, "Private Patents and Public Health", 75.

<sup>290</sup> *Ibid.*

<sup>291</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 50.

know-how, combined data and research facilities in investment and R&D activities for neglected tropical diseases and their medicines<sup>292</sup>.

There are basically two groups in this patent pool: contributors and users. Individuals or organizations that want to contribute to the pool ensure that the possibility of access to medicines is increased by the development of new medicines, especially for neglected tropical diseases<sup>293</sup>. At this point, POINT is "open" and accessible by many contributing institutions and organizations such as academics, pharmaceutical companies, which carry out R&D and investment studies for neglected diseases. However, there are two main conditions that pool contributors must adopt. Firstly, contributors grant licenses to users for the patents they contribute to research, development, manufacture and export activities of neglected disease medicines intended to be made available to underdeveloped countries<sup>294</sup>. Secondly, there is no financial reward as a result of contribution to the pool, and there is no expectation of financial gain. In that regard, medicines will be licensed without royalty for sale in underdeveloped countries<sup>295</sup>. In addition, the license granted here is on a voluntary basis, as in the MPP, and the pool cannot force the patent holders to contribute. There are two main contributors of POINT: Alnylam and the Massachusetts Institute of Technology.

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<sup>292</sup> **Rebecca Goulding and Amrita Palriwala**, "Patent Pools: Assessing Their Value-Added for Global Health Innovation and Access" *Results For Development*, (2012): 34, accessed July 30, 2021, [https://www.r4d.org/wp-content/uploads/R4D\\_PatentPoolsReport\\_0215.pdf](https://www.r4d.org/wp-content/uploads/R4D_PatentPoolsReport_0215.pdf)

<sup>293</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 50.

<sup>294</sup> **Goulding and Palriwala**, "Patent Pools", 35.

<sup>295</sup> Ibid.

Unlike the contributors, users take advantage by using technical information such as know-how and patents licensed by the contributors and included in the pool, and play an encouraging and supportive role in the production of drugs for neglected tropical diseases, particularly in LDCs such as South Africa. In that regard, as a user, iThemba Pharmaceuticals is the first commercial enterprise to benefit from POINT. It is clear that patent pools support increasing access to drugs in developing and LDCs. However, the emphasis on generic medicine production rather than the promotion and development of R&D studies for new drugs and the fact that the success of the patent pool relies on the voluntary participation of right owners has revealed controversies regarding this mechanism.

## **2. The System of Research Grants**

Research grants are alternative push mechanisms designed to encourage R&D. In this context, grants are given to research institutions to carry out R&D and investment activities in certain areas that are considered to have low profit returns, such as neglected and rare diseases. In other words, with these grants, R&D investments to be made by research institutions at the beginning of the medicine production process are eliminated or reduced, i.e., R&D activities are encouraged by allocation of preliminary funds<sup>296</sup>.

This mechanism includes various problems. When evaluated in terms of grant recipients, it is considered as a disadvantage that the grant given is time-limited, that is, temporary, and it has no certainty whether it will be renewed or not. At this point, pharmaceutical companies receiving grants will only have the opportunity to focus on short-term R&D and investments if the grant is given piecemeal within a specific

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<sup>296</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 56.

duration<sup>297</sup>. Due to the fact that the said grant is not sufficient in the long term, it is thought that sufficient financing will not be provided during the development, production and distribution phases of the product after the initial stages of R&D are completed.

In terms of the providers, they have no real authority or control over the purpose and how the grant recipients will use this grant, both the objectives of the work for which the grant is given and the final product being presented to the public<sup>298</sup>.

### C. Evaluation of Output-Oriented Systems: Pull Mechanisms

#### 1. Differential Pricing Mechanism

Another mechanism that plays a role in promoting the right to access medicines for developing countries is differential pricing. This mechanism, also known as "*pricing regulation*" or "*price discrimination*", generally means that the same medicine is priced differently in different markets<sup>299</sup>.

This mechanism is generally used by some large monopolist pharmaceutical companies because the same medicine is sold in different markets especially in developing and developed countries with different elasticity of demand and this situation differs greatly in terms of profits to be obtained from different markets<sup>300</sup>. At this point,

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<sup>297</sup> Ibid.

<sup>298</sup> Ibid.

<sup>299</sup> Min, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries" 33.

