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**Comparative analysis of Compulsory Licensing of Patented Pharmaceuticals under TRIPS  
and Doha Declaration**

Master Thesis

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London 2015

I hereby declare that I am the sole author of this Master Thesis  
and it has not been presented to  
any other university of examination.

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## **List of Abbreviations**

AIDS - Acquired Immunodeficiency Syndrome

CL - Compulsory Licensing

EPO - European Patent Office

EU - European Union

FTA - Free Trade Agreement

GATT - General Agreement on Tariffs and Trade

HIV - Human Immunodeficiency Virus

IP - Intellectual Property

IPAB - India's Intellectual Property Appellate Board

IPO - Intellectual Property Office

IPR - Intellectual Property Rights

KA - Knowledge Agency

LDC - Least Developed Countries

MS - Member States

R&D - Research and Development

TRIPS - Agreement on Trade Related Aspects of Intellectual Property Rights

UK - United Kingdom

UMIC - Upper-Middle-Income Countries

US - United States of America

WHO - World Health Organization

WIPO - World Intellectual Property Organization

WTO - World Trade Organization

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## **Thesis Questions**

### **This research will be answering following questions:**

Is Compulsory Licensing loosely regulated by TRIPS agreement and Doha declaration? Why?

What are the legal solutions for the Compulsory Licensing issue?

Is Compulsory Licensing advantageous or disadvantageous legal tool? Is Compulsory Licensing the best legal policy of the country?

Do developed countries approach this subject differently from developing countries? Given India and the United Kingdom (UK) as examples.

### **Research Methodology**

For this Master's degree research methodology the author will use academic literature, laws and regulations, case law, articles from law journals, official publications, press releases, interview and other primary and secondary sources (the Internet, etc). The author will interview representatives from IPO (Intellectual Property Office) in UK.

## Introduction

IPR (Intellectual Property Rights) have a very high importance in the current commercial world. IPR encourages investments, innovation and development. The mostly used IPR include: design, utility model, patents, copyright, trademark, trade secrets. Patents protect the invention. Copyright covers artistic or literary works, while trademark covers distinctive logos or marks which distinguish one product or service from another one and design protects layout of the object. Considering the purpose of this research, the author will be focusing on patents and in particular CL (Compulsory Licensing) of patented pharmaceuticals. Patent protection in pharma industry has a crucial importance. Patent protection can be used to protect markets for the owner and/or licensees, both in the short term by refusing competitors access to product/processes and also in the longer term by diverting active research and progress.<sup>1</sup> An efficient patent portfolio is, thus, generally the key to authorizing the owner to build up its own manufacturing capacity, make income by licensing to one or more producers, or put up for sale the technology once sufficient work has been done one to demonstrate that manufactured goods have business prospective.<sup>2</sup>

Recently, patenting of pharmaceutical products attracted much of attention. Newly emerging diseases created a need of developing a legal tool which would balance drug distribution, manufacturing and availability between developed and developing countries (country announces by itself if it is developing or developed), strong and weak market players. This is why CL of patented pharmaceutical products was established. Though, as it appears, CL is a double-edged sword. It has many advantages, but at the same time also many disadvantages. Using compulsory licences does not necessarily mean that will bring positive outcomes and make drugs more accessible to the public. It also seems that the TRIPS agreement and the Doha Ministerial Declaration regulate CL very loosely, which raises many questions and creates flexibilities for MS (Member States). It might be quite dangerous as some developed countries may use these flexibilities and establish anti-competitive practices. Author of this work will explore in the research the legal gaps left in these

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<sup>1</sup> Pharma leaders and IP Conference 2015, JA.Kemp, briefing on “Patent applications in the pharmaceutical Field”, 22 September 2015, London

<sup>2</sup> Ibid

two documents regulating CL of pharmaceuticals and analyse if CL is the solution of emerging problem in pharmaceutical industry from the developed and developing country perspective.

“In recent years, the international IP (Intellectual Property) community has discussed at length patent law’s perceived shortcomings in relation to the pharmaceutical industry. Developed and developing nations have fought bitterly over the consequences of granting entities monopoly rights for lifesaving drugs and necessary medicines. Communities devastated by AIDS (Acquired Immunodeficiency Syndrome) and other debilitating diseases have argued passionately that it is abhorrent on a moralistic level for pharmaceutical companies to value profit over thousands, or even millions, of lives.”<sup>3</sup>

Starting from the Paris Convention, this subject undergoes a long legislative path both internationally and nationally. The TRIPS agreement and the Doha Ministerial Declaration introduced relatively efficient mechanism for regulating patenting of pharmaceutical products for developing and developed MS. According to the TRIPS Agreement, developing countries shall extend their protection also to the pharmaceutical products. This aspect was rather vaguely stated in the Paris convention, which gave great freedom in deciding patenting field to the MS. In addition, because of the TRIPS and Doha fourth Ministerial declaration, currently, the contracting parties have to meet several procedural requirements in order to be granted compulsory license.<sup>4</sup> “Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner”.<sup>5</sup> Nowadays, majority of the MS of the TRIPS agreement and Doha declaration have introduced compulsory license in their domestic legislation.<sup>6</sup>

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<sup>3</sup> Tyler, N. Patent Nonuse and Technology suppression: the use of compulsory licensing to promote progress. University of Pennsylvania Law Review, 2014, 162 (451)

<sup>4</sup> WTO, TRIPS: Agreement On Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Part II, Sec. 5, Art. 31

<sup>5</sup> TRIPS and Health: Frequently Asked Questions. Compulsory licensing of pharmaceuticals and TRIPS. WTO, September 2006,

[https://www.wto.org/English/tratop\\_E/trips\\_e/public\\_health\\_faq\\_e.htm](https://www.wto.org/English/tratop_E/trips_e/public_health_faq_e.htm). (11.11.2015)

<sup>6</sup> Unni, V. K. Compulsory Licensing of Pharmaceutical Patents in India: Whether Natco Decision Will Meet The Global Benchmarks?. European Intellectual Property Review, 2015, 37 (5), p. 296-304.

After compulsory license is issued to the person or the company, patent holder has no rights to define independently the conditions under which the pharmaceuticals are marketed.<sup>7</sup>

“The grant of a compulsory patent license typically requires the sanction of a governmental entity and provides for compensation to the patent owner. Compulsory licenses in the patent system most often relate to pharmaceuticals and other inventions pertaining to public health, but they potentially apply to any patented invention.”<sup>8</sup>

CL was created to enable the highly important medicines to all citizens of MS. Compulsory license is one of the flexibilities that relates patents and is introduced in the TRIPS Agreement by WTO (World Trade Organization).<sup>9</sup> Legislative changes triggered heated debates on articles of the TRIPS agreement and Doha Ministerial Declaration relating CL in the pharmaceutical sector. The practice clearly showed that CL has both – positive and negative aspects. It has number of advantages, but at the same time many disadvantages. Scholars who are against CL believe that issuance of such a licence will decrease the motivation of individuals and firms to innovate, which might be very disadvantageous for the society in the long term. One of the main characteristics of patent is that the patent holder has exclusive rights on its creation, therefore, this kind of legal tool would put under question crucial aspects of IP rights-exclusivity.

However, numerous studies have cast doubt on these critiques and predictions. Some scholars, for example Neil S. Tyler, have noted that CL would create a high motivation for patent holders and licensees to improved use of patents that otherwise would not be marketed. Additionally, compulsory license can be beneficial for the public as whole while avoiding unreasonably high prices of the drugs and two-sided monopolies.<sup>10</sup> The fear of the external regulation of CL can motivate the parties to negotiate the deal in order to avoid pricy litigation and non-working of the patented pharmaceutical.<sup>11</sup> Are there more pros or shortcomings from CL of Pharmaceutical products? What is the developing country perspective of CL of patented pharmaceuticals and how they can benefit from it? Is CL loosely regulated by the TRIPS agreement and Doha declaration? Is

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<sup>7</sup> Supreme Court of the Netherlands, 9 July 1985, E.C.R. 1985-02281, Case 19/84, *Pharmon BV v. Hoechst*.

<sup>8</sup> Thomas, J. Compulsory Licensing of patented inventions. Congressional Research Service, 2014, [http://ipmall.info/hosted\\_resources/crs/R43266\\_140114.pdf](http://ipmall.info/hosted_resources/crs/R43266_140114.pdf). (11.11.2015)

<sup>9</sup> TRIPS and Health: Frequently Asked Questions (2006), *supra nota 5*.

<sup>10</sup> Tyler, N. (2014), *supra nota 3*.

<sup>11</sup> *Ibid*.

CL the best legal policy of the country? Do developed countries approach this subject differently from developing countries? Why? What are the legal solutions for the CL issue? While analyzing these and more other important aspects the author will introduce the findings and also give some recommendations for more efficient regulation of CL of patented pharmaceuticals.

## **1. Creation of CL of Patented Pharmaceuticals**

Nowadays CL is highly important legal tool, but the institute by itself is centuries old. CL as a legal tool was created in the eighteenth century. It started with America approving IP laws, which made possible CL of printed materials. CL at the beginning was only covering copyrighted materials. The first of this kind of law was Connecticut's 1783 *An act for the Encouragement of Literature* and it stated following:

“And whereas it is equally necessary, for the encouragement of learning, that the inhabitants of this State be furnished with useful books, &c., at reasonable prices<sup>12</sup>:

Be it further enacted, that whenever any such author or proprietor of such book, pamphlet, map or chart, shall neglect to furnish to public with sufficient editions thereof, or shall sell the same at a price unreasonable, and beyond what may be adjudged a sufficient compensation for his labour, time, expense, and risqué of sale, the judge of the superior court in this State, on complaint thereof made to him in writing, is hereby authorized and empowered to summon such author or proprietor to appear before the next superior court [...] and if the [complaint] be found true, [...] he shall within such reasonable time [...] publish and offer the sale in this State, a sufficient number of copies of such book, pamphlet, map, or chart, at such reasonable price as said court shall, on due consideration affix: And if such author or proprietor shall, before said court, neglect or refuse to give such security as aforesaid, the said court are hereby authorized and empowered to give such complainant, a full and ample license to re-print and publish such book, pamphlet, map or chart, in

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<sup>12</sup> Mezher, M. Group Wants to See Stricter Limits on Compulsory Licensing. Regulatory Affairs Professional Society, March 2015, <http://www.raps.org/Regulatory-Focus/News/2015/03/02/21594/Trade-Group-Wants-to-See-Stricter-Limits-on-Compulsory-Licensing/> (11.11.2015)

such numbers and for such terms as said court shall judge just and reasonable prices as said court shall thereto affix.”<sup>13</sup>

Nowadays, this Act is not in force anymore.

## 1.1 Paris Convention introducing Patent System

Before 1994, IP and global trading policies were fundamentally different bodies which were extremely limited in power and capacity.<sup>14-15</sup> The Paris Treaty and Berne convention were one of the first international treaties that regulated IP, aiming to stop the MS to issue discriminatory IP laws.<sup>16</sup>

Historically, patenting of the products has always been a very controversial topic. From the seventeenth century, scholars have been arguing on how much exclusivity the patent owner shall have and how to keep patent system properly.<sup>17</sup> In 1883, the Paris Convention was concluded which introduced the final international regulation of the patenting among the MS. However, it has to be said that the Paris Convention, while trying to strike a fair balance between the interests of the MS and patent owners, left lots of freedom for the MS upon determining their local legal policies relating patent system, including subject of patenting, protection period, basis for issuing the

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<sup>13</sup> Ibid.

<sup>14</sup> Kim, D. H. Research Guide on TRIPS and Compulsory Licensing: Access to Innovative Pharmaceuticals for Least Developed Countries. February 2007, [http://www.nyulawglobal.org/globalex/TRIPS\\_Compulsory\\_Licensing.htm#\\_edn5](http://www.nyulawglobal.org/globalex/TRIPS_Compulsory_Licensing.htm#_edn5). (11.11.2015)

<sup>15</sup> Santoro, M. A. Human Rights and Human Needs: Diverse Moral Principles Justifying third World Access to Affordable HIV/AIDS Drugs. North Carolina Journal of International Law and Commercial Regulation, 2006, 31(4).

<sup>16</sup> Kim, D. H. (2007), *supra nota 14*.

<sup>17</sup> Machlup, F., Penrose, E. The Patent Controversy in the Nineteenth Century. The Journal of Economic History, 1950, 10(1), pp. 1-29.

protection and other crucial topics.<sup>18</sup> Consequently, MS of the Paris Convention were enabled to leave out number of patent subject matters from their patent system. Among them were pharmaceutical products, even though the process by itself could be subject to patenting. Afterwards, MS legislations introduced just a short duration of the patent granted for pharmaceuticals. In case where foreign patents were involved, contracting parties might subject it to the involuntary usage though CL of patented pharmaceutical products.

The number of the MS of the Paris Convention increased dramatically in seventies. Besides the developed countries, the Convention had already many developing contracting parties. This is when contravening ideas and many debates arouse around the great freedom given by the Paris Convention to its MS. The US (United States of America) were one of the most active MS which started taking actual steps to consolidate developed country position regarding the patenting of pharmaceuticals. “Driven by the actual need to recover losses in their pharmaceutical market United States extended patent protection of pharmaceutical products also to developing contracting parties of the Paris convention”.<sup>19</sup> Many of the WTO MS (except US) had started using CL while permitting it in international agreements.

“Under Article 5 of the Paris Convention, member countries may grant compulsory licenses to prevent abuses that may result from a patent holder’s exercise of exclusive patent rights. The grant of a nonexclusive compulsory license to entities that intend to use the patent in the domestic market, therefore, is meant to combat abusive patent practices, including the failure of a patent holder to work a patent”.<sup>20</sup>

All in all, both developed and developing countries came at the conclusion that major changes were needed to regulate CL of patented pharmaceuticals. This led to the creation of the TRIPS agreement (Agreement on Trade Related Aspects of Intellectual Property Rights), which brought crucial changes in IPL (Intellectual Property Law) as general and in Patents more specifically.

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<sup>18</sup> Ladas, S. P. Patents, Trademarks, and Related Rights: National and International Protection. Cambridge, Massachusetts: Harvard University Press 1975.

<sup>19</sup> Nogués, J. J. Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries. *The Developing Economies*, 1993, 31 (1), pp. 24-53.

<sup>20</sup> Tyler, N. (2014), *supra nota* 3.

## 1.2 TRIPS Agreement to regulate CL

After many debates in Uruguay, in 1994 the WTO and the TRIPS agreement were established.

The TRIPS agreement mainly introduced three major changes. Firstly, it obliged WTO contracting parties to introduce basic standards of protection of IPR in order to benefit from the GATT (General Agreement on Tariffs and Trade); secondly, it enabled the WTO to solve disputes concerning IP; lastly, it established procedures and remedies in order to resolve the disputes.<sup>21</sup> In addition, it partially resolved the issue of patenting pharmaceuticals by developing countries, by excluding them from patentability during the transitional period until 2016. Developed countries as the US were looking for less moderate regulation of CL and patenting. Nevertheless, developing countries mostly were hoping for affordable medicines derived from economically developed countries.

