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[2020] Vol. 9, Issue 2 NTUT J. of Intell. Prop. L. & Mgmt

EDITORIAL TEAM

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EDITORIAL NOTE ON THE VOLUME 9, ISSUE 1, 2020

Editorial Note

Dr. Christy, Yachi Chiang

Associate Professor,

Graduate Institute of Intellectual Property,

National Taipei University of Technology (Taiwan).

Being the Executive Editor of this issue, firstly I would like to express my gratitude towards all authors who have helped the readers navigate the most frontier issues within the scope of this journal. I would also want to extend my gratitude towards reviewers who have helped to maintain the academic quality of this journal.

As self-explained in the title of this journal, it is aimed at establishing a rigorous and meaningful dialogue between IP laws and IP management issues at regional and international level. We hope that our readers will be pleased and benefit from the publication of this issue.

Executive Editor

Dr. Christy, Yachi Chiang

Associate Professor

Graduate Institute of Intellectual Property

National Taipei University of Technology (Taiwan)

CALL FOR PAPERS

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LIBRARY citation databases, and it welcomes contributions to address IP topics at national, regional and international level.

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3. A regular manuscript has to include an abstract of at most 300 words and at most five keywords.

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Correlation between National Digital Competitiveness and Country's World Place as a Patent Application Activity in Top Fields of Innovations for 2018 Year

Maria Markova *
Professor, Doctor of Economy
University of national and world economy /UNWE/, Sofia, Bulgaria

Abstract

This article is aimed to present the author's point of view for the 4-th industrial revolution, main characteristics of the most intensive fields of the innovations for the latest 5 years; the intellectual property rights in the top fields and the conclusions of the analysis of the IPR rights in these fields for 2018 year and relations to the national digital competitiveness.

The author's thesis is that there is a correlation between the national digital competitiveness and the patent application from the country for technological innovations as a world place. This correlation is proved by a research of patent application activity in the top 3 innovation fields for 2018 by countries and the place in the scale of the national digital competitiveness of the top 15 countries. The focus of this paper is to present the correlation between the national digital competitiveness and the patent application from the country for technological innovations as a world place.

In the complex methodological framework is included the conventional innovation theory, intellectual property rights (IP) and the management theory of competitiveness.

This article follows the structure: (1) Introduction. (2) Defining the top 3 fields of the 4 IR, main characteristics and main results of the analysis of the patent applications as IPR in the 3 top fields of the 4 IR. (3) The national digital competitiveness as a brief concept and the IMD report for it for 2018. (4) Conclusions.

Keywords: 4-th industrial revolution, digital competitiveness, intellectual property rights, intellectual property research

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I. Introduction

The most known identified several universal technological revolutions which occurred during the human history are the following[1]:

- Agricultural revolution (1600–1740);
- Industrial revolution (1780–1840);
- Technical revolution called Second Industrial Revolution (1870–1920);
- Scientific-technical revolution (1940–1970);
- Information and telecommunications revolution, also known as the Digital Revolution or Third Industrial Revolution (1975–present).

A **technological revolution** is a period in which one or more technologies replaced by another technology in a short amount of time. It is an era of accelerated technological progress characterized by new innovations whose rapid application and diffusion cause an abrupt change in society. The technological revolution increases productivity and efficiency. [2] It may involve material or ideological changes caused by the introduction of a device or system with an impact is business management, education, social interactions, finance and research methodology.

From the Watt steam engine in 1709 through Industrial revolution in Great Britain the PC was an invention that dramatically changed professional and personal life of the people in 20 and 21 century. The 3 IR includes a development in technologies that combines hardware, software, and biology and emphasizes advances in communication and connectivity. In emerging technologies in fields such as robotics, artificial intelligence, nanotechnology, quantum computing, biotechnology, the Internet of Things, etc. Digital transmission as a part of telecommunications and electrical engineering, computer science or computer engineering, computer networking and inter-process communication.[3]

The phrase '**Fourth Industrial Revolution**' was first introduced by Klaus Schwab, the executive chairman of the World Economic Forum, in a 2015 in Davos-Klosters, Switzerland. The 4th industrial revolution (4 IR) as a period of the last

[1] There are many discussions on this chronology as terms, periods and their content considering the human history. The author of this article accept s this as an optional and not as a focus of this research.
[2] Maria Markova, *Company competitiveness through intellectual property*, 27(5) IKON. IZSLED. 35, 35-55 (2018).
[3] Wikipedia, https://en.wikipedia.org/wiki/Data_transmission.

5 years is a period of new technological achievements based on the digital technology and transformation. This new field of the human creativity is a field of new impressive and useful products and methods in a production and everyday life of the people and it is field of obtaining intellectual property rights mostly through as a patent applications.

The intellectual property rights (IPR)[4] in the newest achievements in the top innovation fields of the 4th industrial revolution are based on the digital information and communication technology.