<sup>300</sup> Patricia M. Danzon and Adrian Towse, "Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents", *International Journal of Healthcare Finance and*

with the pricing mechanism, companies will be able to maximize their total profit from these markets by determining different sales amounts for the same medicine in various markets<sup>301</sup>.

In that regard, this mechanism has been proposed as a potential solution to increase access to drugs in developing nations in regulation 953/2003 of the Council of European Commissions<sup>302</sup>. This Regulation aims and supports the creation of a legal mechanism that will support companies to manufacture accessible medicines for developing nations, as clearly stated in article 7 <sup>303</sup> of the preamble.

The differential pricing mechanism is argued in the literature to be the best convenient approximation for increasing drug access in developing countries without hampering investment in medicine development<sup>304</sup>. Differential pricing is a mutually

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*Economics* 3, (2003): 183, accessed July 30, 2021, [https://faculty.wharton.upenn.edu/wp-content/uploads/2014/10/differential-pricing\\_3.pdf](https://faculty.wharton.upenn.edu/wp-content/uploads/2014/10/differential-pricing_3.pdf)

<sup>301</sup> Ibid.

<sup>302</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 51.

<sup>303</sup> Article 7 to the Preamble of the Regulation 953/2003; " *There is a need to encourage the pharmaceutical producers to make pharmaceutical products available at heavily reduced prices in significantly increased volumes by ensuring through this Regulation that these products remain on those markets [...].*"

<sup>304</sup> **Frederic M. Scherer and Jayashree Watal**, "Post-TRIPS Options for Access to Patented Medicines in Developing Nations", *Journal of International Economic Law* 5, no.4 (2002), accessed July 30, 2021 <https://academic.oup.com/jiel/article-abstract/5/4/913/948449#no-access-message>; **Danzon and Towse**, "Differential Pricing for Pharmaceuticals"; **Jeffrey Atik and Hans Henrik Lidgard**, "Embracing Price

beneficial approach for both pharmaceutical firms and developing countries, according to this argument.

Although the regulation permits the export of drugs from developed countries to developing country markets at significantly lower prices, it states that these drugs should remain only in export markets and prohibits their re-import to developed markets<sup>305</sup>. In this way, it is provided that these drugs are not sold at a loss in the developed markets, and that essential drugs reach developing countries<sup>306</sup>.

However, differential pricing plays a role in improving access to patented drugs, especially when generics are not existed and cannot be afforded. This raises concerns for pharmaceutical companies that developed countries may increase access to cheaper generic medicines and lead to product diversion, especially when it comes to prohibiting parallel imports of patented medicines between countries. That is, if generics are available in other countries, a country can increase access to medicines in a more efficient and affordable way by importing only those generics without the need for different pricing

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Discrimination: TRIPS and the Suppression of Parallel Trade in Pharmaceuticals", *University of Pennsylvania Journal of International Law* 27, no.4 (2006), accessed July 30, 2021, <https://scholarship.law.upenn.edu/jil/vol27/iss4/3/>.

<sup>305</sup> Article 5 of the Preamble of the Regulation 953/2003; "*Price segmentation between developed country markets and the poorest developing country markets is necessary to ensure that the poorest developing countries are supplied with essential pharmaceutical products at heavily reduced prices. Therefore, these heavily reduced prices cannot be understood as a reference for the price to be paid for the same products in developed country markets.*"

<sup>306</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 52.

from the original medicine manufacturer<sup>307</sup>. This situation gives rise to the discussion that differential pricing may have only minor impacts in lowering medicine prices, but may cause market inefficiencies in the case of imports of generics<sup>308</sup>.

Also, differential pricing mechanism has difficulties in practice, when the price difference between the markets is great. For instance, despite the re-import prohibition, developed market consumers who often spend more for the same medicine than developing market consumers will try to discover a means to import the identical medicine from another country where it is available at more affordable prices<sup>309</sup>.

Lastly, as with patent pools, pharmaceutical companies must participate voluntarily in order for the differential pricing to be implemented effectively. In other words, pharmaceutical companies cannot be forced to cooperate with the differential pricing mechanism. Since it is a voluntary-based mechanism, it is not considered sustainable in terms of increasing access to medicine. For instance, some big pharmaceutical companies have agreed to adopt differential pricing policies in Brazil by negotiating with the Brazilian government to set low prices for patented antiretroviral medicines. However, companies were unable to decrease medicine prices to adequate levels, and the government of Brazil was able to achieve effective pricing by granting compulsory licenses in 2007<sup>310</sup>.