“Ironically, if the developing countries lost the war, in the sense that their generic pharmaceutical industries could no longer freely reverse-engineer the costly products of foreign R&D (Research and Development) under the shield of domestic laws that ignored pharmaceutical patents, then they won a great battle with specific regard to the question of compulsory licenses, which had triggered the drive for the TRIPS Agreement in the first place”.<sup>22</sup>

The TRIPS agreement triggered many debates if patenting and CL was the best legal policy for developing countries in order to have optimal medicine production and distribution. Further debates concerned legislative “gaps” left in the TRIPS agreement which created some uncertainties for the MS. These disagreements between the contracting parties especially developing and developing member state groups, resulted in a round table in Doha, Qatar.

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<sup>21</sup> Kim, D. H. (2007), *supra nota 14*.

<sup>22</sup> Reichman, J. H. Compulsory licensing of patented pharmaceutical inventions: evaluating the options. *The Journal of Law, Medicine & Ethics*, 2009, 37(2), pp. 247-263

### 1.2.1 Article 31 of the TRIPS Agreement and Grounds for CL

According to the article 31<sup>23</sup> of the TRIPS Agreement there are certain grounds only in which compulsory license of the patented pharmaceutical products can be granted. The grounds are following:

public non-commercial use;  
emergency and an extreme urgency;  
dependent patents;  
anti-competitive practices.

WTO member countries do not argue on existing grounds for issuing compulsory licence. What raises doubts is if there are other grounds to issue CL. The discussion basically stresses on two aspects: not enough or non-working of patents within the patent-granting state; grounds based on the public interest such as high prices of medical products and a denial to license a patent to a local company offering reasonable remuneration in exchange for the requested license. The supporters of this argument base their conclusions on article 7<sup>24</sup>, article 8<sup>25</sup> of the TRIPS Agreement. Thomas Cottier, Chief Swiss Negotiator for TRIPS believes that WTO contracting parties have a freedom to

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<sup>23</sup> TRIPS and Health: Frequently Asked Questions (2006), *supra nota* 5.

<sup>24</sup> WTO (1994), *supra nota* 4, Part I, Art. 7

#### Objectives

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.

please see at: [https://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm2\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm) (last accessed 1 March 2015)

<sup>25</sup> *Ibid*, Art. 8.

#### Principles

1. 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.

decide the grounds of compulsory licenses.<sup>26</sup> However, the MS shall strictly fulfil the proper substantive and procedural conditions of Article 31 of the Agreement. To sum up, the WTO enables the MS to decide the grounds for granting CL on pharmaceuticals.

The majority of the contracting parties introduced grounds for granting compulsory licence in their legislation, which included grounds as: “public health”, “national security”, “anti-competitive practices and/or unfair competition”, “national emergency and/or extreme urgency” , “non-working or insufficient working” , “refusal to grant licenses on reasonable terms” , “dependent patents” and “other grounds”.<sup>27</sup>

Moreover, according to the WIPO (World Intellectual Property Office) official document, in “other grounds” or in addition to the grounds listed above MS may use grounds to issue CL as:

“development of other vital sectors of the national economy”, “needs of national economy”, “public interest”, “public necessity”, “serious public interest menace”, “failure to meet market demand on reasonable terms”, “non-exploitation of the patent for failure to manufacture or incomplete manufacture of the product [...] or commercialization that does not satisfy the needs of the market”, “public non-commercial use; reasonable requirement of the public not satisfied; the patented invention is not available to the public at a reasonably affordable price”, “sold at unreasonably high prices or not meet the public demand”, “a market for the patented invention is not being supplied, or is not being supplied on reasonable terms”, etc.<sup>28</sup>

Some contracting parties also introduced articles in their national laws, which specifically regulate granting of compulsory license to the developing countries which lack manufacturing capacity to make the drugs accessible for them. In the UK, for instance, the legal grounds based on which CL is granted varies considering the fact if the patent holder is WTO proprietor, is national/domiciled in WTO contracting party or enjoys true and efficient business establishment in such country.<sup>29</sup> MS

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<sup>26</sup> Cottier, T., Lalani, S., Temmerman, M. Use It or Lose It: Assessing the Compatibility of the Paris Convention and TRIPS Agreement with Respect to Local Working Requirements. *Journal of International Economic Law*, 2014, 17 (2), pp. 437-471.

<sup>27</sup> Exceptions And Limitations To Patents Rights: Compulsory Licenses And/Or Government Use (Part I). Geneva, Standing Committee on the Law of Patents (WIPO) 2014, [http://www.wipo.int/edocs/mdocs/scp/en/scp\\_21/scp\\_21\\_4\\_rev.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_4_rev.pdf). (11.11.2015)

<sup>28</sup> Ibid.

<sup>29</sup> Ibid.

have a large room for interpreting and introducing grounds for compulsory license. The examples of the grounds discussed in this section are not comprehensive and may vary from country to country. Such a broad definition for grounds can be beneficial for developing countries to issue compulsory license effortlessly ; however, in the long run, it can be counter-productive.

### 1.2.2 National Emergencies

Neither the Doha Declaration nor the TRIPS Agreement give definition to what is meant under term “National Emergency” or “other circumstances of extreme urgency”, which are both a legitimate ground for granting CL. However, differently from the TRIPS agreement, the Doha Declaration states that “HIV (Human Immunodeficiency Virus)/AIDS, tuberculosis, malaria, and other epidemics” are good examples of “national emergencies” or “other circumstances of extreme urgency”. It is an important addition to the Article 31, mainly in view of the fact that at the pre-Doha discussions, the US had unwillingly pointed out that just HIV/AIDS should be considered under the emergency criteria.<sup>30</sup> HIV/AIDS outburst in Brazil, South Africa and Thailand is a perfect illustration of the emergency situation.<sup>31</sup> Pursuant to the Declaration's encouragement that all articles of the TRIPS Agreement be read and defined considering its objectives and principles, it is indefensible to propose that the invocation of CL under Article 31 to tackle a public health emergency would essentially be overruled by the provisions of Article 27.1 on patent rights or the rights to ordinary usage and lawful interests of patent holders referred to in Article 30.<sup>32</sup>

Whether or not it was the legislator's intention, the MS of the WTO shall decide independently how “National Emergency” is determined, which may easily lead to many misunderstandings and unfair practices.

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<sup>30</sup> Gathii, J. T. The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties. *Harvard Journal of Law & Technology*, 2002, 15 (2), pp. 292-317.

<sup>31</sup> Li, P. *Health Technologies and International Intellectual Property Law: A Precautionary Approach*. Oxon, Routledge Research in Intellectual Property 2014

<sup>32</sup> Gathii, J. T. (2002), *supra nota 30*.

The WIPO contracting parties which granted compulsory license on the ground of “national emergency” or “other circumstances of extreme urgency” did not give any explanation and definition of the abovementioned circumstances. Some countries simply introduced examples of such cases: “war”, “state security, protection of public interest in the field of health and nutrition, protection and improvement of human environment, or special interest in a particular branch of economy<sup>33</sup>”, “disasters, catastrophes or big accidents”, “national defence”. For instance, in WIPO questionnaires, India and China stated HIV, Tuberculosis and malaria as such. While the Republic of Moldova defined “national emergency” as “interruption of normal life and activity of the population [...] in a region as a result of accidents, disasters, natural or socio-biological calamities which resulted or could result within human and economic losses”.<sup>34</sup> Several member countries simply referred to cases of “public interest” with broad term, for instance Denmark. Spain’s Law on Patents states: “Reasons of public interest shall be deemed to exist when the initiation, increase or generalization of working of the invention, or improvement of the conditions in which it is being worked, are of paramount importance for public health or national defence. Reasons of public interest shall also be deemed to exist when failure to work or the insufficient quality or quantity of working leads to serious prejudice for Spain’s economic or technological development”.<sup>35</sup>

In regard with issuing CL, some countries stated in their responses to WIPO that when there is a case of “public interest”, CL will be granted without any specific time limit.

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<sup>33</sup> Standing Committee on the Law of Patents (WIPO) (2014), *supra nota 27*;  
Parliamentary Assembly of Bosnia and Herzegovina, Patent Law of Bosnia and Herzegovina, 7 April 2010, art. 80 (1).

<sup>34</sup> The State Agency on Intellectual Property Republic of Moldova - Questionnaire submitted to WIPO, 2011, <http://www.wipo.int/scp/en/exceptions/replies/moldova.html>. (27.11.2015)

<sup>35</sup> Standing Committee on the Law of Patents (WIPO) (2014), *supra nota 27*;  
Ley 11/1986, de 20 de marzo, de Patentes (as last amended by Law No. 14/2011 of June 1, 2011), 20 March 1986.

### 1.3 Creation of Doha Ministerial Declaration

High prices of essential medicines, raising problems in manufacturing drugs for local use, confusing flexibilities left in the TRIPS agreement and demand by developing countries towards developed countries to remove constraints on public health (guaranteed by the TRIPS agreement) and many other reasons resulted in the Fourth Ministerial Conference in Doha, Qatar in 2001. The result was the Doha Declaration, made in 2001, on the TRIPS Agreement and Public Health, which in paragraph 4, avowed that this treaty “can and should be interpreted and implemented in a manner supportive of WTO Members’ rights to protect public health *and, in particular, to promote access to medicines for all.*”<sup>36</sup> The Doha declaration simply re-confirmed flexibilities guaranteed by the TRIPS Agreement. One major change this declaration brought in the pharmaceutical industry was the paragraph relating countries which lack manufacturing capacity and introducing proper regulation for these types of MS.

#### 1.3.1 Compulsory Licenses for Patented Pharmaceuticals since Doha Declaration

Since the Doha Declaration was issued, various opposing ideas about it started to arise. Some thought that giving the freedom to MS and legislative flexibilities would increase the number of claims for CL of pharmaceuticals; on the other hand, some experts thought that developing countries would not be claiming it often because of their health system imperfections and political constraints. While analyzing this topic, researchers used to evaluate the impact of the Doha Ministerial Declaration on CL of drugs. The findings carried out by Reed Beall and Randal Kuhn showed the following:

“By systematically searching media archives for reports of WTO MS considering or announcing compulsory licensing of pharmaceuticals, the researchers identified 24 verified compulsory licensing episodes in 17 nations that occurred between January 1995 and June 2011. Half of these episodes ended with an announcement of a compulsory license, and the majority ended in a price

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<sup>36</sup> Reichman (2009), *supra nota* 22.

reduction for a specific pharmaceutical product for the potential issuing nation through a compulsory license, a voluntary license, or a negotiated discount".<sup>37</sup>

Majority of compulsory licenses were issued on HIV/AIDS medicines, others involved cancer and other diseases. In more than 50 % of cases, the CL took place in UMIC (Upper-Middle-Income Countries), such as Brazil and Thailand. Finally, mainly CL cases were identified from 2003 to 2005. The above mentioned is demonstrated in details in Figure 1<sup>38</sup>.

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<sup>37</sup> Beall, R., Kuhn, R. Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis. PLoS Med, 2012, 9(1), e1001154.

<sup>38</sup>Ibid.

Year(s)	Nation	National Income Group	Disease	Disease Group	Total Products	Outcome
2001 (2007)	Brazil	UMIC	HIV/AIDS	HIV/AIDS	2	CL/discount
2001	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2001	Canada	HIC	Anthrax	CD	1	Discount
2001–2003	South Africa	UMIC	HIV/AIDS	HIV/AIDS	8	VL/discount/none
2001	United States	HIC	Anthrax	CD	1	Discount
2002	Egypt	LIC	Erectile dysfunction	NCD	1	CL
2003–2004	Malaysia	UMIC	HIV/AIDS	HIV/AIDS	3	CL
2003, 2007	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2003	Zimbabwe	LIC	HIV/AIDS	HIV/AIDS	All	CL
2004	Mozambique	LDC	HIV/AIDS	HIV/AIDS	3	CL
2004	Zambia	LDC	HIV/AIDS	HIV/AIDS	3	CL
2005–2006	Argentina	UMIC	Pandemic flu	CD	1	VL
2005–2007	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2005–2009	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2005	Ghana	LIC	HIV/AIDS	HIV/AIDS	All	CL
2005	Indonesia	LIC	HIV/AIDS	HIV/AIDS	2	CL
2005	Taiwan	HIC	Pandemic flu	CD	1	VL
2006–2007	India	LIC	Cancer	NCD	1	None
2006 (2010)	Thailand	UMIC	HIV/AIDS	HIV/AIDS	1	CL
2007	Rwanda	LDC	HIV/AIDS	HIV/AIDS	1	CL
2007 (2010)	Thailand	UMIC	HIV/AIDS, CVD	HIV/AIDS, NCD	2	CL
2007–2008	Thailand	UMIC	Cancer	NCD	1	Discount
2007–2008	Thailand	UMIC	Cancer	NCD	3	CL
2010	Ecuador	UMIC	HIV/AIDS	HIV/AIDS	1	CL

Totals: 24 Episodes, 17 Nations, 40 Unique Drug-Nation Combinations +2 Categorical CLs. Years in parentheses indicate CL renewals.  
CVD, cardiovascular disease.  
doi:10.1371/journal.pmed.1001154.t001

Figure 1

Figure 2<sup>39</sup> shows that not always applications ended up in issuing compulsory license, voluntary license or sometimes even a discount.