Considering the latest written statements of the researchers of emerging technologies, the annual reports of EPO and WIPO and their analyses the new trends of 4 IR the most intensive fields of 4 IR for the last 10 years are the following: robotics, artificial intelligence, nanotechnology, quantum computing, biotechnology, the Internet of Things, the Industrial Internet of Things (IIoT), decentralized consensus, fifth-generation wireless technologies (5G), 3D printing and fully autonomous vehicles. [5] Considering the relevant publications the most intensive IP fields of the innovations for the latest 5 years are the following subfields: artificial intelligence (AI), self-driving vehicle and block chain.[6]

The national digital competitiveness is presented as a brief author's view/concept and the world rank place of countries is cited directly by the IMD record for 2018.[7]

The annually published statistics and report of the European patent office[8] shows that the European patent applications related to smart connected objects are achieving a growth rate of 54% in the last three years and reveals[9] that the patent information tools the EPO identified over 48 000 patent applications filed until the end of 2016 and relating to three relevant technology sectors of 4 IR: Firstly the core technologies in the ICT field that make it possible to create connected objects; secondly, the enabling technologies that complement core technologies, such as Artificial intelligence (AI) and User interfaces; and thirdly, application domains of these technologies, such as

[4] IPR for the innovations as a general are the following: patent for inventions, utility models, topology of the integrated circuits, according to the Paris convention for the protection of industrial property. For more information: https://www.wipo.int/portal/en/index.html

[5] Wikipedia, https://en.wikipedia.org/wiki/Industry_4.0

[6] European Patent Office, www.epo.org. ; CORNELL UNIVERSITY, INSEAD, & WORLD INTELLECTUAl PROPERTY ORGANIZATION, GLOBAL INNOVATION INDEX 2018: ENERGIZING THE WORLD WITH INNOVATION (2018).

[7] The quoted IMD record is based on the business statistics and is acceptable for business analysis and used by business schools. For more information: https://www.imd.org/wcc/world-competitiveness-center-rankings/world-competitiveness-ranking-2018/

[8] YANN MÉNIÈRE, ILJA RUDYK, & JAVIER VALDÉS, PATENTS AND THE FOURTH INDUSTRIAL REVOLUTION: THE INVENTIONS BEHIND DIGITAL TRANSFORMATION (2017).

[9] European Patent Office, www.epo.org/about-us/annual-reports-statistics/statistics.html.

Vehicles, Enterprise and Home. Looking at all European patent applications related to smart objects up to 2016, the study finds that numbers began to rise steeply in the mid-1990s in all three 4 IR sectors. More than 5 000 patent applications for inventions relating to autonomous objects were filed at the EPO in 2016 alone and in the last three years, the rate of growth for 4 IR patent applications was 54%. The majority of the inventions filed concern new applications domains (e.g. Personal, Enterprise, Vehicles) and inventions related to core technologies (Connectivity, Hardware and Software). However, the fastest growth rates are observed in enabling technologies such as 3D systems, Artificial intelligence or Power supply.