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<sup>307</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries" 35.

<sup>308</sup> *Ibid*.

<sup>309</sup> *Ibid*.

<sup>310</sup> **Nathan Ford et al.**, "Sustaining Access to Antiretroviral Therapy'."

In general, although the pricing mechanism enables some medicines to be offered to the developing countries at more affordable prices, it has not an active part in promoting R&D and innovation of new life-saving drugs, especially diseases such as AIDS/HIV, malaria and tuberculosis<sup>311</sup>.

## **2. Prizes: Public Incentives**

Prizes, which create incentives to support R&D and innovation in the pharmaceutical field are another mechanism that takes a part in increasing access to drugs in developing nations. This mechanism plays a major role in encouraging investment, especially in the drug development for diseases such as rare diseases, neglected diseases and tropical diseases that are not considered profitable and economically feasible by pharmaceutical companies. With the prize mechanism, a certain amount of compensation is given to pharmaceutical companies depending on the result of the medicine they produce and the benefit it provides, especially the desired technical features<sup>312</sup>. In other words, a fund has been created for pharmaceutical companies by the public. Due to this feature, the prize mechanism is considered as a type of payment for realizing research and investment in areas that are not studied particularly<sup>313</sup>.

While there are various ways to set up and operate the prize mechanism, there are two core proposal for this. The first is the Medical Innovation Prize Fund Act, which

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<sup>311</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 52.

<sup>312</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries", 37.

<sup>313</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 53.

recommends the use of prizes as a tool to address the problem of high R&D costs in non-profit diseases<sup>314</sup>. This Act is based on the “de-linkage” approach of Love and Hubbard.

#### **a) Medical Innovation Prize Fund: "De-Linkage" Based**

The "de-linkage" approach offered by Love and Hubbard in 2007 ensures a mandatory prize system in the field of pharmaceutical R&D<sup>315</sup>. The main aim of this approach is to cut off the connection between final sale prices and the R&D costs of medicines<sup>316</sup>. According to this approach, prize funds are alternative for patent protection, and prizes will be directly given to companies, without providing a choice between the patent or prize. In other words, this approach replaces the patent-based award model with a prize fund. With this model, it is recommended to create a prize fund for the awards to be given to developed and developing countries, inventors who produce drugs that are needed in specific areas where R&D is scarce, such as rare, neglected or tropical diseases<sup>317</sup>. In return for this award, drug inventors will give up the exclusive and monopoly rights they obtained due to patents and allow the production of generics.

The Medical Innovation Prize Fund Act, which is based on the approach advocated by Love and Hubbard, sees the prize method as a substitute for patents in

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<sup>314</sup> Ibid.

<sup>315</sup> **Frank Mueller-Langer**, "Neglected Infectious Diseases: Are Push and Pull Incentive Mechanisms Suitable for Promoting Drug Development Research?", *Health Economics Policy and Law* 8, no.2 (2013): 191, accessed July 31, 2021, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2206759](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2206759)

<sup>316</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries", 42.

<sup>317</sup> Ibid.

promoting R&D, especially on unprofitable medicines<sup>318</sup>. The main idea here is to ensure that the incentives for innovation and R&D are separated from the price of medicines and reach the consumer. With this Act, the prize will be given on the condition that the new medicines introduced to cause a significant impact on public health<sup>319</sup>. Thanks to the prize mechanism, innovation and research will be carried out in areas where pharmaceutical companies do not attach importance to investment and R&D studies because of the consideration that medicines for certain diseases will not bring profit. This system will lead to 'open' research and innovation, but still reward the innovation financially<sup>320</sup>. However, this prize model causes controversies as it directly replaces exclusive patent rights with prize funds and creates contradictions and incompatibilities with the main conditions of the TRIPS agreement<sup>321</sup>.

#### **b) The Approach of Health Impact Fund**

Another prominent prize model is the "Health Impact Fund", proposed by Hollis and Pogge. Contrary to the mandatory prize fund proposed by Love and Hubbard, the Health Impact Fund gives pharmaceutical companies a choice between patent protection or the Health Impact Fund for medicines they produce<sup>322</sup>. In this context, pharmaceutical companies will abandon the monopoly pricing arising from patents and finance their products with the prizes to be given by the Health Impact Fund ("HIF").