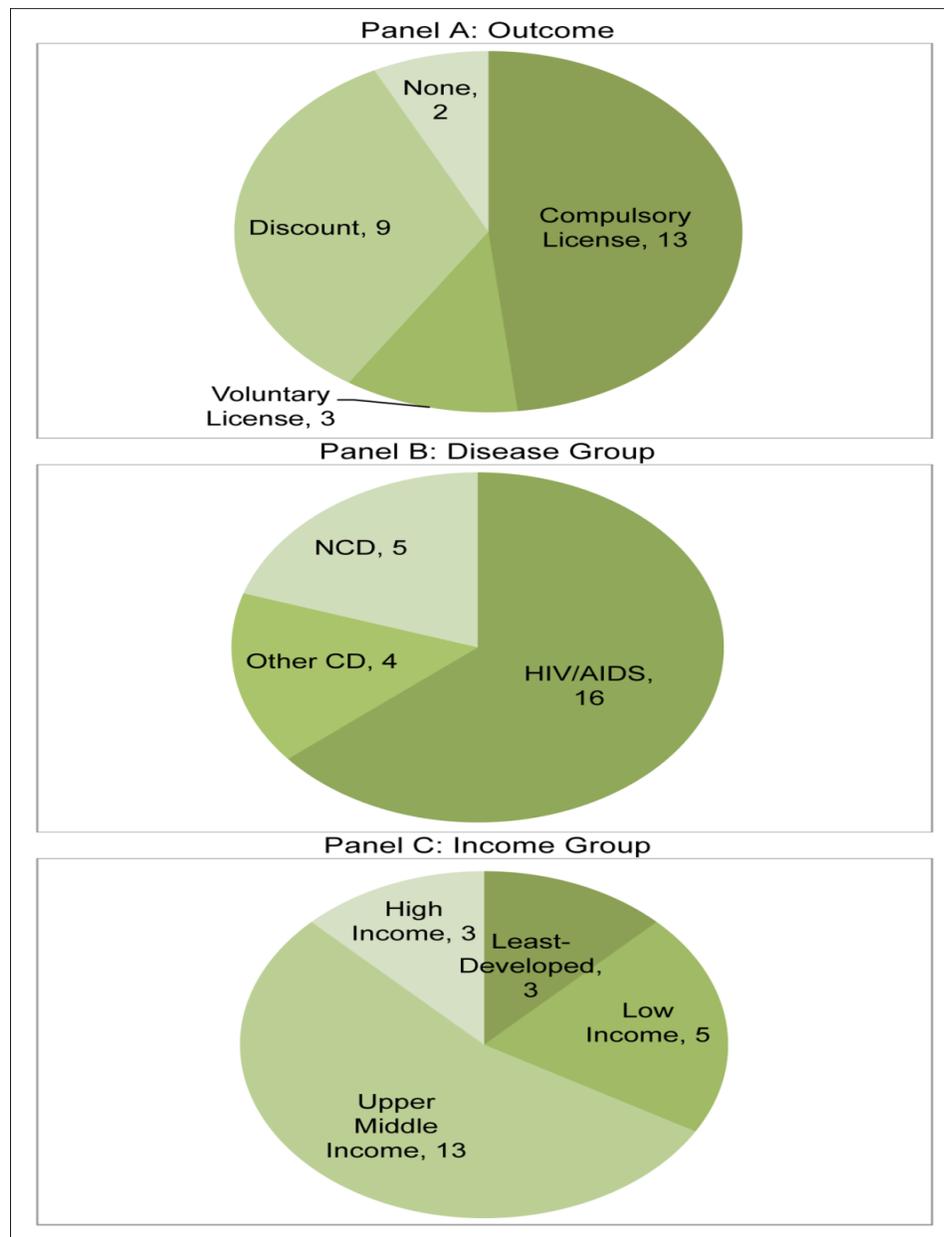


Figure 2

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<sup>39</sup> Ibid.

Since the Doha Declaration has been issued, there have been a certain number of cases when government of the country issued compulsory license on patented pharmaceuticals in order to access a highly important medicine.

According to the author's observation, it can be concluded by saying that the Doha Declaration promoted issuing of the CL. Comparing its effect to the TRIPS Agreement, it created better legal environment for developing countries. Statistical researches presented in this section clearly demonstrate that there has been an increase in compulsory license numbers since the Doha declaration was adopted. Nonetheless, not in all the cases CL showed to be productive, for example especially for those developing countries which do not have or lack manufacturing capacity.

## **2. Legislative gaps under TRIPS and Doha Declaration flexibilities**

When the MS decided to create TRIPS they left several legal gaps in the agreement. It was mostly because the countries were divided in two camps between developed and developing countries. Legislator had to take into consideration both parties controversial opinions and interests and draft the agreement accordingly. Flexibilities in TRIPS agreement included vague terms, room left for the MS for their own interpretation, conditions and grounds under which CL could be used etc. There are controversial opinions in this regard. Some scholars believe that this was made to favour developing nations, while others believe that article regarding the compulsory license was initiated by developed nations to regulate more precisely such licensing of patented pharmaceutical products. The author of this work would not agree with any of these extreme opinions. Obviously there were established beneficial aspects in the agreement for developing countries but some provisions were comfortable just for developed nations. In Doha fourth Ministerial Declaration several uncertainties left in TRIPS agreement were explained, though not all of them. Practically, Doha Declaration simply reconfirmed the flexibilities established under the TRIPS agreement, though it added some value in regards to developing countries that lack manufacturing capacity.

## 2.1 Legal uncertainties under TRIPS Agreement

According to the TRIPS Agreement, Compulsory License can be granted only under certain conditions, including obligation to inform and negotiate with the patentee. However, the circumstances established by law are refrained in the case of “national emergency” or other circumstances of “extreme urgency” or in cases of “public non-commercial” (for instance governmental usage).<sup>40</sup> This practically granted the right to the contracting parties to turn to CL when the country would prefer to do so, based on its own national interests. Obviously, the legislation left the ‘gap’ in the TRIPS agreement which gives a considerable degree of flexibility to the MS to justify their actions of resorting CL of patented pharmaceuticals with “national emergency” or “other circumstances of extreme urgency”. Undoubtedly, both of the terms used in the Article 31 of the TRIPS Agreement may have a very broad definition and be interpreted in various convenient ways. Despite this, it has to be noted that Article 31 of the TRIPS Agreement established conditions for issuing CL:

The person/company applying for a licence must try to obtain voluntary license at the first place from the patent holder. If the latter refuses to do so, the CL can be issued after the application made by license seeker.

Patent owner has to be paid even if the compulsory license is granted to the person/company. According to TRIPS: “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”<sup>41</sup>. It is strange but there is nothing said about how “adequate remuneration” can be defined and what does “economic value” mean.

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<sup>40</sup> World Trade Organization (WTO) (1994), *supra nota 4*.

<sup>41</sup> TRIPS and Health: Frequently Asked Questions (2006), *supra nota 5*.

## 2.2 Reconfirming TRIPS flexibilities in Doha Declaration

The Doha Declaration left uncovered some parts of the TRIPS agreement where flexibilities were introduced, for instance exclusions of the patent rights (Article 30) and the protection of data given for the registration of medical products (Article 39.3).<sup>42</sup> Nor did it address the freedom given to member countries to define the patentability standards.<sup>43</sup> Importantly, it stated that the TRIPS Agreement shall not stop members from taking actions to safeguard public health and that TRIPS shall be defined and implemented in a way which is respectful of WTO contracting parties right to guarantee public health and, in particular, to endorse accessibility to essential drugs for everyone.<sup>44</sup>

The Paragraph 5 of the Doha Declaration welcomes the balancing approach as the MS accept a number of flexibilities included therein "while maintaining [their] commitments in the TRIPS Agreement."<sup>45</sup> According to the TRIPS agreement, these flexibilities include:

Reading TRIPS provisions taking into consideration its object and purpose;

The nearly absolute freedom to decide on what grounds to grant Compulsory License;

The ability to define "national emergency" or "other circumstances of extreme urgency";

The right to establish the ways of exclusion;

Extending conformity period till 2016 for LDC (Least Developed Countries).

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<sup>42</sup> Correa, C. M. Implications of the Doha Declaration on the TRIPS Agreement and Public Health. 2002, <http://apps.who.int/medicinedocs/en/d/Js2301e/15.html>. (06.12.2015)

<sup>43</sup> Ibid.

<sup>44</sup> Wakely, J. Compulsory Licensing Under TRIPS: an effective tool to increase access to medicines in developing and least developed countries?. European Intellectual Property Review 2011, 33(5), pp. 299-309.

<sup>45</sup> WTO, Declaration On the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 20 November 2001, Art.5.

In practice, the Doha Declaration simply reconfirmed the flexibilities granted by TRIPS Agreement by leaving terms as “national emergency” and “Extreme Urgency” undefined. This means that interpretation of these terms depends on what country’s interests are in a specific case.

Moreover, in paragraph 6, it provided a mandate for:

“establishing legal machinery to enable countries lacking the capacity to manufacture generic substitutes for costly patented medicines under domestically issued compulsory licenses to obtain imports from countries able and willing to assist them without interference from the relevant patent holders.”<sup>46</sup>

From the legal standpoint, the Doha declaration did not help very much in filling TRIPS gaps. It encourages interpretation of the TRIPS Agreement, while considering objectives and main values of the agreement, and thus enabling MS to make a decision based on their public policies legally.<sup>47</sup> For instance, in the Arbitration Proceedings (Canada) - Protection of Pharmaceuticals,<sup>48</sup> Canada claimed that it should enjoy longer time period in order to meet the terms of revocation of the provisions in its Patent Act for the reason of the political responsiveness of altering its "long standing policy of providing relatively low cost medication to consumers as soon as possible."<sup>49</sup>

After close observation, it can be concluded that the Doha Declaration added a low legal value to regulating CL of patented pharmaceuticals. Reconfirming TRIPS flexibilities did not solve numerous practical issues.

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<sup>46</sup> Reichman (2009), *supra nota* 22.

<sup>47</sup> Schermers, H. G. International Institutional Law. 2<sup>nd</sup> ed. Kluwer Law International, 1980.

<sup>48</sup> Report of the Panel, Canada - Patent Protection of Pharmaceutical Products, WT/DS114/R. 2000, <http://jolt.law.harvard.edu/articles/pdf/v15/15HarvJLTech291.pdf>. (11.11.2015)

<sup>49</sup> Howse, R. L. The Canadian Generic Medicines Panel - A Dangerous Precedent in Dangerous Times. The Journal of World Intellectual Property 2000, 3 (4), pp. 493-507.

### **2.3 Legal changes in distributing licensed generic copies**

Even though the Doha Declaration did not introduce many different provisions and mostly reinforced TRIPS flexibilities, one important thing has been changed. The Article 31 (f) of the TRIPS agreement stated that compulsory license must be granted to supply the domestic market. The Doha Ministerial Declaration changed this rule by granting the right to obtain cheap copies of medicines elsewhere for countries with very limited or no manufacturing capacities.

This change was agreed in 2003. The General Council waived the provision and made generic copies under CL available for exportation in countries with small or no manufacturing capacity under certain circumstances and conditions.

All WTO contracting parties are legally entitled to import according to this decision, though twenty three of the developed countries declared that they will not use the new system. Among them are: Australia, Canada, Czech Republic, Slovak Republic and Slovenia, Denmark, Estonia, Finland, Germany, Greece, Iceland, Italy, Japan, Lithuania, Luxembourg, Netherlands, New Zealand, Poland, Spain, the UK and the US.

There were some countries which stated that they will use the new system only in case of “national emergency” or “extreme urgency”, those are: China, Israel, Korea, Kuwait, Mexico, Qatar, Singapore, Turkey, and the United Arab Emirates.

From the very beginning, it was obvious that developed and developing countries had contradicting opinions about using the new system enabling cheap medicines for countries that lack manufacturing capacity. Most of the European countries refrain from using this system, while other will use it only under “national emergency” or other circumstances of “extreme urgency”.

Maskus made a survey and concluded that CL of pharmaceutical products put poor and developing countries in a very unattractive situation. With the great chance of having their markets monopolized

exporting patentees and strong patents “could also permit firms to choose not to license their closely held technologies except in cross-licensing or patent-pooling arrangements”<sup>50</sup>.

Regardless the risk of monopoly on developing country internal markets, the TRIPS agreement and the Doha declaration enhanced patenting system influence on MS economic and social welfare. The Article 27.1<sup>51</sup> of the TRIPS agreement makes patent protection available in any possible sphere, while the Article 33<sup>52</sup> gives a definition to the patent term. A stronger protection of patented pharmaceuticals for developing countries resulted in a considerable increase of medicine prices and high costs for implementing the TRIPS Agreement. Some scholars believe that not only cost but also the availability of pharmaceuticals has been negatively affected. For instance, “negative impact of protecting patents in India is not only limited to the affordability of medicines, but also to their availability”.<sup>53</sup> While there might be a number of reasons which stop many deprived patients in developing nations from obtaining the vital drugs, the lack of accessibility on the market and high price of pharmaceutical products can be named as the key factors.<sup>54</sup> The Doha declaration established numerous alterations which were particularly referred to developing nations.<sup>55</sup>

The Paragraph 5<sup>56</sup> of the Doha re-declared the rights of developing nations to issue under the local legislation, without being afraid of legal provocations by developed countries, basis as non-working

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<sup>50</sup> Maskus, K. E. The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer. *Duke Journal of Comparative & International Law* 1998, 9 (109), pp. 109-161

<sup>51</sup> WTO (1994), *supra nota 4*, Art. 27.

<sup>52</sup> WTO (1994), *supra nota 4*, Art. 33.

#### Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date

<sup>53</sup> Chaudhuri, S., Goldberg, P. K., Jia, P. Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India. *American Economic Review* 2003, 96(5), pp. 1477-1514.

<sup>54</sup> Abbott, F. M., Van Puymbroeck, R. V. Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision. *World Bank Working Paper* 2005, No 61, p.1.

<sup>55</sup> WTO (2001), *supra nota 45*.

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

of patents nationally, denial to license on rational business terms, and irrationally high medicine prices.<sup>57</sup> In addition, the declaration gave LDC contracting parties' 10-year period until 2016 to implement patent protection for pharmaceuticals. This means that supplying country has to grant a CL to export a generic copy of a pharmaceutical product that is patented in that country. Despite of some positive changes, the Declaration left unresolved the Article 31 (f). This article prohibits issuing compulsory licenses for exportation reasons. As a result developing countries with poor manufacturing abilities will not make an efficient use of this kind of CL and the only option to get important drugs accessible for the citizens would be importation. As a solution the Decision has been made for implementation of paragraph 5 of the Doha declaration. In 2003, the General Council of WTO accepted the Implementation Decision.<sup>58</sup> The Decision sets out the framework to be adopted where a country without a significant manufacturing capacity seeks to take advantage of the system. Solely LDC along with the contracting parties with poor or no manufacturing capacity can use this system.<sup>59</sup> This decision introduced two kinds of renunciations. One of this concerns the Article 31 (f) and grants MS ability to issue compulsory licences for exporting reasons as well under certain conditions, and the second waiver enabled patent holders to being remunerated in case of CL. This arouses many debates. Many scholars do believe that this is quite a complex to do bureaucratically. The same highly bureaucratic is paragraph 6 system. The result is a limited number of acceptances of the Protocol. The TRIPS agreement has been amended and now includes waiver, the Article 31bis and Annex.

According to Mr. Tudor, "Even though the Doha Declaration loosened the TRIPS limitation ability of countries to issue compulsory licenses to domestic firms to allow them to manufacture and export patented medicines to countries that would otherwise qualify to issue a compulsory license".<sup>60</sup>

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<sup>57</sup>t Hoen, E. F. M. TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha. *Chicago Journal of International Law* 2002, 3 (1), pp. 40-41.

<sup>58</sup> Owoeye, O. International Patents Law and Public Health: Revisiting the TRIPS Compulsory Licensing Regime and the Doha Paragraph 6 System. *European Intellectual Property Review* 2015, 37(12), pp. 782-795.

<sup>59</sup> General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc WT/L/540, 30 August 2003, 2(ii).

<sup>60</sup> Tudor, J. Compulsory Licensing in the European Union, *George Mason Journal of International Commercial Law*, 2011, 4 (2), pp. 222-258.

The Doha Declaration states that, the WHO (World Health Organization) is the organ which defines if the country in question has a manufacturing capacity to produce protected pharmaceuticals or not.<sup>61</sup> Practically the final decision is up to WHO on this matter.