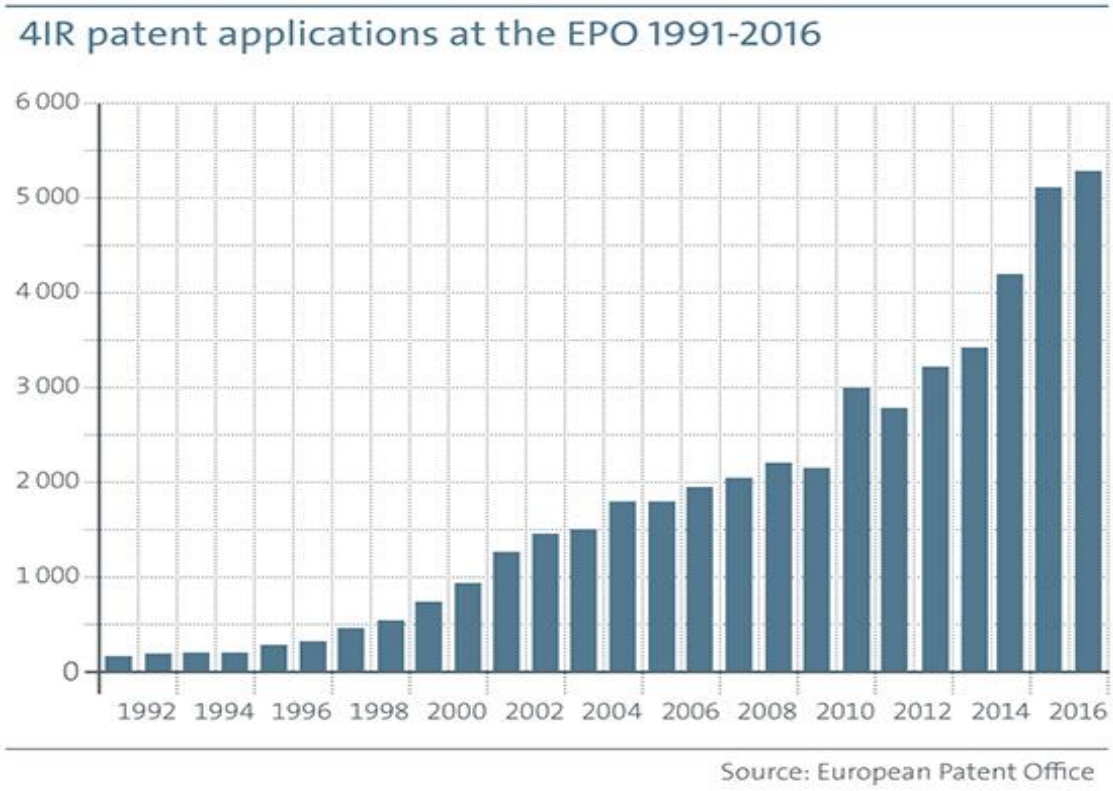


Figure 1:
4 IR patent applications at the EPO 1991-2016
Source: European Patent Office

Europe, the USA and Japan are the established leaders.

The leading patent applicants involved in 4 IR and the regions of origin of the patent applications for 4 IR inventions filed with the EPO. It highlights that in 2016, Europe, the USA and Japan were the main innovation centers. However, the findings also demonstrate that inventions coming from the Republic of Korea and the People's Republic of China have been increasing at a faster rate in recent years. 4 IR patent applications from these two countries are highly concentrated among a few large ICT companies.

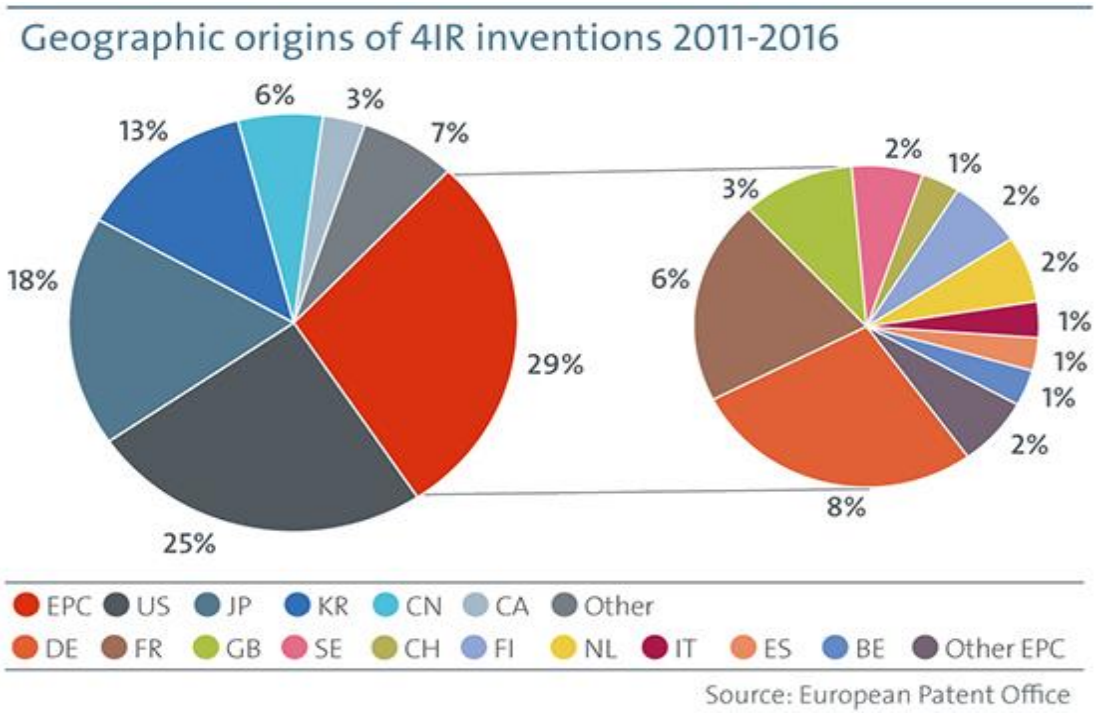


Figure 2:
Geographic origins of 4 IR inventions 2011-2016
Source: European Patent Office

In Europe, Germany and France are foremost in 4 IR innovation. Germany stands out in the application domains of Vehicles, Infrastructure and Manufacturing, while France leads in enabling technologies such as Artificial intelligence, Security, User interfaces and 3D systems. In terms of regions, the greater Paris area (Île-de-France) and the greater Munich area are the leading European locations in 4 IR technologies. A further finding is that 25 companies, most of them located in Asia, accounted for about half of all 4 IR patent applications filed with the EPO between 2011 and 2016. The study shows that innovation in core technologies is mainly led by a limited number of large companies focused on information and communication technology (ICT), while inventions in enabling technologies and application domains are less concentrated, and the top applicants in these sectors originate from a larger variety of industries[10].

[10] The Infographics and these conclusions in Introduction are made in the quoted before sources, published on www.epo.org.