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<sup>318</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 53.

<sup>319</sup> **Mueller-Langer**, "Neglected Infectious Diseases", 192.

<sup>320</sup> *Ibid.*

<sup>321</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries", 43.

<sup>322</sup> *Ibid.*

In other words, the HIF does not oppose to the granting of patent protection to pharmaceutical companies, but gives the opportunity to waive the exclusive and monopoly rights arising from the patent in case of making use of this fund<sup>323</sup>. However, unlike the medicines for rare or neglected diseases, medicines for diseases with high market and profit returns will continue to be protected under the patent system.

This prize model adopts the "pay for performance" system. Under this system, products will be awarded in proportion to their measurable health effects on human or public health<sup>324</sup>. This fund will be financed by the participating states and the awards will be priced according to the average cost of production of the products. In this way, new medicines produced will be sold at low prices globally, without the use of exclusive rights arising from patents by pharmaceutical companies<sup>325</sup>.

While this model will increase access to medicines with the decrease in medicine prices in developing countries, it will encourage companies to investment of new drugs, especially in neglected and rare diseases.

However, in addition to the positive qualities, the prize mechanisms also have some difficulties. First, for pharmaceutical companies to benefit from the Health Impact Fund instead of benefiting from patent protection and rights, the prize amount provided

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<sup>323</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries", 38.

<sup>324</sup> **Mueller-Langer**, "Neglected Infectious Diseases", 192.

<sup>325</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries", 39.

to companies is expected to be higher or close to the potential profit from patents<sup>326</sup>. This situation causes the Health Impact Fund to require high costs.

Secondly, it is necessary to evaluate the effects of the medicines produced on public and human health by experts and to determine the prize according to this evaluation. The mechanism slows down because the situation in question is costly and requires time.

Finally, the effective functioning of the Health Impact Fund depends on the voluntary participation of companies with patent rights by giving up these rights. In addition, if the medicine to be produced contains different inventions protected under patents belonging to more than one different company, the Fund will not be able to prize medicine production without the consent of other relevant patent holders<sup>327</sup>.

### **3. The System of Advanced Market Commitment**

The other mechanism advocated to improve access to medicine in developing nations is the Advanced Market Commitments. With this pull mechanism, donors such as governments, international organizations or private organizations commit to the manufacturers who will produce medicines for rare or neglected diseases, to purchase a significant amount of patented medicines at accessible prices and to offer these drugs to the market of especially developing countries in need<sup>328</sup>. The main purpose of this mechanism is to create a large market, especially for rare and neglected diseases, thus

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<sup>326</sup> Ibid.

<sup>327</sup> Ibid., 40.

<sup>328</sup> Min, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries", 40.

enabling firms to spend in research activities. With the commitment to purchase put forward by the donors and the guarantee of a large and developed market, pharmaceutical companies agree to supply the medicines they produce at a fixed and low price<sup>329</sup>.

The basis of this mechanism is the successful research output, that is, the rewarding of the result, rather than the research inputs put forward in the medicine production process<sup>330</sup>. In this way, pharmaceutical companies will benefit from incentives and commitments as a result of the production and success of a medicine that is effective for human health, related to a rare or neglected disease.

However, this mechanism also faces several challenges and controversies. Firstly, the Advanced Market Commitment mechanism has inconsistency in time and demand<sup>331</sup>. Manufacturer pharmaceutical companies produce medicines with the pricing and market coverage committed by the donors. It is difficult to keep the medicines subject to the commitment at accessible prices and in enough quantities after the commitment expires<sup>332</sup>.

Secondly, with this mechanism, incentives and markets are provided for the medicine produced at the end of the process, not for the development process of the medicine. This situation requires pharmaceutical companies to be economically

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<sup>329</sup> Ibid., 41.

<sup>330</sup> **Mueller-Langer**, "Neglected Infectious Diseases", 200.

<sup>331</sup> Ibid.

<sup>332</sup> **Min**, "Compulsory Licensing of Pharmaceutical Patents in Developing Countries", 41.

dependent on donors in order to benefit from these incentives, but this dependence is seen as risky and costly by them<sup>333</sup>.