As a scholar, Mr. Tudor believes “Many of the world’s large pharmaceutical firms also fear abuse of compulsory licensing practices if the Doha Declaration were implemented, especially if the royalty rates are low and firms with compulsory licenses are able to produce at low expense and then export.<sup>62</sup> There is some evidence that this concern is overstated. Many Asian and African nations have successfully granted compulsory licenses for antiretroviral drugs for domestic consumption with virtually no threat that any excess supply is being created or exported. Regardless, the world’s largest pharmaceutical firms are challenging domestic compulsory licensing laws that make it easier for governments to grant, and competing drug producers to produce, needed pharmaceuticals”.<sup>63</sup>

WTO waiver is not enough to execute the new system properly. Exporting MS have to change their national laws as well, which previously in accordance with the TRIPS agreement required that compulsory license would be issued for the domestic market mostly. Most of the EU (European Union) countries have already made these changes.

### 2.3.1 Eligibility for using Paragraph 6 mechanism and Legal Policy Implications

The scope of developing country eligibility for the new CL system promoted debates. The term ‘developing country’ can be addressed to a very wide range of countries in the WTO including the poorest, LDC and UMIC which still enjoy their own production capacity. Even though TRIPS makes possible for each country to grant CL to their local manufacturers, still many practical complexities remain unaddressed in the pharmaceutical industry of developing nations. For example, a member state might be able to produce paracetamol, but unable to reengineer sophisticated and complex medicines in order to benefit from compulsory license in accordance with

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<sup>61</sup>t Hoen (2002), *supra nota* 57.

<sup>62</sup> Tudor, J. (2011), *supra nota* 60.

<sup>63</sup> Ibid.

TRIPS. The question is if a nation with manufacturing capacity, but not enough specialized knowledge in pharmaceutical industry, still uses the Paragraph 6 system to issue CL to a more complex industry in another member state to manufacture a drug. After almost two years of tough discussions, a compromise, attractive for developing MS, has been reached as WTO's General Council.<sup>64</sup> The Decision<sup>65</sup> stated certain criteria in defining what is meant under having low or no production capacity, though MS would announce themselves voluntarily as eligible by informing the TRIPS council. In practice, developing countries refused to limit their ability to self-declare themselves. There were no official legal mechanisms introduced in the Decision to review self-declaration by developing nations, even though, for example the US suggested doing so. This mechanism was not supposed to serve nations commercial policies, as there were serious concerns that countries would use it to expand the size of generic pharmaceutical industries.

Compulsory licences made it easier for developing nations lacking manufacturing capacity to get relatively reasonably priced drugs to treat their citizens with HIV/AIDS or other outbreaks. However, the CL system has a slight effect on accessibility of drugs in developing countries. In reality, legal changes that have been introduced solved just a very few of the accessibility problems of drugs by developing MS. It also named improper delivery system for pharmaceuticals and untrained personnel that would hamper the efficiency of new policy. Compulsory licences have been issued rarely by developing countries, which might be caused by poor patent protection in many of them. It is mostly because, these countries were not obliged by the TRIPS agreement to create patent system which would be introducing same TRIPS principles till 2005 and the date has been extended to 2016. Not all the developing countries are unable to issue compulsory licences. Some of them, for example Brazil, has relatively powerful patent regime. Brazil can develop and create novel drugs, which enabled to bargain more attractive prices for medicines with developed countries, while threatening them to grant CL on the products created in such developed country.<sup>66</sup> Brazil is a very illustrative case of threatening with issuing the compulsory license in order to get access to vital drugs.<sup>67</sup> In 2003, Brazil issued the law according to which government has the right to import generic drugs without prior consent of the patent owner if there is a "national emergency" or a

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<sup>64</sup> Abbott, F. M., Van Puymbroeck, R. V.. (2005), *supra nota* 54.

<sup>65</sup> General Council (2003), *supra nota* 59.

<sup>66</sup> Compulsory Licensing: Background, Thailand Law Journal, 2012, 15 (1), p.2.

<sup>67</sup> Yu, P. K. Access to Medicines, BRICS Alliances, and Collective Action. American Journal of Law & Medicine, 2008, 3, pp. 345-349.

“public interest”. Other significant examples are Indonesia and Malaysia that authorized their governments to grant CL for medicines treating AIDS. The manufacturers and suppliers of the pharmaceuticals have very little economic reasons to produce medicines in case of developing countries issuing CL. According to the Decision, the developing member state which lacks manufacturing capacity can use CL to get a product from drug producer from developed country. Though, this drug producer may have no motivation to do it for the LDC in limited quantities. There are several aspects that make this deal even more unattractive for the generic medicine manufacturer. They have to pack the medicines in distinctive manner to avoid inconveniences. Considering these aspects, it is very doubtful that drug supplier would undertake all these additional costs for limited developing markets. For example, one of the AIDS campaigners was saying that limitations, such as particular wrapping and notification obligation, make “a watertight system so that no generic drugs ever get through to the patients in developing countries who desperately need them”<sup>68</sup>. However, the US authorities have asserted that these limitations stopping diversion is in the interest of receiver countries by introducing extra guarantees that the drugs will be used by the planned receivers.<sup>69</sup>

### 2.3.2 Analysis of Practices across Jurisdictions

The way CL is regulated by MS may vary country by country. This is because contracting parties are not on the same level of development, some are developing and others are developed nations. In this section, the author will explore how CL is regulated in developing countries.

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<sup>68</sup> Fergusson, I. F. *The WTO, Intellectual Property Rights, and Access to Medicines Controversy*. 2006, <http://fas.org/sgp/crs/misc/RL33750.pdf> (11.11.2015).

<sup>69</sup>Ibid.

### 2.3.2.1 Latin America

In Latin America there are various grounds guaranteed by the national legislations for granting compulsory license to patented pharmaceutical products. These grounds are shown in the table 1<sup>70</sup> below:

Grounds for issuing CLs	Countries were these grounds are provided for
Failure to exploit a patent	Andean Community, Argentina, Brazil, Dominican Republic, Honduras, Mexico, Chile, Uruguay, Costa Rica
Public interest	Andean Community, Brazil, Dominican Republic, Honduras, Mexico, Chile, Uruguay, Guatemala, Costa Rica
National emergency and other circumstances of urgency	Andean Community, Argentina, Brazil, Dominican Republic, Honduras, Mexico, Chile, Uruguay, Guatemala, Costa Rica, El Salvador
Remedy for anti-competitive practices	Andean Community, Argentina, Brazil, Dominican Republic, Chile, Uruguay, Guatemala, Costa Rica
Failure to obtain a licence under reasonable terms	Argentina, Dominican Republic, Honduras, Uruguay
Dependent patents (when a patent cannot be exploited without using another patent)	Andean Community, Argentina, Brazil, Dominican Republic, Honduras, Chile, Uruguay, Costa Rica

Table 1

Many Latin American countries signed a FTA (Free Trade Agreement), which never defined the limitations on grounds for granting CL. This might be an outcome by the Doha Declaration re-confirming the rights of the contracting parties of the TRIPS agreement to decide the grounds for granting compulsory license. In some cases, when test data is subject to exclusive rights, CL might not be possible to execute because of the FTAs made between the countries is question. In accordance with the Article 39 of TRIPS, this kind of data shall be protected from unfair competition. However, the FTA between America and EU established the “data exclusivity” according to which in some situations a generic firm cannot get marketing approval of a drug that contains the identical chemical consistence.<sup>71</sup> If this is the case, it is likely that compulsory license makes possible the use of the patent, but not the marketing permission for its drugs. For instance,

<sup>70</sup> Hilty, R. M., Liu, K. Compulsory Licensing: Practical Experiences And Ways Forward. MPI Studies on Intellectual Property and Competition Law Vol. 22, Springer-Verlag Berlin Heidelberg, 2015, pp.43-59.

<sup>71</sup> Correa, C. M. The Use of Compulsory Licenses In Latin America. South Bulletin, 28 February 2013, Issue 71, pp. 15-20.

Brazil, Uruguay and Argentina do not approve data exclusivity. To avoid uncertainties between test data and compulsory license regulations, in some FTA, MS tried to negotiate this subject through “side letters” which served the purpose of allowing MS to take considerable measures in case there is a need to protect public health. This kind of measures basically would be taken in case of “national emergency” or “extreme urgency” and in particular when it concerns diseases like HIV/AIDS, tuberculosis and other epidemics. The US and the Dominican Republic dedicated one chapter within their FTA to defining and regulating the above mentioned public health protection measures. For instance, Chile attempted to leave no room for interpretation of the co-relation between CL and data exclusivity. Provided by Industrial Property Law of Chile (Art. 91), data exclusivity will not be protected in case the pharmaceutical product is subject to CL.

#### *2.3.2.2 Thailand*

Differently from Malaysia and Indonesia’s lengthy processes for granting the compulsory license, the Thailand national laws enable its government to use compulsory license more easily and conveniently.<sup>72</sup> In 2006-2008, the Thai government granted governmental use licenses on three pharmaceutical products: Clopidogrel, Efavirenze and Lopinavir. Clopidogrel is a drug for treating heart diseases. In Thailand, many people were suffering from heart diseases and this was the reason why there was a need for compulsory license. What is different and unusual in case of Thailand is that it is one of the first countries who issued compulsory license for non-HIV medicine. Practically, the Thai Government clearly showed their policy-compulsory license could be issued for any kind of patented pharmaceutical product and not only for the ones designated to treat HIV/AIDS.

The US were not happy for Thailand issuing a number of compulsory licenses. The US threatened the Thai government to invoke trade privileges. America’s pressure on Thailand previously resulted

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<sup>72</sup> Wakely, J. The Impact Of External Factors On The Effectiveness Of Compulsory Licensing As A Means Of Increasing Access To Medicines In Developing Countries. *European Intellectual Property Review*, 2011, 33(12), pp. 756-770.

in Thailand making amendments in its patented law on governing pharmaceutical products. The US further pursued this topic with Thailand and tried to restrict and limit the grounds for granting CL with FTAs and bilateral agreements with Thailand.

According to Thailand Patent Act B.E 2522 (1979), Compulsory License can be issued in four cases:

- “non-working or inadequate working of patents to meet the local demand (section 46);
- Use for working for dependent patents (sections 47 and 47bis);
- Public non-commercial use to meet public needs (section 51);
- Public interest due to war or national emergency (section 52)”<sup>73</sup>.

As it is obvious in the first two cases, CL can be granted to private competitor while, in the last two scenarios, it issued to satisfy public interests. In case of “non-working” patents, the legislation does not define what is meant under this term, which can be abusive and give a chance to anyone to apply for compulsory license.

Thailand is a developing country that has introduced many grounds for granting compulsory license and some legal uncertainties. Their policy indeed is giving a high importance to public needs by any means.

### 2.3.2.3 *Sub-Saharan Africa*

In some cases “fear” to issue CL helped some countries to get more affordable drugs. For instance, the fact that Brazil has literally threatened to grant CL along with the possibility of non-recognition of medical patents before acceptance of TRIPS, allowed the country to issue gratis ARVs in the state.<sup>74</sup> Moreover, even Kenya enabled Cosmos Pharmaceuticals to produce drugs for West African Countries and in this way made GlaxoSmithKline to reduce medicine prices. Nonetheless, CL is a

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<sup>73</sup> King Bhumibol Adulyadej and National Parliament of Thailand, Patent Act of Thailand B.E. 2522 (1979) As Amended by the Patent Act (No. 2) B.E 2535 (1992) and the Patent Act (No. 3) B.E. 2542 (1999), 11 March 1979, TH007EN, Sec. 52.

<sup>74</sup> Adusei, P. *Patenting of Pharmaceuticals and Development in Sub-Saharan Africa: Law, Institutions, Practices, and Politics*. Springer-Verlag Berlin Heidelberg, 2013, p.143.

very sensitive subject for developing countries. Granting compulsory license shall not distress the local drug manufacturers. For instance, Canada in the 70s, 80s and 90s issued more than six hundred compulsory licenses. Grant of these only promoted fair prices and competition between the drug manufacturers as well as helped local drug producers to develop and increase their manufacturing capacity. In some sub-Saharan countries, such as Mozambique, Zimbabwe and Zambia, CL showed to be counter-productive. With the use of such licenses, their governments created some distress in novel pharmaceutical manufacturers. Some of the scholars, for example Noehrenberg, explain the reasons for this kind of failure. Countries which lack manufacturing capacity shall consider parallel imports as a measure for low priced, affordable medicines rather than CL and this was the case with Zambia and Zimbabwe. The nonexistence of production capacity in Sub Saharan Africa has mainly made the WTO project for CL useless.<sup>75</sup> Remarkably, tries by MS to use the flexibilities have failed as a consequent of administrative complications, and this resulted in the fact that solely Rwanda obtained access to the vital drugs by using compulsory license.<sup>76</sup> In contrast, South Africa made successful usage of CL with desirable outcome in accordance with *Medicines and Related Substances Control Act*<sup>77</sup>, as South Africa is a country which has enough manufacturing capacity to produce pharmaceutical products. In case of Sub Saharan African countries, CL will not guarantee a proper means of vital drugs considering their national financial and political barriers.<sup>78</sup>

There are several reasons why Sub-Saharan Africa does not benefit from flexibilities introduced by the TRIPS Agreement. The first reason would be the lack of technical/scientific know-how and skills.<sup>79</sup> Not only these countries lack technical knowledge, but also legal capabilities. Policy-definers do not have ability to construct a sufficient legal infrastructure to put into practice the flexibilities in their local laws as the result of their insufficient understanding of the methods of

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<sup>75</sup> Hardon, A. Confronting the HIV/AIDS Epidemic in sub-Saharan Africa: Policy versus Practice. *International Social Science Journal*, 2005, 57(186), pp.601-608.

<sup>76</sup> Cohen-Kohler, J., Esmail, L., Cosio, A. Canada's Implementation of the Paragraph 6 Decision: Is it sustainable Public Policy?. *Globalization and Health*, 2007, 3(1), pt. 12

<sup>77</sup> The Parliament of the Republic of South Africa, *Medicines and Related Substances Amendment Act*. No.90, 12 December 1997.

<sup>78</sup> Manu, T. N. Essential Medicines and the Complexity of Implementing Nationally Based Compulsory Licensing: On the Need for a Regional System of Compulsory Licensing in Sub-Sahara African. *European Intellectual Property Review*, 2014, 36(1), pp. 39-52.

<sup>79</sup> Avafia, T. Berger, J, Hartzenberg, T. The Ability of Select Sub-Saharan African Countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries. 2006, <http://apps.who.int/medicinedocs/documents/s18249en/s18249en.pdf>. (10.12.2015).

using these flexibilities.<sup>80</sup> Last, but not the least, the fear generated by developed nations to impose certain financial sanctions on the developing countries makes the latter reconsider this legal tool.