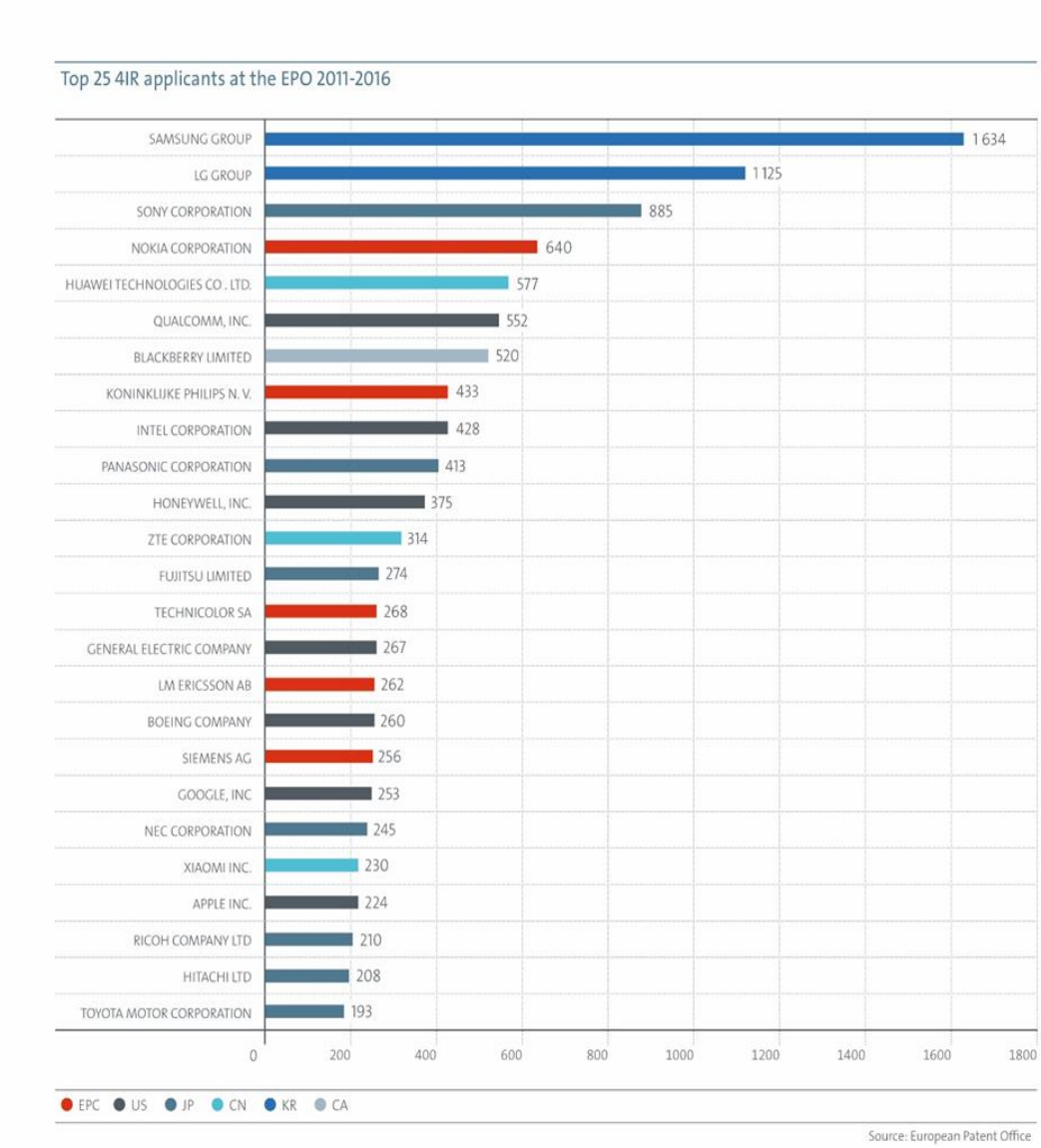


Figure 3:
Top 25 4 IR applicants at the EPO 2011-2016
Source: European Patent Office

Following the 2017 and 2018 reports on patents and 4 IR, the EP Office has identified the most intensive and important patent trends in digital technology: patents in self-driving vehicles (SDVs)[11], AI[12] and block chain[13] technology with many areas of spreading and increase of the economic reflection to users, industry and trade.

[11] EUROPEAN PATENT OFFICE, PATENTS AND SELF-DRIVING VEHICLES: THE INVENTIONS BEHIND AUTOMATED DRIVING (2018).
[12] European Patent Office, *EPO hosts first conference on patenting Artificial Intelligence*, EPO (May 30, 2018), https://www.epo.org/news-events/news/2018/20180530.html.
[13] European Patent Office, *EPO holds first major conference on blockchain*, EPO (Dec. 5, 2018), https://www.epo.org/news-events/news/2018/20181205.html.

The SDVs study [14] showed that both the automotive and ICT sectors are undergoing significant transformations. Investment in R&D for SDVs has been substantial and resulted in a steep growth in patent applications. Between 2011 and 2018, patent applications related to SDV technologies outstripped the baseline rate of growth across all technologies twenty-fold: Compared to 16% for all technologies, the EPO noted a 334% increase for SDVs for the same period.