Finally, this output-based commitment mechanism prevents the determination of a certain price within the scope of incentives and commitments, due to the high variability and inconsistency in R&D expenditures. This may result in pharmaceutical companies earning incomplete or excess revenue. In particular, if the amount promised for a medicine is determined lower than the guaranteed price, R&D will not be encouraged<sup>334</sup> and investment activities will suffer.

#### **D. Integration of Push and Pull Mechanisms: Orphan Drug Schemes**

Another mechanism that takes part in increasing access to drugs is the Orphan Drug Schemes. With this mechanism, the development and production of orphan drugs for rare diseases that affect relatively few people in a society and therefore are not seen as profitable by pharmaceutical companies are encouraged and various benefits are provided to companies. These benefits, introduced to encourage pharmaceutical companies to R&D and investment in orphan medicines, consist of push mechanisms such as tax credits, fee exemptions, protocol benefits and scientific advice for clinical trials, and pull mechanisms such as the market exclusivity for a certain period<sup>335</sup>. In order to benefit from these incentives and be covered under the orphan drug schemes, the medicine must be produced for a rare disease.

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<sup>333</sup> **Mueller-Langer**, "Neglected Infectious Diseases", 200.

<sup>334</sup> *Ibid.*, 201.

<sup>335</sup> **Mueller-Langer**, "Neglected Infectious Diseases", 198.

Orphan Drug Acts have been passed by various countries under the orphan drug schemes. First of all, with the US Orphan Drug Act of 1983, various incentives and assistance are provided for R&D and investment activities for medicines to be developed in the treatment of rare diseases. In particular, these incentives include seven years of market exclusivity, tax reduction of 50% of the clinical trial cost, grants for R&D activities, shorter trial periods, and exemption from the fee required by the FDA<sup>336</sup>. With the 7-year exclusivity provided, the production of the same medicine for the same disease and the introduction of a lower-priced generic to the market can be prevented, that is, competition can be prohibited during the exclusivity period<sup>337</sup>.

Secondly, within the scope of Orphan Drug Legislation EC 141/2000, which entered into force in the EU in 1999, various incentives were provided to companies that would produce medicines for rare diseases. Within the scope of this legislation, there are 10 years of market exclusivity, fee reduction or exemption for clinical trials and studies, a central approval process for the whole EU, protocol assistance and scientific advice incentives<sup>338</sup>. In addition to this situation, tax advantages and grants are considered within the scope of these incentives.

It is argued that Orphan Drug Act/Legislation adopted in both the US and the EU increases clinical trials, resulting in real progress in R&D and growth in the development and production of such medicines<sup>339</sup>. Especially with the reduction of regulatory obstacles in medicine production, more research on orphan drugs and drug production will be in

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<sup>336</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 56.

<sup>337</sup> **Mueller-Langer**, "Neglected Infectious Diseases", 198.

<sup>338</sup> **Shahaf (Segev)**, "The Complex Relationship Between the Right to Health, " 57.

<sup>339</sup> *Ibid.*

question. In other words, the orphan drugs scheme encourages R&D and investment activities for necessary medicines for rare diseases. Moreover, under market economy conditions, a government's encouragement of pharmaceutical companies to develop and market medicines for rare diseases means that especially patients' access to medicines can increase<sup>340</sup>.

However, although the need for orphan medicines is widely acknowledged, there is also a controversy that the industry benefits from the incentive system to maximize their profits and that health systems will not cope with such pricing in the long run<sup>341</sup>.

Various alternative mechanisms have been put forward in addition to the compulsory license instrument in order to improve access to drugs in developing nations and to increase R&D activities and investment, especially in medicines for rare and neglected diseases. As examined above, the models under the push and pull mechanisms cannot provide full benefit on their own, and each model has various advantages and disadvantages in the balance of access to medicines. This situation reveals that a single mechanism, especially on a voluntary basis, cannot fully solve the problem of increasing investment in research activities and access to drugs in developing countries. Models created by the integration of various push and pull mechanisms can be an alternative to the compulsory license instrument. At this point, on the one side, first-stage research on R&D activities is supported by push mechanisms, on the other side, medicines obtained as a result of research activities are rewarded with pull mechanisms, that is, R&D is

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<sup>340</sup> **Gong and Jin**, "Current Progress in the Management of Rare Diseases", 52.