### 3. CL of patented pharmaceuticals Advantages and Shortcomings

To understand whether compulsory license is advantageous for the country or not, many social, political and economical aspects have to be taken into consideration coupled with the development level of the MS. Some scholars think that there are many pros for CL to which the author of this research would agree at certain extent. One of the biggest benefits from developing country perspective is the access to the highly important medicines and break monopolies. Enlargement of the market portion can be deemed abusive if it does not allow a fair competition and all the activities are reliant on the major one.<sup>81</sup> On the other hand, as discussed above, there are even high risks of reducing direct investment and in making pharmaceutical companies less likely to innovate. Besides this, when a developing country lacks manufacturing capacity, using compulsory license based on Paragraph 6 of the Doha Declaration could be counter-productive as proved in Zimbabwe example. It is also questionable how beneficial is using CL for developing countries in terms of political trade. Insufficient organization in order to obtain pharmaceutical products from developed countries along with lengthy bureaucratic processes may consequently cause denial by developing nations to use articles regarding compulsory license in the TRIPS agreement.<sup>82</sup> Practically, abuse can be made in various ways, by putting unreasonable prices or possibly other business requirements, by conducting selective trading, product tying, undercutting,<sup>83</sup> or by denying the access to crucial amenities.<sup>84-85</sup>

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<sup>80</sup> United Nations Development Programme, Human Development Report 2001 - Making New Technologies Work for Human Development, New York, Oxford University Press, 2001, Ch.5, p.107.

<sup>81</sup> Tsonchev, G. Latest Development In The Microsoft Case In The European Union: Microsoft Officially Allows Browser Choice to Customers. Columbia Journal Of European Law Online, 2010, 16, pp. 85-88; E.C.R. 1974-00223, 6 March 1974, Joined Cases 6 and 7/73, *Istituto Chemioterapico Italiano S.p.A. & Commercial Solvents Corp. v. Commission of the European Communities*.

<sup>82</sup> Souto, E. B. Patenting Nanomedicines: Legal Aspects, Intellectual Property and Grant Opportunities. Springer-Verlag Berlin Heidelberg 2012, p. 15.

<sup>83</sup> E.C.R. 2007 II-00107, 30 January 2007, Case T-340/03, *France Telecom SA v. Commission of the European Communities*.

<sup>84</sup> E.C.R. 1998 I-07791, 26 November 1998, Case C-7/97, *Oscar Bronner GmbH & Co. KG v. Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co.*

Most of the developed countries see compulsory license as the last and the most extreme resort to use. The reason is that this kind of authorization by government in practice breaches patentee's rights on their exclusive property. In short term, granting compulsory license will make essential drugs to treat epidemics available to the people in need but in the long run, local pharmaceuticals as well as pharma companies in developed countries will have a very few incentives for creating new drugs. For example the UK, one of the most economically developed countries in the world, offers voluntary licensing as the best solution and basically the substitution to CL. The author of this research would absolutely support this policy. It would be more efficient to assist countries from inside to invent and patent in pharmaceuticals than artificially imposing compulsory licenses on patented products. Issuing compulsory license definitely breaches patent holder's IPR.

Some scholars, for instance B. Lehman, believe that because of the CL the countries will look for prices which are considerably lower than those the market can offer naturally; at the same time, it will increase the financial involvement of developed country drug consumers for innovating new drugs. Many scholars are of the opinion that the Doha Ministerial Declaration coupled with the TRIPS agreement created a comfortable environment for developing countries, which makes them passive and inert to invest in creation and development of their own pharmaceutical products. The Professors Bird, Lybecker, and Fowler are concerned that, when there is the threat of CL, pharmaceutical firms may leave the current situation and find more beneficial environment for them.<sup>86</sup> For instance, firms who own the patent on the drug may call off or decrease investment in the pharmaceutical or reject to introduce or remove their goods in the country which seeks CL of the patented pharmaceutical.

According to Reichman, "Chief among the social costs warranting the concerns are: a risk of diminished direct investment in countries that resort to compulsory licensing because patent owners will seek out more business-friendly legal environments; a risk that those who obtain compulsory licenses will "shadow price" the patentees and thus generate deadweight loss of their own in pursuit

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<sup>85</sup> Tsonchev, G. (2010), *supra nota 81*.

<sup>86</sup> Reichman, J. H. (2009), *supra nota 22*.

of profits; a risk that compulsory licensing will reduce the research-driven pharmaceutical sector's incentives to innovate; and a risk that the patentees' governments will retaliate with trade sanctions that could "cripple the economy of the licensing nation".<sup>87</sup>

As underlined before, CL shall be issued only in exceptional cases. The fear of CL can encourage patent holder and patent seeker to avoid high transaction costs, as well as monopolies and other aspects which does not enable the parties to make an agreement. If a patent owner does not manage to commercialize their patented pharmaceutical after a reasonable period of time, this kind of product shall be compulsory licensed in benefit of the larger interest of society. Some scholars, for instance Neil S. Tyler, believe that patent holders who are not capable or reluctant to obtain the resources vital to introduce the medicine to market or are unsuccessful to hit upon a proper licensee shall be exposed to the market-forcing instrument of CL.<sup>88</sup> This kind of products would be marketed for more affordable prices as well. The fear of CL for non-use could possibly decrease the occurrence of patent stoppage and nonworking by influencing entities to manage disagreements and grant licenses considering their own price estimations.<sup>89</sup> Some critics consider compulsory license on patented pharmaceuticals a way to reduce the amount of inventions; while others (e.g. Neil S. Tyler) think that, as it occurs in limited cases, it will promote the company incentive to innovate. It is difficult to imagine which side of the scholars is right. Even though there have been several countries that issued CL, there are still few cases to evaluate how it reflects on the development of the pharmaceutical industry and how it exactly affects other MS of the TRIPS.

### **3.1 Granting Voluntary License**

According to the Article 31(b) and the Article 31(h) of the TRIPS agreement, in order to use compulsory license the person or company first must apply for the voluntary license to the patent owner with a sensible commercial offer and remuneration for such a license. Only after patent

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<sup>87</sup> Ibid.

<sup>88</sup> Tyler, N. (2014), *supra nota 3*.

<sup>89</sup> Ibid.

holder reject to grant voluntary license within a reasonable time period and reasonable remuneration for such a grant, person or company seeking the CL can apply for it. However, if there is a case of “national emergency”, “public non-commercial, governmental use”, “anti-competitive practises”, “other circumstances of extreme urgency”, according to the Article 31 (b) there is no need to first try to obtain voluntary license.

One of the most complicated and difficult organ to issue voluntary license under reasonable commercial terms are Universities, which in most cases are very actively involved in innovating. The reason is that they are involved in the process initially. If they deny granting CL, it might be because the rights are already granted to another company or person or it is still in progress. This is obviously one of the explanations why Institutions of higher education shall be persuaded to keep hold of humanitarian-use rights.<sup>90</sup>

### **3.2 Results of CL**

The use of compulsory license has to be the last resort to ensure public health. There are many unattractive results that it can bring to.

Firstly, the fact that CL shall be granted mainly to supply provide drugs to national markets of MS in according to the TRIPS agreement, the Article 31(f) may help creating grey markets. Such markets can be established around the state borders where countries with pricy patented pharmaceuticals import from the country with less expensive offers. Countries might have certain kind of agreements to avoid this kind of cases but there is nothing or very little can be done in regards with individuals importing the drugs. Grey markets already affect the sale of patented pharmaceuticals internationally. In 2003, WTO enabled MS to export medicines under compulsory license, but majority of the contracting parties preferred not to be part of such imports and few would do it in case of national emergency or extreme urgency.

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<sup>90</sup> Correa, C. M. Compulsory Licensing: How to Gain Access to Patented Technology. 2007, <http://www.iphandbook.org/handbook/ch03/p10/#>. (10.07.2015)

Secondly, there is a very broad and vague definition of “national emergency” and “public non-commercial use” as it was discussed in previous sections. These are terms which do not have any internationally standardized meaning and leave a wide room for interpretation of MS based on their needs. For instance, Thailand issued four compulsory licenses in 2008 justifying it as “public non-commercial use”. There can be countless reasons and cases when a country can justify its decision to grant compulsory license based on national emergency or national interest which might promote discriminative practices. Most importantly, excessive use of compulsory license may destroy the relationship between the country granting CL and patent holder’s country, which is of high importance for the country from the economic and political standpoint.

Thirdly, there are further issues that imprecise definition of terms in the TRIPS agreement causes. “Adequate remuneration” and “economic value” are again very broad terms. WTO explained that countries that are seeking the license shall offer an adequate payment and the patent holder can appeal it. The question is if the nation would assess this topic fairly and offer proper and adequate economic value to the patent holder. Theoretically, the nation in question and the patent owner shall negotiate the amount of the royalty; in reality, the owner has a very limited power to influence this kind of fee and is always in the least attractive position.

“Guidance as to the correct approach in achieving fair royalty has been given by the Court of Appeal in two cases, namely the Salbutamol case and Smith Kline & French Laboratories Ltd’s<sup>91</sup>”.<sup>92</sup>

Fourthly, compulsory license can significantly influence the innovation and investment in R&D. Many scholars think that compulsory license makes companies less motivated and eager to innovate which reflect very badly on country’s economy. Nevertheless, there have been some researches undertaken which prove the opposite.

A Deli Yang’s study of seventy companies exposed to CL demonstrates a major boost of R&D spending in contrast with companies which have never been under any effect of CL.<sup>93</sup> It can be

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<sup>91</sup> R.P.C. 203, 1990, *Smith Kline & French Laboratories Ltd's (Cimetidine) Patents*.

<sup>92</sup> Case Studies Manual, WIPO 2012, <http://www.wipo.int/edocs/lexdocs/laws/en/gb/gb322en.pdf>. (06.11.2015)

<sup>93</sup> Yang, D. Compulsory Licensing : For Better or For Worse: the Done Deal Lies in the Balance, *Journal of Intellectual Property Rights*, 2012, 17, pp. 76-81.

caused by the fact that the companies which are effected by compulsory license are stressed to carry on creating and innovating to overcome other strong market players.<sup>94</sup>

Lastly, when compulsory license is granted by the member country, the owner of the patent does not receive any royalty. This is very detrimental for the inventor, but in the long run it may promote increasing of voluntary licensing when owner receives at least a certain amount of fee for his work. On one hand, this kind of regulation helps to manufacture cheaper drugs, which is beneficial for the society. On the other hand, it treats the patent holder unfairly while leaving him unremunerated for its efforts in creating something new. This does not seem to be a fair practice that shall be embraced by the MS. This issue has to be balanced accordingly to restore fairness.

### **3.3 CL of pharmaceutical products as country's policy**

While deciding whether or not CL is the best country policy, the development level of the member state has to be taken into account. This kind of division stems from the fact that these two country groups have quite different policy objectives.

To demonstrate the difference between the policies, developing and developed country policies can be compared (Table 1)<sup>95</sup>:

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<sup>94</sup> Ibid.

<sup>95</sup> Table 1 source: Strom, B. L. *Pharmacoepidemiology*. 4<sup>th</sup> ed. John Wiley and Sons Ltd, 2005, p. 381

<b>Developing Country</b>	<b>Developed Country(example of Australia)</b>
To create essential medicines affordable for those in need	To access a sufficient variety of inexpensive medicines
To guarantee security , effectiveness and quality of drugs supplied to the public	To guarantee security , effectiveness and quality of medicines supplied to the public
To advance prescribing and handing out practices and encourage right utilization of medical products by health system employees and the public	To guarantee qualitative usage of drugs and to promote growth of a successful pharmaceutical industry

**Table 1**

The practice, has clearly demonstrated that many developed countries avoid issuing compulsory license on patented pharmaceutical products. Developed countries believe that this tool shall be used only as the last resort. There is a different approach to this subject regarding if the country in question is a developing or developed member state of the TRIPS Agreement. On one hand, in case of “national emergency” and “extreme urgency”, compulsory license can be seen as the last solution; on the other hand, such a license may expose its pharmaceutical industry to great risks and create discriminatory practices which were explained in details in previous sections. The US government established the Special 301 Annual Report where it describes developing countries usage of compulsory licenses in pharmaceutical field. The interest from US in the developing countries current CL policy is so high that they practically “watchlist”<sup>96</sup>, observe and examine the

<sup>96</sup> Maybarduk, P. US Government Special 301 “Watchlist” and Developing Country Use of Compulsory Licenses for Healthcare, 2013, <http://infojustice.org/archives/29493>. (11.11.2015)

plans of such countries. The Section 301 Watch List was accepted straight after the Uruguay Round. Sometimes the US directly criticized ongoing processes concerning CL in the developing MS.<sup>97</sup> Obviously, it is not in developed countries interest to let developing countries issue compulsory licenses frequently as it can bring many economic issues to the private companies and local markets. As the practice has shown, developed countries are opposing the CL and even monitoring developing countries plans and policies in this sense. On the other hand, throughout the past years developing countries have been using compulsory license as access to the highly important medicines more and more often. It would be very difficult to decide which country's policy is better regarding compulsory license. It largely depends if this issue is discussed from the developing or developed country's perspective. MS have different policy objectives and justifications on exceptions and limitations on CL of patented pharmaceutical products.

The countries listed below informed WIPO, through questionnaires, what exceptions their national legislations include to CL in order to grant it without patent holder's consent:

“Albania, Algeria, Argentina, Armenia, Australia, Austria, Azerbaijan, Bangladesh, Belarus, Bhutan, Bolivia, Bosnia and Herzegovina, Brazil, Bulgaria, Burkina Faso, Canada, Chile, China and Hong Kong (China), Congo, Costa Rica, Croatia, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Djibouti, Dominican Republic, El Salvador, Finland, France, Gambia, Germany, Greece, Honduras, Hungary, India, Indonesia, Israel, Italy, Japan, Jordan, Kenya, Kyrgyzstan, Latvia, Lithuania, Madagascar, Malaysia, Mauritius, Mexico, Monaco, Morocco, Netherlands, New Zealand, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Sao Tome and Principe, Saudi Arabia, Serbia, Slovakia, South Africa, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Tajikistan, Thailand, Turkey, Uganda, Ukraine, the United Kingdom, the United Republic of Tanzania, the United States of America, Viet Nam, Zambia and Zimbabwe (87 in total)”.<sup>98</sup>

MS' answers on legal policies can be categorized by different answer groups based on what the country's policy is towards CL of patented pharmaceuticals:

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<sup>97</sup> Access to Medicines in the Developing World, The Parliamentary Office of Science and Technology of UK, 2001, Number 160, <http://www.parliament.uk/documents/post/pn160.pdf>. (05.12.2015)

<sup>98</sup> WIPO (2014), *supra nota* 27.

**Balancing of patent holders and public interests:** several contracting parties, for instance Kenya and Saudi Arabia, justified the exceptions and limitations to CL by their public policy/strategy to stabilize patent holders, third parties and public interests in order “to ensure a balance between the rights of the patentee and the public interest”<sup>99</sup>.

**Avoiding abuses of rights:** another public policy objective of MS can be outcome of exclusive use of patent holders’ rights over its IP. For instance, Germany in its response to WIPO underlined that exceptions to CL could be addressed in order to protect society from exclusive use of such rights.

**Promoting the public interest:** while defining the public policy objectives according to the national laws of member nations, these countries were basically focusing on Country’s and/or society’s interest as such.