AI and block chain are being applied to an ever-increasing variety of technical fields, leading to new inventions susceptible of obtaining patent protection. The EPO is providing a platform for discussion and clarifying our approach to examining related patent applications[15] by outlining the patentability requirements in the field.

The EPO's publications on AI revealed the unparalleled growth in the number of AI inventions: Nearly 6 000 patent applications were filed at the EPO between 2011 and 2016. A similar trend was reported for inventions on block chain. There are now some 4 000 patent families related to this field, with the majority of them having been filed since 2015.

As 4 IR unfolds, ICT industries will continue to be among the most R&D-intensive sectors. The role of patents in the promotion of these technologies is evident as they secure the investment needed for advances in this field. Using the stakeholder feedback obtained in 2018, we will continue to further adapt our practice to the needs of the users in order to effectively support the development of ICT industries.

Considering the latest achievements in the technological development as innovation fields and as a patent activity the focus of the forthcoming analysis is the subfields of artificial intelligence (AI), self-driving vehicles (SDV) and block chain technologies (BCH)

This research is focused on the mentioned 3 new and highly fast raised subfields of the digital communication/transformation: AI (artificial intelligence), SDV (self-driving vehicle), and BCH (block chain). The choice is based on the last statistics of the patent activity in the digital communication.

Each of the sub field is presented as a brief description, trends in patent activity with the whole number and the most active countries in the patent activity in these 3 top fields of the 4 IR.

---

[14] European Patent Office, *Sharp rise in patent applications for self-driving vehicles in Europe, new study finds*, EPO (Nov.6, 2018), https://www.epo.org/news-events/news/2018/20181106.html.

[15] European Patent Office, *Guidelines for Examination*, EPO, https://www.epo.org/law-practice/legal-texts/html/guidelines/e/j.htm.

II. Defining the top 3 fields of the 4 IR, main characteristics and main results of the analysis of the patent applications as IPR in the 3 top fields of the 4 IR

A. Artificial intelligence (AI)

A**rtificial intelligence** [16] , sometimes called **machine intelligence**, is intelligence demonstrated by machines, in contrast to the **natural intelligence** displayed by humans.

Colloquially, the term "artificial intelligence" is often used to describe machines with “cognitive" functions that humans associate with the human mind, such as "learning" and "problem solving".

Artificial intelligence was founded as an academic discipline in 1956, followed by new approaches, success and renewed funding and the sub-fields such as "robotics" or "machine learning".

In the twenty-first century, AI techniques have experienced a resurgence following concurrent advances in computer power, large amounts of data, and theoretical understanding; and AI techniques have become an essential part of the technology industry, helping to solve many challenging problems in computer science, software engineering and operations research

The field of AI research was born at a workshop at Dartmouth College in 1956.

In the early 1980s, AI research was revived by the commercial success of expert systems and forms of AI program that simulated the knowledge and analytical skills of human experts.

By 1985, the market for AI had reached over a billion dollars.

In the late 1990s and early 21st century, AI began to be used for logistics, data mining, medical diagnosis and other areas, statistics, economics, etc.

According to Bloomberg's Jack Clark, 2015 was a landmark year for artificial intelligence, with the number of software projects that use AI Google increased from a "sporadic usage" in 2012 to more than 2,700 projects. In a 2017 survey, one in five companies reported they had "incorporated AI in some offerings or processes. Around 2016, China greatly accelerated its government funding; given its large supply of data and its rapidly increasing research in AI field.

To the end of July, 2019, the system of patent search worldwide Espacenet[17] shows 4116 patent application and issued patent for AI.

The first application for AI was dated of 1996 year.