<sup>341</sup> **Nathan Jessop**, "The Dilemma with Orphan Drugs", *Pharmaceutical Technology Europe* 25, no.8 (2013), accessed August 02, 2021, <https://www.pharmtech.com/view/dilemma-orphan-drugs>

encouraged. However, although there are various incentives for increasing R&D activities, the fact that alternative mechanisms are not binding on states and pharmaceutical companies and are based on volunteerism, lack of adequate policies on public health and access to drugs prevent the active and effective use of these mechanisms.

## **II. Evaluation of Alternative Mechanisms**

The push and pull mechanisms, which are offered as alternatives in the face of disadvantageous features about compulsory licensing, can encourage drug R&D especially for neglected and rare diseases and enable access to drugs by reducing drug prices. Here, the expectation is to resolve the issue of access to affordable drugs, especially for patients suffering from rare and neglected diseases, who have difficulty in accessing drugs due to cost and lack of production.

At this point, it is thought that especially push mechanisms, most of which are financed by the government, come to the forefront within the scope of the first stages of innovation and R&D incentives, aimed at increasing production.

However, both types of mechanisms keep into the background when compared to the compulsory license mechanism, and the applicability of these mechanisms based on "volunteering" is not considered beneficial in the long run. The fact that the said mechanisms are separately input and output oriented will cause problems such as not completing the R&D activities or not reaching the desired product, both for medicine manufacturers and for governments and other actors that provide incentives to the manufacturer.

At this point, it is thought that instead of using alternative push and pull mechanisms separately, the use of mechanisms that include both types of mechanisms (such as orphan drug schemes) or the use of compulsory licensing, which stands out with its binding and mandatory nature, can accelerate governments' access to medicines.



## CONCLUSION

The most fundamental benefit of being an individual is the right to health and the right to access drugs. These are among the most basic rights that the individual should be able to continue his/her vital functions and should not be dependent on age, gender, race, or country in any way, and should be provided fully and equally. However, from the past to the present, it is seen that obstacles have been encountered especially in the provision of the right to access medicines and there are many conflicts between countries.

The right of access to essential drugs has faced many problems, especially due to the fact that the medicines to be described as "essential" differ according to countries and diseases. Diseases such as HIV/AIDS, tuberculosis, and malaria, which have been seen commonly from past to present, especially in developing and underdeveloped countries, have not been seen in the category of diseases that require "essential" medicine for a long time in developed countries. As a result, medicines for these diseases have not been produced, or medicines produced afterward are offered for sale by pharmaceutical companies at extremely high prices. At this point, high medicine prices prevented people of underdeveloped and developing countries suffering from these diseases from accessing medicines.

Today, problems especially related to the rare diseases with very low prevalence affecting only a certain minority in the society, and orphan medicines produced for these diseases are on the agenda. Orphan drugs are not produced especially with the thought of being demanded only by the minority and that profit maximization cannot be achieved. The drugs produced as a result of high costs and investments are offered for sale at very high prices, which creates a major obstacle to access to medicines. At this point, medicine manufacturers that play an effective role in providing access to drugs and developed

countries that host them have to strike a balance between high medicines prices and ensuring the right to access medicines.

Pharmaceuticals produced as a result of various R&D and innovation investments by pharmaceutical companies are protected by a patent document that provides an exclusive and monopolistic right for a certain period of time, and pharmaceutical manufacturers have freedom in pricing. As a result of this right and freedom, a price that covers high investment costs and expenditures is generally determined by pharmaceutical companies and a high pricing policy is adopted by predicting profit maximization. Various flexibility has been brought with international agreements in order to protect human rights and public interest by keeping the rights and pricing obtained through patent protection in balance, and a balance has been tried to be established between both the patent holder pharmaceutical companies and the public interests.

At this point, the compulsory license, which has come to the fore with the TRIPS agreement and the Doha Declaration, has been one of the most important tools in providing access to medicines. In general, the compulsory license, which gives authorization to another party to use the innovation subject to the patent, is applied directly to the needs of the public and is used for the production or export of generics of high-cost medicines.