“These national legislations include terms as “public interest and interest of society”, “public interest considerations”, “urgent needs of the society”, “development of the economy and the well-being of the society”, “vital interest to the economy of the country, public health or national defence, or where non-working or insufficient working of such patents seriously compromises the country’s needs” and “situations of public interest and emergency motivated by considerations of public health, nutrition and national security”( for instance, responses from Burkina Faso, Congo, Gambia, Honduras, Hungary, Poland, the Republic of Belarus, the Russian Federation, the South Africa, Spain, the United Kingdom, Viet Nam and Zambia)”.<sup>100</sup>

To sum up, there is no unified approach towards compulsory license of patented pharmaceuticals. Some MS prefer not to use it as their state policy, for example the US: many others, especially developing MS, tend to justify granting of CL exactly by their national public policy. There is no right or wrong in this situation. This flexibility is granted to the contracting parties by law and they are free to interpret it in the most convenient way for them.

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<sup>99</sup> Ibid.

<sup>100</sup> Ibid.

#### 4. UK's perspective of CL of Patented Pharmaceuticals

For the purpose of this research, the UK is picked as a country of focus as it clearly represents developed countries regulation of CL. Even though the articles regarding CL in developed member countries may vary from state to state, one thing they have in common is the legislation which normally encourages negotiations between parties rather than CL.

The appearance of CL starts from UK's Statute of Monopolies issued in 1624, which encourage the innovation in country.<sup>101</sup> In 1883 Patent Act, the law was already familiar with CL and the grounds for issuing it, the patent could not be working in the UK. Practically, this regulation had a great impact on many other countries laws regulating CL as well as on the Paris Convention.

The Articles 48 to 54 of the UK Patents Act (1977) permit issue of compulsory licences to tackle anti-competitive utilizations.<sup>102</sup> The Section 48 allows for:

“An application for the grant of a compulsory licence,  
The endorsement of the register that licences are available as of right and  
If the applicant is a government department, for the grant of a licence under the patent to any person named in the application”.<sup>103</sup>

Any individual, company (Article 48 and Article 48 B) or WTO proprietor (article 48 A) can apply for CL after expiration of three years period or any other period given by proper legislation. The organ before which such request can be made is Comptroller. Comptroller is the member of the National Audit Office of the UK that basically deals with financial cases. Afterwards, the IPO and Comptroller will consider the request and make the decision in accordance with the Article 48 of the

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<sup>101</sup> Hilty, R. M., Liu, K. (2015), *supra nota 70*.

<sup>102</sup> Compulsory Licences, the IPO of UK, 2015, [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/404696/ipo-foi-2014-425-compulsory-licences.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404696/ipo-foi-2014-425-compulsory-licences.pdf) . (06.11.15)

<sup>103</sup> Ibid.

Act. According to the Patent Act, the applicant seeking compulsory license has to demonstrate that some important aspects on the pharmaceutical market are not met and/or the patent is available, but only under irrational conditions. He has to present actual evidences to prove that he has a legislative right to apply for such license. The case will be presented before Comptroller. The IP owner will also attend the proceedings and present his own evidences to support his position. After detailed analysis of the case and evidences presented by both parties, Comptroller makes a decision to grant or to refuse Compulsory License. There are several aspects with which Comptroller has to be satisfied to issue such license. According to the Patent Act, Article 49:

“Where the comptroller is satisfied, on an application made under section 48 above in respect of a patent, that the manufacture, use or disposal of materials not protected by the patent is unfairly prejudiced by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or the use of the patented process, he may (subject to the provisions of that section) order the grant of licences under the patent to such customers of the applicant as he thinks fit as well as to the applicant.”<sup>104</sup>

Comptroller will also take into account if the compulsory license seeker tried to negotiate the license with the patent holder, if he undertook reasonable time to obtain the license unsuccessfully, if the patent holder made a full use of its patented invention, licensee’s ability to use the CL and related risks.

One of the purposes of the Patent Act is exactly to fill in the gap and grant compulsory license where there is such a need.

According to the IPO’s statistics, after the Patent Act of the UK came into force, there was not even one application for CL in a year and there have been even less cases in UK when CL was issued.<sup>105</sup> Two of these cases are *Swansea Imports Limited v Carver Technology Limited BL*<sup>106</sup> and *Cohmor Holdings Plc v Therma-Tru Corp*<sup>107</sup>, where the IPO considered the cases, but gave negative responses. The goal of the Act is to encourage the parties to negotiate the terms and conditions of

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<sup>104</sup> Parliament of the United Kingdom, Patents Act 1977 (Chapter 37, as amended by the Tribunals, Courts and Enforcement Act 2007), 29 July 1977, Art. 49.

<sup>105</sup> IPO (2015), *supra nota* 102.

<sup>106</sup> The Patent Office, BL O/170/04, 10 June 2004, *Swansea Imports Limited v Carver Technology Limited*.

<sup>107</sup> R.P.C. 777 , 1997, *Cohmor Holdings Plc v Therma-Tru Corp*.

the license. In this sense, the law acted as discouragement for the CL seeker to get it through the IPO. The UK Government tried to minimize its engagement on this aspect to promote negotiations between the parties and fair trade. Regarding the importation and the manufacturing of pharmaceutical drugs, the case *Allen & Hanburys Ltd v Generics* has to be noted.

The ECJ held in *Allen & Hanburys Ltd v Generics*<sup>108</sup> stated that:

“a person importing from another member state should be treated the same as one manufacturing in the UK, i.e. the importation should only be banned by injunction or by the terms of a licence if such manufacture would be banned”.<sup>109</sup>

The UK’s position on the compulsory licences is very straightforward. The UK strives to avoid granting CL as much as possible. This subject matter was confirmed by IPO representatives in their interview with the author of this research.

“In terms of IP, currently the UK has the balanced approach. The balanced approach basically takes into account the UK’s commercial interests, but also balances them against the growth of the developing world. Therefore, the UK wants an International IP system that is properly designed and enforced to meet both of these objectives. In terms of advantages, the IPO believes that compulsory licenses can actually be used as a legal tool in some instances to encourage voluntary licensing. However, voluntary licensing can be beneficial for both the patent owner and the country that is issuing the compulsory licenses, as a result of more financially appealing solution for the patent owner and also for the developing country, as it can possibly get the tech transfer on the voluntary bases again.”<sup>110</sup>

Even though UK has a balanced approach, there has not been even one case when CL was issued, as confirmed by the IPO representatives.

“The UK actually never had issued compulsory license per se. The IPO believes that, if the country in question has generics industry, while issuing compulsory license the cost will be high. Accordingly to the UK legislative policy and from UK perspective, voluntary licensing is the better

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<sup>108</sup> E.C.R. 1988 -01245, 3 March 1988, *Allen & Hanburys Ltd v Generics (UK) Ltd*.

<sup>109</sup> WIPO (2012), *supra nota* 92.

<sup>110</sup> Interview with IPO (UK) representatives Mr. Rahul Raghavan, Global Policy Adviser and Patent Examiner Ms. Nicki Curtis, London, UK, January, 2015.

option than CL in terms of both-partnership and tech transfer. Also, this route allows generic version to be produced more quickly in long-run.

Another disadvantage per se that has to be taken into account is that under the Doha Declaration, the term “national emergency” is down to individual definition by country and it is up to local interpretation. This term can be interpreted in various ways. When answering the question if the CL country is best policy, manufacturing capability of the country in question has to be taken into account. Also, it has to be checked if there is a legislative need to grant compulsory license. In most of the cases generic pharmaceuticals need to be commercially viable, but commercial viability does not necessarily address public health crises. Non-exclusive voluntary licensing is the best alternative to CL as the IPO believes. Non-exclusive licensing is a key to the compulsory license problem. All in all, if the CL is more advantageous or more disadvantageous largely depends on country needs in question. The UK believes that existed “gaps” in the Doha declaration and the TRIPS agreement can be filled by international partnerships in terms of R&D, public sector initiatives and with private sector-philanthropy, for instance with DNI”.<sup>111</sup>

The UK’s policy is to avoid CL and support global development and creation of essential drugs. The IPO representative says:

“In terms of strengthening health system, the UK has lots of things to do, they work on global access to medicines, global line for vaccines and immunization, and they support patentable medicines. In the UK, there is Industry government formal access to medicines so that is where government and pharmaceutical stakeholders meet to look at access issues and discuss the best ways of addressing them. Pharmaceutical industry in terms of R&D is a very important subject for UK”.<sup>112</sup>

“For UK in developing-developed country perspective on CL of patented pharmaceuticals, the key point is that countries that have been accused of abusing the TRIPS have not been found to be in breach of the TRIPS itself. No dispute has been launched so far which would result in a judgment. From the UK’s perspective, compulsory license is the last resort in case of “national emergency”, but they do accept in some cases where it is necessary for developing LDC. The UK by itself has never issued compulsory license on pharmaceutical product. The Government has suggested that

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<sup>111</sup> Ibid.

<sup>112</sup> Ibid.

the WTO finds ways where voluntary licensing is even more extensive and efficient as a method of gaining access to essential drugs”.<sup>113</sup>

## **5. India perspective of CL of patented pharmaceuticals**

For the purpose of this study, India has been chosen as one of the focus country along with the UK. While the latter represents the developed countries perspective of CL and legal/economic policy, India represents the developing countries standpoint with relatively large manufacturing capacity on regulating CL. India has recently played a crucial role in showing current CL global practices and how to keep up with the global changes in the pharmaceutical industry. Lately, it has undoubtedly come out as the pharmaceutical supplier of the developing countries, as it exports more than sixty percent of its substantial production of generic drugs to developing MS.<sup>114</sup> What makes India so highly competitive is affordable drugs, medicine manufacturing skills, ability to make drugs with English packaging and instructions, highly qualified professionals and strong chemical industry.

According to Makhan Saikia, “historically, the Indian patent system was governed by colonial laws, particularly the Indian Patents and Designs Act of 1911 up to 1970”.<sup>115</sup> Later in 1970, the Indian Government assigned Mr. Justice Rajagopala Ayyangar the duty to explore the patent legislation and consider this to introduce the Indian Patent Act.

The Indian Patent Act included some articles to limit the power of the Act itself. These articles concerned: the expansion of the basis for granting CL, the ability to avoid research and the shortened patent term. The 1970 Patent Act increased patent renewal amount and made patent

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<sup>113</sup> The Parliamentary Office of Science and Technology of UK (2001), *supra nota* 97.

<sup>114</sup> Bazzle, T. Pharmacy of The Developing World: Reconciling Intellectual Property Rights in India With the Right to Health: TRIPS, India’s Patent System and Essential Medicines. *Georgetown Journal of International Law*, 2011, 42 (3), pp. 785-786.

<sup>115</sup> Saikia, M. Impact of the TRIPs Agreement on the Indian Pharmaceutical Industry: an Assessment from 1995 to 2011-12. *European Intellectual Property Review*, 2015, 37(8), pp. 515-522.

assessment more precise. At last, the Act barred patents in medicine, and permitted CL after three years would past from the patent issue.<sup>116</sup>

Reducing the power of the Indian Patent Act resulted in a growth of the local manufacturing abilities, especially in the pharmaceutical industry. By the old law, international companies could obtain patent protection on drugs in India, bring an action and defeat Indian based companies. The new Patent Act promoted the creation of a larger pharmaceutical sector. In practice, the Act helped newly established local companies to get in this industry and old ones to develop.

According to Sudip Chaudhuri, India holds "the capabilities to produce three-quarters of bulk drugs and nearly all of the formulations sold in India".<sup>117</sup> Current evaluations show that from 70s until 2000, the market portion of Indian pharmaceutical companies enlarged to more than sixty percent.<sup>118</sup> More essentially, several companies commenced to perfect their innovative abilities and turned into creators rather than copiers.<sup>119</sup> The legal agenda, which encouraged innovation, was abolished in 2005 after India was forced to accept the TRIPS principles.<sup>120</sup>

In 1995, India joined the WTO hoping to gain global partners and progress economically. Joining the WTO was a very solid step ahead for India, but there was a price they had to pay for it: the reception of the TRIPS Agreement. "TRIPS was the culmination of developed countries' efforts to obtain stronger IP protection abroad, especially in developing countries".<sup>121</sup> Even though the TRIPS responsibilities obviously privileged innovation-sending developed nations, developing nations like India had no other options left than assent to the conditions of the agreement, if they really desired to be member of the WTO.<sup>122</sup>

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<sup>116</sup> Odagiri, H. *et al.* Intellectual Property Rights, Development and Catch-Up: An International Comparative Study - The Accumulation of Capabilities in Indian Pharmaceuticals and Software. Oxford, Oxford University Press, 2010, p.366.

<sup>117</sup> Chaudhuri, S. The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries. Oxford, Oxford University Press, 2005.

<sup>118</sup> Bazzle, T. (2011) and Saikia, M. (2015), *supra nota 114-115*.

<sup>119</sup> Odagiri, H. *et al.* (2010), *supra nota 116*, p. 369.

<sup>120</sup> Elmahjub, E. A Case for Flexible Intellectual Property Protection in Developing Countries: Brief Lessons from History, Psychology and Economics. *European Intellectual Property Review*, 2016, 38(1), pp. 31-42.

<sup>121</sup> Liu, J. Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act. *Harvard International Law Journal*, 2015, 56 (1), pp. 207-227.

<sup>122</sup> *Ibid.*

In 2005, India made amendments to its Patent Act. The new Patent act introduced the “TRIPS flexibilities”. There were two main flexibilities established:

- CL articles, which stated that if there was a public interest patent holders on drugs might be subject to CL;
- Articles concerning anti-ever greening strategies.

The changes highlighted the reasons of these articles: the compulsory license articles were designed to guarantee public health was met and anti-evergreening articles were meant to remove useless attempts to uphold patents which are not strong.<sup>123</sup> The above named amendments to the India’s Patent Act have been further discussed in two major cases in IP: *Bayer v. Natco* and *Novartis v. Union of India*.

Many developing countries can take an example from India how to use the TRIPS Agreement and the Doha declaration for their own country’s good. The TRIPS Agreement has many flexibilities and “legal gaps” which enables the MS to interpret the provisions according to their public interests and needs. India's intention is to allow access to patented drugs for countries that joined the TRIPS agreement and are obliged to grant patents. However, the TRIPS flexibility may be controlled from time to time by international agreements or by favourable provisions introduced in the FTA made between the developing and developed MS.<sup>124</sup>

The division of Pharmaceuticals has made a "Pharma Vision 2020" strategy for turning India into the most profitable place for drug innovation and creation.<sup>125</sup> “Under this vision, the Government has proposed to provide world class infrastructure, internationally competitive scientific manpower for pharma R&D and venture funds for research in the public and private domains”.<sup>126</sup>

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<sup>123</sup> Ibid.

<sup>124</sup> Ho, C. Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights. Oxford, Oxford University Press, 2011

<sup>125</sup> Saikia, M. (2015), *supra nota 115*.

<sup>126</sup> Press Release, iPHEX 2013 to showcase on Indian pharma exports; R&D capabilities. 2012, [http://www.iphex-india.com/images/press/Pharmexcil\\_Mumbai\\_press\\_release\\_0512.pdf](http://www.iphex-india.com/images/press/Pharmexcil_Mumbai_press_release_0512.pdf) . (05.11.2015)

## 5.1 Novartis AG. v. Union of India and Others

The case was about a medical preparation of Novartis, introduced as Glivec in India.<sup>127</sup> The active chemical component of the pharmaceutical product is a molecule named beta crystal of Imatinib Mesylate.<sup>128</sup> In 1993, Novartis made an application for the patent in the US. America issued the patent after three years, in 1996.