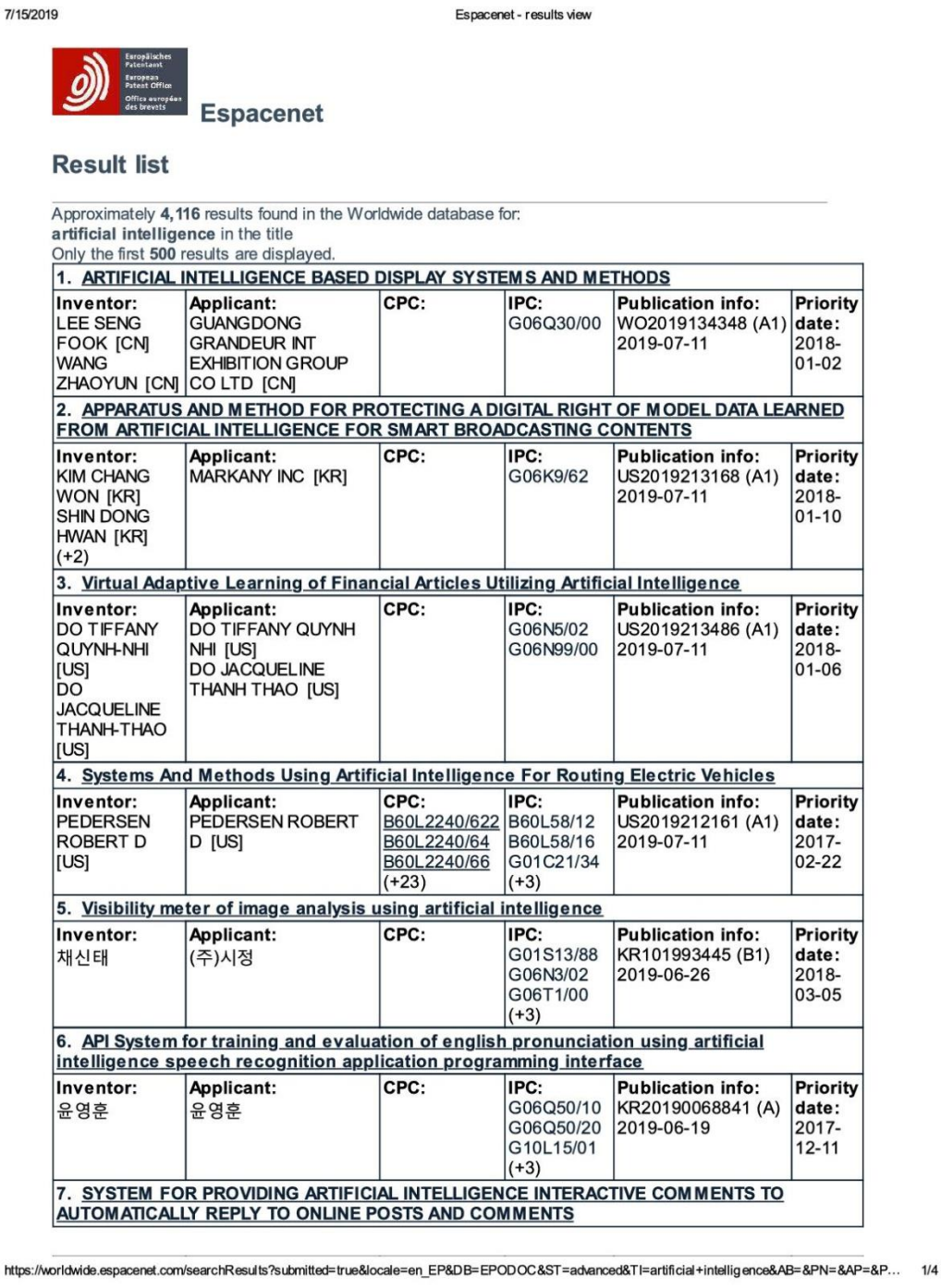
[16] AI, SDV and BCH are described following the most common source: www.en.wikipeida.org.

[17] European Patent Office, www.epo.org/espacenet. The European Patent Office offers Espacenet as a free tool for free access to over 110 million patent documents for beginners and experts to perform patent searches for inventions and technical decisions from all over the world.

Table 1: The number of application for AI per year.

Year	Number of patent appl.
1980	0
1996-1999	5-24
2000	55
2001-2009	Between 22-43
2010	43
2013	90
2014	114
2015	200
2016	629
2017	1389
2018	1272

The last not least applications shown on the epo.org site are the following:



7/15/2019 Espacenet - results view

Espacenet

Result list

Approximately **4,116** results found in the Worldwide database for:
artificial intelligence in the title
Only the first **500** results are displayed.

1. ARTIFICIAL INTELLIGENCE BASED DISPLAY SYSTEMS AND METHODS					
Inventor: LEE SENG FOOK [CN] WANG ZHAOYUN [CN]	**Applicant:** GUANGDONG GRANDEUR INT EXHIBITION GROUP CO LTD [CN]	**CPC:**	**IPC:** G06Q30/00	**Publication info:** WO2019134348 (A1) 2019-07-11	**Priority date:** 2018-01-02
2. APPARATUS AND METHOD FOR PROTECTING A DIGITAL RIGHT OF MODEL DATA LEARNED FROM ARTIFICIAL INTELLIGENCE FOR SMART BROADCASTING CONTENTS					
Inventor: KIM CHANG WON [KR] SHIN DONG HWAN [KR] (+2)	**Applicant:** MARKANY INC [KR]	**CPC:**	**IPC:** G06K9/62	**Publication info:** US2019213168 (A1) 2019-07-11	**Priority date:** 2018-01-10
3. Virtual Adaptive Learning of Financial Articles Utilizing Artificial Intelligence					
Inventor: DO TIFFANY QUYNH-NHI [US] DO JACQUELINE THANH-THAO [US]	**Applicant:** DO TIFFANY QUYNH NHI [US] DO JACQUELINE THANH THAO [US]	**CPC:**	**IPC:** G06N5/02 G06N99/00	**Publication info:** US2019213486 (A1) 2019-07-11	**Priority date:** 2018-01-06
4. Systems And Methods Using Artificial Intelligence For Routing Electric Vehicles					
Inventor: PEDERSEN ROBERT D [US]	**Applicant:** PEDERSEN ROBERT D [US]	**CPC:** B60L2240/622 B60L2240/64 B60L2240/66 (+23)	**IPC:** B60L58/12 B60L58/16 G01C21/34 (+3)	**Publication info:** US2019212161 (A1) 2019-07-11	**Priority date:** 2017-02-22
5. Visibility meter of image analysis using artificial intelligence					
Inventor: 채신태	**Applicant:** (주)시정	**CPC:**	**IPC:** G01S13/88 G06N3/02 G06T1/00 (+3)	**Publication info:** KR101993445 (B1) 2019-06-26	**Priority date:** 2018-03-05
6. API System for training and evaluation of english pronunciation using artificial intelligence speech recognition application programming interface					
Inventor: 윤영훈	**Applicant:** 윤영훈	**CPC:**	**IPC:** G06Q50/10 G06Q50/20 G10L15/01 (+3)	**Publication info:** KR20190068841 (A) 2019-06-19	**Priority date:** 2017-12-11
7. SYSTEM FOR PROVIDING ARTIFICIAL INTELLIGENCE INTERACTIVE COMMENTS TO AUTOMATICALLY REPLY TO ONLINE POSTS AND COMMENTS					