Although the compulsory license has an active and important role in accessing medicines, there are various positive and negative opinions in terms of developed countries, pharmaceutical companies, and developing countries. Pharmaceutical manufacturers and developed countries, who defend the view that compulsory licensing will be damaged the incentives for innovation, medicine production, and R&D activities, see the compulsory license institution as a threat and argue that the patent system will be

damaged. However, for developing and underdeveloped countries that need medicine, compulsory licensing is a tool by keeping economic concerns in the background, based on human life and thus providing access to medicine. This difference of opinion has been evaluated in terms of countries, especially within the scope of orphan drugs. At this point, while compulsory registration of drugs for diseases that affect only a certain part of the society, namely the minority, is seen as negative and risky for those who adopt utilitarianism; It does not pose a risk for those who adopt the principle of social justice, on the contrary, it must be applied.

Controversies on whether or not the compulsory license should be applied in orphan drugs still continue today and differ according to the principles adopted.

The fact that there are many positive and negative opinions about the compulsory license and that there are various disagreements about its applicability has led to the need to seek alternative mechanisms to provide access to drugs which is one of the basic human rights. Various push and pull mechanisms have been put forward to manufacture, develop and sell more affordable medicines, especially for orphan drugs and neglected diseases, which are less profitable and low in demand.

Although these mechanisms have positive and negative qualities, it is argued that in cases where they are used together, they have the impact of increasing access to drugs together with compulsory licensing. However, the fact that the mechanisms are incentive-oriented and based on volunteerism makes the compulsory license institution, which is binding and mandatory, more applicable in the long run.

## ABSTRACT

*The objective of this work is to analyze the effects of compulsory license use within the scope of orphan drugs developed for rare diseases in respect of the right to health and right to access to medicines, especially in underdeveloped and developing countries. The study starts with the definition of rare diseases on the basis of country and prevalence, the general evaluation of human rights on the basis of the right to health and the right to access to drugs, as well as the analysis of the correlation between these rights and patent rights. Subsequently, the development process of the compulsory license is discussed within the legal framework and international agreements. After the development process is mentioned, the concept and general principles of compulsory license are emphasized, and the reasons for issuing compulsory licenses are examined in terms of case studies. Then, the positive and negative features of the compulsory license, especially in terms of developing and developed nations, are examined. In consequence of this examination, the impact of compulsory license on R&D activities and orphan drugs is analyzed. In the last chapter of the study, alternative mechanisms against compulsory licensing, especially in increasing access to orphan drugs, are presented and these mechanisms are evaluated.*

**Key Words:** *Compulsory License, Orphan Drugs, Rare Disease, Essential Medicines, The Right to Access to Medicines, The Right to Health.*

## ÖZET

*Bu çalışmanın amacı, özellikle az gelişmiş ülkelerde ve gelişmekte olan ülkelerde, görülen nadir hastalıklar için geliştirilen yetim ilaçlar kapsamında zorunlu lisans kullanımının sağlık hakkı ve ilaca erişim açısından etkilerini incelemektir. Çalışma nadir hastalıkların ülke ve prevelans bazında tanımlaması, sağlık hakkı ve ilaca erişim hakkı temelinde insan haklarının genel çerçevede değerlendirilmesi ve bu hakların patent hakkı ile ilişkisine yönelik analiz ile başlamaktadır. Devamında, zorunlu lisansın gelişim süreci hukuki çerçevede ve uluslararası anlaşmalarla ele alınmaktadır. Gelişim sürecine değinildikten sonra, zorunlu lisansa ilişkin genel ilke ve koşullar üzerinde durulmakta, zorunlu lisans verilme sebepleri örnek olaylar nezdinde incelenmektedir. Daha sonra, zorunlu lisansın özellikle gelişmekte olan ülkeler ve gelişmiş ülkeler açısından olumlu ve olumsuz özellikleri incelenmektedir. Bu inceleme sonucunda zorunlu lisansın Ar-Ge faaliyetleri ve yetim ilaç üzerindeki etkisi analiz edilmektedir. Çalışmanın son bölümü ile, özellikle nadir ilaçlara erişimin artırılmasında zorunlu lisansa karşı alternatif mekanizmalar sunulmakta ve bu mekanizmalar değerlendirilmektedir.*

**Anahtar Kelimeler:** Zorunlu Lisans, Yetim İlaç, Temel ilaçlar, Nadir Hastalık, İlaça Erişim Hakkı, Sağlık Hakkı

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