In 1998, Novartis made a product patent request in India for Imatinib Mesylate, declaring it as a novel, beforehand unidentified and created molecule.<sup>129</sup>

The IPO about the rejected Novartis request said that the invention in question was not novel and did not demonstrate the inventive step. The IPO allowed the oppositions, rejected the application and held that it was influenced by the Article 3 (d). Nothing has been changed after Novartis appealed the decision at the IPAB (Intellectual Property Appellate Board). Even though the Board stated that the invention complied with novelty and inventive step requirement guaranteed by law, it refused the application based on the Article 3(d) of the Indian Patent Act as there was absence of “efficacy”.

Finally, the case was brought before the Supreme Court of India. The Supreme Court of India had a very important role as it was supposed to determine some aspects of patentability in connection with the Article 3 (d) which had never been done before. There was a great interest in the development of this case as there were several cases alike to the latter one pending in the Indian courts.

In 2013, the Indian Supreme Court, in different important verdict, held that the Novartis cancer medicine Gleevec did not manage to fulfil the patentability conditions in accordance with the Indian law.<sup>130</sup>

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<sup>127</sup> Kinge, P. The Supreme Court of India on the Protection of Incremental Inventions. *Journal of Intellectual Property Law & Practice*, 2013, 8 (8), pp. 581-583.

<sup>128</sup> Ibid.

<sup>129</sup> Ibid.

<sup>130</sup> Owoeye, O. (2015), *supra nota* 58.

The importance of this case is derived from the fact that the Novartis case created a case law defining novelty, inventive step and “efficacy” in accordance with the Indian Patent Act. Finally, it must be stressed that the decisions of Indian courts on cases involving the relationship between patent rights and access to medicines can influence the decisions of policy-makers in other developing countries. For instance, the recent decision on *Novartis v Union of India*, where the patenting of novel form of identified medicine was considered to be rejected under Indian Patents Act, has obviously affected nations like South Africa and Brazil that think to introduce identical articles into their national patent legislation.<sup>131</sup>

## 5.2 Bayer Corporation v. Natco Pharma Ltd

One of the most significant cases in compulsory license and voluntary license history is the *Natco vs. Bayer*<sup>132</sup> case and court decision. It was the first time India granted compulsory license to the patented pharmaceutical product.

The case developed as following: Bayer, a well known producer of innovative medicines, owned the rights to a patent of a cancer pharmaceutical called “SorafenibTosylate”, better known as “Nexavar”. Bayer filed a patent application in the US and consequently made an international filing on January 12, 2000. Natco filed the application for compulsory licence in July 2011 and months later, in March 2012, the controller held in favour of Natco by holding that:

“The reasonable requirements of the public with respect to the patented drug were not satisfied;  
the patented drug was not available at a reasonable price; and  
the invention was not worked in India”.<sup>133</sup>

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<sup>131</sup> Oke, E. K. Can importation satisfy local working requirements?. *European Intellectual Property Review*, 2015, 37(5), pp. 278-284.

<sup>132</sup> Controller of Patents, Mumbai, No 1 of 2011, 9 March 2012, *Natco Pharma Ltd. v. Bayer Corporation by the Controller of Patents*.

<sup>133</sup> Unni, V. K. (2015), *supra nota 6*.

There were no doubts about first two grounds to grant CL, the last ground though regarding non-working of protected article rouse some opposing opinions. Some scholars have expressed their negative thoughts on Controller's analysis of India's national working requirement that seems to be breaching India's duties imposed by TRIPS Agreement.<sup>134</sup> The Controller introduced very well justified reasoning for making the decision.

The Indian Patent Office issued a patent on this drug in 2008. Before applying for the compulsory license, Natco, a very strong manufacturer of drugs in India, had tried to obtain voluntary license from Bayer. Natco developed the relevant processes to produce the drug and, after receiving permission from the Drug Controller General, started producing the medicine in tablets in very large quantities.

Natco's request for a CL on Nexavar was submitted to the Controller in 2011, under the Article 84(1) of the Indian Patents Act.<sup>135</sup> In 2012, the Controller issued a compulsory license to Natco. This decision was then appealed by Bayer. The IPAB's decision was mostly the same as by Controllers.

Granting India's first ever compulsory license raise controversy between the scholars. Dr. Sharma says:

"by awarding compulsory licenses (on impulse), we are destroying this natural market equilibrium, hence, the best way in such case would be that the government chips in by providing these essential medicines at subsidized rates to people rather than destroying the market equilibrium under the guise of compulsory licensing."<sup>136</sup>

One thing is sure, this case changed not only Indian reality but played as an example for many developing countries.

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<sup>134</sup> Barsoumian, L. India's Use it or Lose it: Time to Revisit TRIPS?. The John Marshall Review of Intellectual Property Law, 2012, 11, pp. 797-814.

<sup>135</sup> Sood, M. Natco Pharma Ltd. V. Bayer Corporation and the Compulsory Licensing Regime in India. NUJS Law Review, 2013, 6 NUJS L. rev. 99, p.114.

<sup>136</sup> Kulkarni, N. Is Compulsory Licensing the Only Way to Handle the Exorbitant Prices of Patented Drugs?

BioSpectrum Explores with Experts from the Field, 2012,

[http://www.biospectrumasia.com/biospectrum/analysis/23528/compulsory-licensing-the-debate-continues/page/1?WT.rss\\_f=pharma](http://www.biospectrumasia.com/biospectrum/analysis/23528/compulsory-licensing-the-debate-continues/page/1?WT.rss_f=pharma). (11.11.2015)

This decision will definitely encourage other manufacturers to apply for the compulsory licenses. In short term, it might increase the competition on the market and make the drugs more accessible, though in long-term it may lower the motivation for seeking compulsory license as patent holder threatened by CL will be more likely to issue voluntary license. Voluntary license would improve effectiveness and shorten the time period for the development of essential drugs without governmental involvement.

Historically, India was not the first country to issue Compulsory License. Developing countries like Malaysia, Zimbabwe, Indonesia, and Thailand had issued CL before. There are still many discussions if the decision in *Natco vs Bayer* was right. Many thought that after this decision India would be involved in discriminatory practices; however, India proved this thought to be groundless by refusing twice to issue CL in 2013.

Many international companies in the pharmaceutical industry might be unhappy about India's decision on this case, as they would consider it against common practices of CL in the pharma sector. Nonetheless, India might argue that its decision is following up the best global practices on CL and keeping up with the changes. India proved that the legal flexibilities provided by the TRIPS Agreement can be successfully and efficiently used by developing nations without putting aside their own interests.

## **6. Looking to the Future**

Essential medicines can be accessed through skilled and professional staff and advanced, developed pharmaceutical industry. From the short-term perspective, it seems that the same goal can be achieved by issuing Compulsory Licenses on patented pharmaceutical products. As there are more and more patients every year, the need to essential drugs is only increasing. Courts have to take into account both aspects: affordability of the drugs and need in public, as well as Intellectual Rights Protection. Therefore, Courts have to strike a fair balance between these two. In case developing countries start to constantly use compulsory license to get the access to the drug, their domestic research centres and innovation amount will dramatically decrease. In this kind of scenario, governments of the countries will not be able to support their research centres. The duties and responsibilities to research and create generic drugs do not only lay with developed countries.

Developing countries have to also contribute towards innovating this type of pharmaceuticals. If countries will not limit the number of such licenses only to extreme necessities precisely defined by law, there will be health crises in the world and few generic medicines for patients in need.

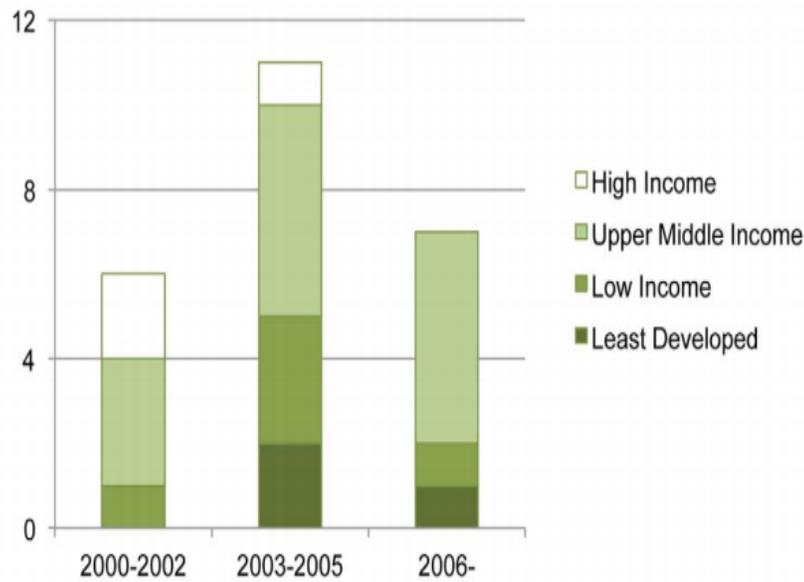
The EPO (European Patent Office) in its scenario series described how compulsory license will look like in 2025 and how the public will react on it:

“In the year 2025, patents have survived only in some traditional fields such as mechanical and chemical engineering. Most patent offices have closed or changed into so-called KAs (Knowledge Agencies), dealing with the implementation of the various innovation incentive programs and providing support for academic researchers and SMEs. How did this massive change come about? Demonstrations took place in front of patent offices all over the world with slogans like “Patents kill.” In spite of fierce protests from the pharma industry, governments reacted: first they granted compulsory licences in the interest of public health and broadened research and clinical trial exemptions. In parallel, patent grant numbers were limited to ensure that only the most ‘inventive’ ideas would receive a monopoly protection. All this led to a further shift of pharma industries’ investments away from areas crucial for public health, while other industries also responded by shifting their investments to IP-insensitive areas. The risk that they may never recoup their investment in those ‘hot’ areas was simply too big.<sup>137</sup>

The negative outcome of CL is inevitable if developing countries continue and even increase granting compulsory license on patented pharmaceutical products. If the current statistics illustrated in Figure 3 will not change, the pharmaceutical industry will face major IP related issues.

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<sup>137</sup> Trees of Knowledge Scenario: the Journey to 2025, EPO Scenarios for the Future: Green Scenario: Trees of Knowledge, EPO,  
[http://documents.epo.org/projects/babylon/eponet.nsf/0/43CF1B36AF150C63C12572CA00481837/\\$File/Scenarios\\_Trees\\_of\\_Knowledge.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/43CF1B36AF150C63C12572CA00481837/$File/Scenarios_Trees_of_Knowledge.pdf). (06.11.2015)



**Figure 2. Classification of CL episodes by time period and national income group.**  
doi:10.1371/journal.pmed.1001154.g002

Figure 3<sup>138</sup>

## 7. Recommendations and Legal Solutions

Compulsory License showed to be a good quick solution in cases of urgency for most of the developing countries to access essential medicines. Nevertheless, for some of the developing countries which lack manufacturing as Zimbabwe, it even proved to be counter-productive. Almost all the developed Member Nations reached the conclusion that compulsory license can be very disadvantageous not only for the developed country where the pharmaceutical company is

<sup>138</sup> Beall, R., Kuhn, R. (2012), *supra nota* 37.

established, but also for the developing country which is seeking such license. As compulsory license is a prompt solution in many cases, it is very tempting for developing countries to use it frequently and justify it with its extreme necessity and high public interest. However, a frequent use of this legal tool will make developing countries even more passive and less motivated to innovate. This will increase developed countries responsibilities in creating generic drugs as they will be the only ones innovating. To avoid all these inconveniences, there are several short-term and long-term solutions.

Short-term and fast solutions would be various schemes for specific medicines. Developing countries could develop a legislation which would guarantee these kinds of schemes for certain individuals who are in need. Although it cannot bring major economic benefits to the country, it will still give a relief to patients and keep the local pharmaceutical industry active.

Long-term solutions for CL would be capacity building in R&D and in producing innovative pharmaceutical products. If a country focuses only on short term goal, such as providing quick access to the essential drugs, it will never add any value to the country's development within the pharmaceutical industry. The less dependent on foreign investments a country is, the less there will be need for CL, the lower the prices will be on the locally manufactured pharmaceutical products.

Among the long-term solutions, enhancing domestic health infrastructures and its accessibility to the patients could bring a substantial benefit for a developing country. Many developing countries have very poor or no health infrastructures due to a lack of funds and social policies. Creating a good health system and improving it constantly to administer and supply drugs would be very beneficial for the country in question.

In terms of legislation, an effective strategy would be establishing novel research clusters in developing countries. With the introduction of national laws which promote creation of new research clusters, the MS will tend to avoid CL and create their own patented pharmaceuticals in the long run.

In countries where even compulsory licensed pharmaceuticals have high and inaccessible prices, a change in the taxation system could work as a positive stimulus for the R&D of the country. High-

rate taxes established by governments are often a restraint on the national R&D plans. If countries would tax the pharmaceutical industry less, it would result in increased activities in this sector.

Contracting Parties of the TRIPS may introduce detailed and specific grounds for granting CL every year. This would guarantee that member nations would not use this flexibility by the TRIPS unfairly and illegally. For example, Thailand issued CL for heart disease, which is not among the epidemics for which CL is generally issued.

Another practical solution for developed and developing countries would be introducing articles in national legislation to promote voluntary licenses. If a country promoted negotiations in order to get voluntary license, it would decrease amount of applications for CL and have positive economic impact on the local and international markets. For instance, the UK believes that the reason of a very limited amount of application for CL in the Great Britain is its domestic law, which encourages the parties to negotiate rather than use extreme measures as CL.

Lastly, introducing basic royalty amount by MS to be offered to the patent holder could be implemented as viable solution. Minimum royalty fees in some cases would guarantee the agreement between the parties on voluntary licensing and in this way CL seeker would not apply for it. Fair trade would be beneficial not only for the patent holder, but also for the compulsory license seeker and the local market.

The bottom line of IP is to promote development and progress while protected patent holders rights on its product. It is guarantee of accessibility rather than barrier. Without IP protection companies would not be motivated to invest so much resources and money in developing new drugs. Even if the main idea of Compulsory License is to make essential medicines available for patients in poor states, countries have to use it as a last resort as it may result with many negative outcomes affecting it politically and economically.