https://worldwide.espacenet.com/searchResults?submitted=true&locale=en_EP&DB=EPODOC&ST=advanced&TI=artificial+intelligence&AB=&PN=&AP=&P... 1/4

Figure 4:
Information of application for AI
Source: Espacenet

Most of the applicants are from the following countries: Korea and USA.

B. Self - driving vehicle (SDV)

A **self-driving car**[18] is a vehicle that is capable of sensing its environment and moving with little or no human influence. They combine a variety of sensors as radar, sonar, GPS, other inertial measurement units. Advanced control systems interpret sensory information to identify appropriate navigation paths, as well as obstacles and relevant signage.

Experiments have been begun in the 1950s. The first semi-automated car was developed in 1977, by Japan's Tsukuba Mechanical Engineering Laboratory, which required specially marked streets that were interpreted by two cameras on the vehicle and an analog computer. The vehicle reached speeds up to 30 kilometers per hour.

A major milestone was achieved in 1995, with CMU's NavLab 5 completing the first autonomous coast-to-coast drive of the United States. In 2005, automated vehicle research in the U.S. was primarily funded by DARPA, the US Army, and the U.S. Navy.

To the end of July, 2019 the system of patent search worldwide Espacenet shows 335 patent application and issued patent for self-driving vehicle.

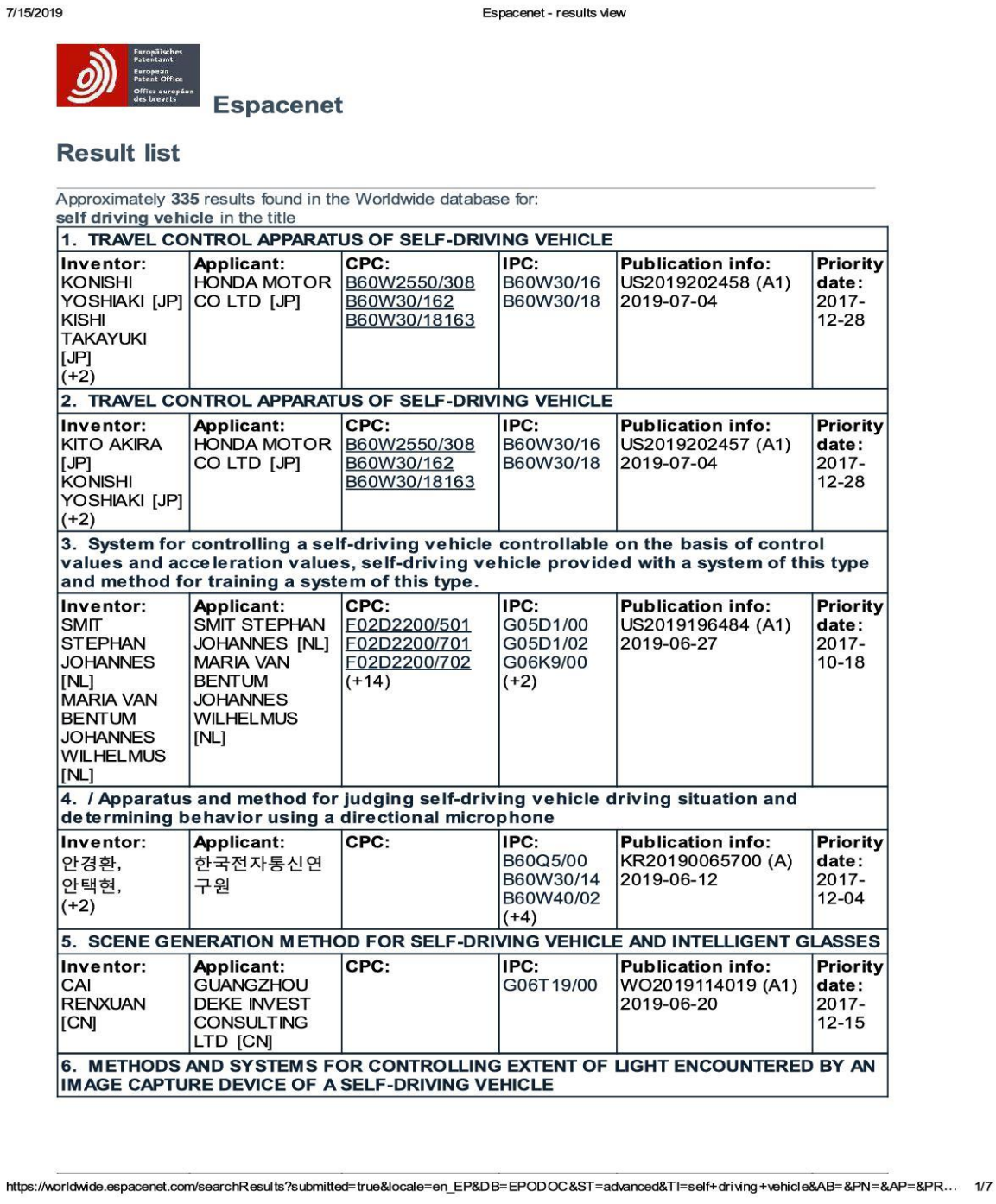
The first application for SDV was dated of 1979 year.