## 8. Concluding Remarks

There is no doubt that the TRIPS Agreement left some legislative gaps in the agreement, which are often referred as TRIPS “flexibilities”. The Doha Ministerial Declaration only re-affirmed those flexibilities. The legislator left that room for member nations on purpose. MS avail from interpreting the articles according to their interest of the particular case. There are several legal terms in these two documents which can be interpreted in any possible way. The most easily interpreted and flexible article of the TRIPS agreement regarding CL is the Article 31. Ambiguous terms like “adequate remuneration”, “economic value”, “national emergency”, “extreme urgency” and “public non-commercial use” give a large room for interpretation to the contracting parties. Mainly, all these flexibilities in the TRIPS and the Doha declaration are left for developing countries, which might be in a great need of this kind of flexibility. Some scholars even believe that “compulsory licensing is for developing countries”.<sup>139</sup>

To balance the member state positions, the WTO and the WHO have a central role. Even though there are very few possibilities that a perfect solution will be found, the WTO has to determine some basic aspects that concern CL. Ambiguous terms in the law might give more chances to the country seeking compulsory license to justify this need legally, but at the same time it will harm patent holders exclusive rights on its IP and make one sided convenient decision based on its own interest. Grounds based on which compulsory license is granted have to be defined more narrowly and precisely. Before applying for the compulsory license, first the voluntary license has to be discussed with the IP holder on this product. According to the TRIPS, voluntary license has to be asked under “reasonable” commercial terms. There is no exact definition what is meant under “reasonable”. More ambiguous term that the reader may encounter with is “economic value”. These terms are very broad ones and can be interpreted in many convenient ways for the compulsory license seeker. In addition, terms like “national emergency” and “public non-commercial use” still remain undefined. Thailand for example used this flexibility while granting compulsory license to pharmaceutical products which is not for HIV/AID, tuberculosis, hepatitis or any other epidemics but a heart disease.

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<sup>139</sup> Ho, C. (2011), *supra nota* 124.

As consequence of all these uncertainties, country granting compulsory license is in much more favourable position than the pharmaceutical company which holds the patent rights on their product. Therefore, a compulsory license granted unfairly based on biased interpretation from the country, can equal to the breach of patent holder's basic IPR. This will also enable countries to grant compulsory license more frequently which will cause unfair practices and, in long term, economic issues.

Actually, the TRIPS agreement and the Doha declaration give a certain kind of freedom to interpret the law to both the country and the pharmaceutical company. On one hand, MS have the power to specify their legal policy in a certain case. On another hand, companies may demand them to first negotiate for voluntary license and, in case the patent holder rejects to grant it, issue the compulsory license. The situation becomes more complicated when the company to which license is asked, is from another country. In this scenario, two countries would be in involved.

Besides all these legal uncertainties connected to the terminology used in the TRIPS agreement, another major issue in the law is that there is no precise list based on which governmental body can issue a compulsory license. The Doha declaration once and again re-confirmed member countries' right to define and decide the grounds for granting such a license independently. This kind of loose regulation on the CL grounds will inevitably create a considerable number of unfair practices.

The comparative analysis represented in the present work, clearly demonstrates that developing countries regulate and approach CL issue differently from developed countries. The reason is that MS have different legal policies based on their economic development level and pharmaceutical product manufacturing capacity. The author would even categorize the countries by developed, developing and developing countries with manufacturing capacity, as CL changes its importance and nature in each of these cases. This research illustrated these differences by giving country examples. For instance, the UK had few cases regarding CL, but they have never issued such a license. The number of applications is very small-scale in this country. As they believe, this is because UK's domestic law creates the perfect environment for the parties to negotiate the voluntary license rather than apply for compulsory license. This could be a great example how a country can encourage the parties to use voluntary license. In general, the UK seems to be very careful in determining its policy in regard to this matter. The state policy is to help MS from inside to create their own domestic pharmaceutical products rather than promote CL as the legal tool.

India, differently from the UK, issued couple of compulsory licenses on pharmaceutical products. Many experts had a fear that India would be engaged in unfair practises, but the *Bayer* case was very well argued and justified by the local judges. India would be a fine example of country's benefits after using CL fairly. Developed countries which lack manufacturing capacity would need to reconsider their country policies regarding CL as, in some sub-Saharan African countries' cases (for instance, Zimbabwe), the use of compulsory license proved to be not only ineffective, but also counterproductive.

Basically, developed countries' policy is to minimize the amount and need of CL as much as it is possible and to promote R&D and voluntary licensing. Therefore, historically there was hardly any case in which a developed country issued CL on patented pharmaceutical products. In contrast, developing countries prefer to follow a shortcut and use compulsory license to access essential medicines. The statistics clearly show that all the countries that have used CL as legal instrument are developing countries and include: Zimbabwe (2003), Zambia (2004), Thailand (2006 and 2007), Brazil (2007) and Indonesia (several times in past decade).

It is obvious that developed countries try to avoid using CL at their best. What is the reason for it? Why is CL considered as the least attractive way to solve the issue? There have been many debates on this topic. Obviously, developed countries believe compulsory license is disadvantageous and ineffective way of addressing the issues; this is why they refrain from using it. On the other hand, there are several cases where developing countries issued compulsory license on pharmaceuticals. Objectively, the key point is if CL is more advantageous or disadvantageous for the MS. In the present research it has been analysed in detail what downsides and upsides CL bring. To summarize, compulsory license may cause several problems.

In long-term, compulsory license can make local R&D very passive and decrease the interest of the domestic pharmaceutical companies to innovate. This will have a negative effect on the country in question, economically and politically.

Compulsory License used by the developing country might bring negative results and be counter-productive for those countries which lack manufacturing capacity. For example, Zimbabwe used CL to access essential drugs, but as they lack manufacturing capacity they made no use of such a license.

Compulsory License is ineffective also for those developing countries which have a great manufacturing capacity, but lack expertise and skills to produce licensed drugs. Perfect example of this would be Russia. The Russian Federation has great manufacturing abilities, but they lack human and technological resources to produce highly complex drugs. A poor health system and health infrastructures, the inability to produce high quality, safe drugs, the lack of human and technological recourses would make CL ineffective to create and supply licensed pharmaceutical products.

One of the main objectives of compulsory license is to guarantee lower, accessible prices for the essential medicines. However, CL cannot lower the price of the patented pharmaceutical in all the individual cases. In certain situations, the price will remain as high as it was before licensing mainly due to the taxes on medicines that are applied in the country.

The Article 31 may promote creation of so called “grey markets”. Countries or companies may be tempted to import cheaper drugs that are sold on their local markets from the neighbouring countries. Grey markets will affect the prices of the pharmaceuticals on international level and bring many negative economical results.

Compulsory license will affect foreign direct investments and make pharmaceutical companies less motivated to invest in the country seeking compulsory license. In addition, it will oblige developing countries to sign FTAs with developed countries, which in most of the cases is only beneficial for the developed member state.

In long term, an excessive use of CL will harm pharmaceutical industry and IPR at large. Nowadays, absolute majority of the pharmaceutical companies which innovate and create new drugs are based in developed countries. This is because, the medicine creation process is connected to very big amount of financial capitals. Pharmaceutical companies in developing countries have very little or no material assistance from developing countries to create such drugs. If developing countries use CL excessively, pharmaceutical companies established in developed countries will have no stimulus to invest so much money, human resources and time to create a drug. This will obviously negatively reflect on the pharmaceutical industry. All the MS of the WTO shall try to innovate and this responsibility shall not fall only on developed countries. Companies continue to innovate because their IPR are respected. If governments continue to intervene and abolish their basis IPR, pharmaceutical companies will not have any motivation to continue innovating.

Obviously, CL is not only entirely a disadvantageous legal tool. If it was the case, not so many developing countries would apply for it. The advantages that compulsory license under the Article 31 of the TRIPS Agreement proved to bring are numerous.

Firstly, an immediate access to essential drugs in times of epidemics or other cases of extreme urgency. Many countries, including Thailand, Indonesia and Brazil benefited from the Article 31 of the TRIPS agreement and the Doha Declaration when they had a high public interest and needed to obtain CL on certain essential patented pharmaceutical products. Even though the author of this work would recommend avoiding CL as much as possible while improving and enabling the developing countries from inside to create, develop and manufacture their own drugs, in short-term, compulsory license is still the best choice for countries in emergency cases to address major health issues promptly.

Secondly, CL can decrease and lowered drug prices in several country cases. The main idea of compulsory license is to lower the high prices of medicines produced by pharmaceutical companies established in developed countries. In majority of the cases, this idea has worked and decreased the price of the essential drugs. However, not always CL can guarantee this kind of decrease.

Lastly, CL will give motivation to pharmaceutical companies to innovate in the long run. There are experts who believe that compulsory license will motivate companies to innovate even more instead of decreasing incentive to innovation. The reason would be that they would be more enthusiastic to negotiate to obtain voluntary license and to be more competitive on the market. The author of this research would still share the opinion of those who think it will decrease incentive of domestic pharmaceutical companies as well as reduce direct investment.

The author of this work, analysed on developing/developed country comparative basis the advantages and shortcomings of CL, explained the existence of legislative gaps and flexibilities established by the TRIPS agreement and then reconfirmed by the Doha declaration, demonstrated that compulsory license subject is not unified and this legislative tool is used differently based on the development level of the country in question. The UK example illustrated and represented developed countries' camp in this regard and its policy, while India showed developing nations standpoint. India's example also served the reason to show that even within the developing nations, there are various state policies concerning CL, especially in regards with the manufacturing capacity

of the member state. The author also analysed possible results that excessive usage of compulsory license can bring and offered some solutions which can be introduced by MS in order to avoid negative effects on country's economy and IPR in general.

To summarize, the TRIPS agreement and the Doha declaration left some flexibilities and legal gaps for countries to interpret CL based on their national interests. Even though compulsory license guarantees immediate access to the essential drugs, in long term it will bring many negative results including: reduced incentive for innovating, decreased direct investment, breach of basic IPR, economic disadvantages nationally and internationally, create grey markets, and work as counter-productive for countries which lack manufacturing capacity. However, there are some legal solutions which can be implemented to resolve CL issue including: implementing CL in the most effective way, defining the grounds for granting CL by member nations by their national laws precisely, establish basic royalty fee, promote with national laws voluntary licensing, give some tax stimulus, create research clusters and coverage schemes. As for the current moment, compulsory license is the speediest solution in urgent cases for developing countries, this mechanism shall continue to exist though meanwhile developing countries have to start to promote Science, R&D in their own countries to contribute to the general benefit of all and create drugs affordable for every patient in developed and developing worlds.

## KOKKUVÕTE

Tänapäeval tõstatab paljusid arutelusid patenteeritud ravimite sundlitsenseerimine. Legislatiivsed lüngad intellektuaalomandi õiguste kaubandusaspektide lepingus (TRIPS-lepingus) ja Doha ministrite deklaratsioonis (Doha deklaratsioonis), mis on kaks kõige olulisemat sundlitsenseerimist reguleerivat dokumenti, jätavad liikmesriikidele suure tõlgendamisruumi, mis võib viia ebaõiglaste praktikateni. TRIPS-leping ja Doha deklaratsioon on paindlikud ning mõningate juriidiliste lünkadega selleks, et liikmesriigid saaksid tõlgendada sundlitsenseerimist lähtudes oma rahvuslikest huvidest, mis omakorda võib kergesti viia liigse sundlitsentsi kasutamiseni. Kuigi sundlitsenseerimine tagab vahetu juurdepääsu hädavajalikele ravimitele siis pikemas perspektiivis toob see kaasa palju negatiivseid tagajärgi, sealhulgas: vähenenud ajendid innovatsiooniks, vähenenud otseinvesteeringud, põhiliste intellektuaalomandi õiguste rikkumised, siseriiklikud ja rahvusvahelised majanduslikud halvemad olukorrad, poollegaalsete turgude loomised, ning kahjulik mõju nendes riikides, kus puudub tootmisvõimsus. Siiski esinevad ka legaalsed viisid, mida saab rakendada selleks, et lahendada sundlitsenseerimise probleeme, sealhulgas: sundlitsentsi rakendamine kõige efektiivsemal viisil, määratleda liikmesriikide siseriiklikes õigusaktides täpselt ära sundlitsentsi saamise alused, kehtestada litsentsitasud, edendada vabatahtlikku litsentseerimist läbi siseriikliku õiguse, välja töötada maksu soodustused stiimuliteks, luua teadusuuringute klastrid ning katvusskeemid. Käesoleval ajal sundlitsenseerimine on arengumaadele kiireim lahendus kiireloomulistel juhtudel; selline mehhanism jätkub eksisteerimast kuid samaaegselt peavad arengumaad edendama teadus- ja arendustegevust, viima sisse siseriiklikusse õigusesse üheselt mõistetavad sätted ja panustama üldisesse hüvanguusse luues taskukohaseid ravimeid igale patsiendile.

## **APPENDIX**

Questions asked during the interview with Mr. Rahul Raghavan, Global Policy Adviser, UK's IPO and Patent Examiner Ms. Nicki Curtis in London, UK, January, 2015.

1. What are the advantages of Compulsory Licensing of Patented Pharmaceutical Products?
2. What are the disadvantages of CL?
3. Are there more advantages or shortcoming from CL?
4. Is Compulsory Licensing of patented pharmaceuticals country's best policy?
5. What are the legal solutions and alternatives to the CL of pharmaceutical products from TRIPS agreement and Doha Declaration standpoint?
6. CL of patented pharmaceuticals for developing and developed countries.
7. What is the UK's practice and legal policy regarding Compulsory Licensing of pharmaceutical products?

### **Answers:**

In terms of IP, currently the UK has the balanced approach. The balanced approach basically takes into account the UK's commercial interests, but also balances them against the growth of the developing world. Therefore, the UK wants an International IP system that is property designed and enforced to meet both of these objectives. In terms of advantages, the IPO believes that compulsory licenses can actually be used as a legal tool in some instances to encourage voluntary licensing. However, voluntary licensing can be beneficial for both the patent owner and the country that is issuing the compulsory licenses, as a result of more financially appealing solution for the patent owner and also for the developing country, as it can possibly get the tech transfer on the voluntary bases again.

The UK actually never had issued compulsory license per se. The IPO believes that, if the country in question has generics industry, while issuing compulsory license the cost will be high. Accordingly to the UK legislative policy and from UK perspective, voluntary licensing is the better option than CL in terms of both-partnership and tech transfer. Also, this route allows generic version to be produced more quickly in long-run.

Another disadvantage per se that has to be taken into account is that under the Doha Declaration, the term “national emergency” is down to individual definition by country and it is up to local interpretation. This term can be interpreted in various ways. When answering the question if the CL country is the best policy, manufacturing capability of the country in question has to be taken into account. Also, it has to be checked if there is a legislative need to grant compulsory license. In most of the cases generic pharmaceuticals need to be commercially viable, but commercial viability does not necessarily address public health crises. Non-exclusive voluntary licensing is the best alternative to CL as the IPO believes. Non-exclusive licensing is a key to the compulsory license problem. All in all, if the CL is more advantageous or more disadvantageous largely depends on country needs in question. The UK believes that existed “gaps” in the Doha declaration and the TRIPS agreement can be filled by international partnerships in terms of R&D, public sector initiatives and with private sector-philanthropy, for instance with DNI.

In terms of strengthening health system, the UK has lots of things to do, we work on global access to medicines, global line for vaccines and immunization, and they support patentable medicines. In the UK, there is Industry government formal access to medicines so that is where government and pharmaceutical stakeholders meet to look at access issues and discuss the best ways of addressing them. Pharmaceutical industry in terms of R&D is a very important subject for UK.

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