[18] Also known as an autonomous car and robotic car.

Table 2: The number of application for SDV per year.

Year	Number of patent appl.
1980	5
1996-1999	Average 5 per year
2000	3
2001-2009	Average 5 per year
2010	2
2013	–
2014	–
2015	21
2016	50
2017	92
2018	42

The last not least applications shown on the epo.org site are the following:



7/15/2019 Espacenet - results view

Espacenet

Result list

Approximately **335** results found in the Worldwide database for:
self driving vehicle in the title

1. TRAVEL CONTROL APPARATUS OF SELF-DRIVING VEHICLE					
Inventor: KONISHI YOSHIAKI [JP] KISHI TAKAYUKI [JP] (+2)	**Applicant:** HONDA MOTOR CO LTD [JP]	**CPC:** B60W2550/308 B60W30/162 B60W30/18163	**IPC:** B60W30/16 B60W30/18	**Publication info:** US2019202458 (A1) 2019-07-04	**Priority date:** 2017-12-28
2. TRAVEL CONTROL APPARATUS OF SELF-DRIVING VEHICLE					
Inventor: KITO AKIRA [JP] KONISHI YOSHIAKI [JP] (+2)	**Applicant:** HONDA MOTOR CO LTD [JP]	**CPC:** B60W2550/308 B60W30/162 B60W30/18163	**IPC:** B60W30/16 B60W30/18	**Publication info:** US2019202457 (A1) 2019-07-04	**Priority date:** 2017-12-28
3. System for controlling a self-driving vehicle controllable on the basis of control values and acceleration values, self-driving vehicle provided with a system of this type and method for training a system of this type.					
Inventor: SMIT STEPHAN JOHANNES [NL] MARIA VAN BENTUM JOHANNES WILHELMUS [NL]	**Applicant:** SMIT STEPHAN JOHANNES [NL] MARIA VAN BENTUM JOHANNES WILHELMUS [NL]	**CPC:** F02D2200/501 F02D2200/701 F02D2200/702 (+14)	**IPC:** G05D1/00 G05D1/02 G06K9/00 (+2)	**Publication info:** US2019196484 (A1) 2019-06-27	**Priority date:** 2017-10-18
4. / Apparatus and method for judging self-driving vehicle driving situation and determining behavior using a directional microphone					
Inventor: 안경환, 안택현, (+2)	**Applicant:** 한국전자통신연구원	**CPC:**	**IPC:** B60Q5/00 B60W30/14 B60W40/02 (+4)	**Publication info:** KR20190065700 (A) 2019-06-12	**Priority date:** 2017-12-04
5. SCENE GENERATION METHOD FOR SELF-DRIVING VEHICLE AND INTELLIGENT GLASSES					
Inventor: CAI RENXUAN [CN]	**Applicant:** GUANGZHOU DEKE INVEST CONSULTING LTD [CN]	**CPC:**	**IPC:** G06T19/00	**Publication info:** WO2019114019 (A1) 2019-06-20	**Priority date:** 2017-12-15
6. METHODS AND SYSTEMS FOR CONTROLLING EXTENT OF LIGHT ENCOUNTERED BY AN IMAGE CAPTURE DEVICE OF A SELF-DRIVING VEHICLE					

https://worldwide.espacenet.com/searchResults?submitted=true&locale=en_EP&DB=EPODOC&ST=advanced&TI=self+driving+vehicle&AB=&PN=&AP=&PR… 1/7

Figure 5:
Information of application for SDV
Source: Espacenet

Most of the applicants are from the following countries: Japan, Nederland, China, Korea, USA and Canada.

C. Block chain (BCH)

A **block chain**s a growing list of records, called blocks that are linked using cryptography. Each block contains a cryptographic hash of the previous block, a timestamp, and transaction data.

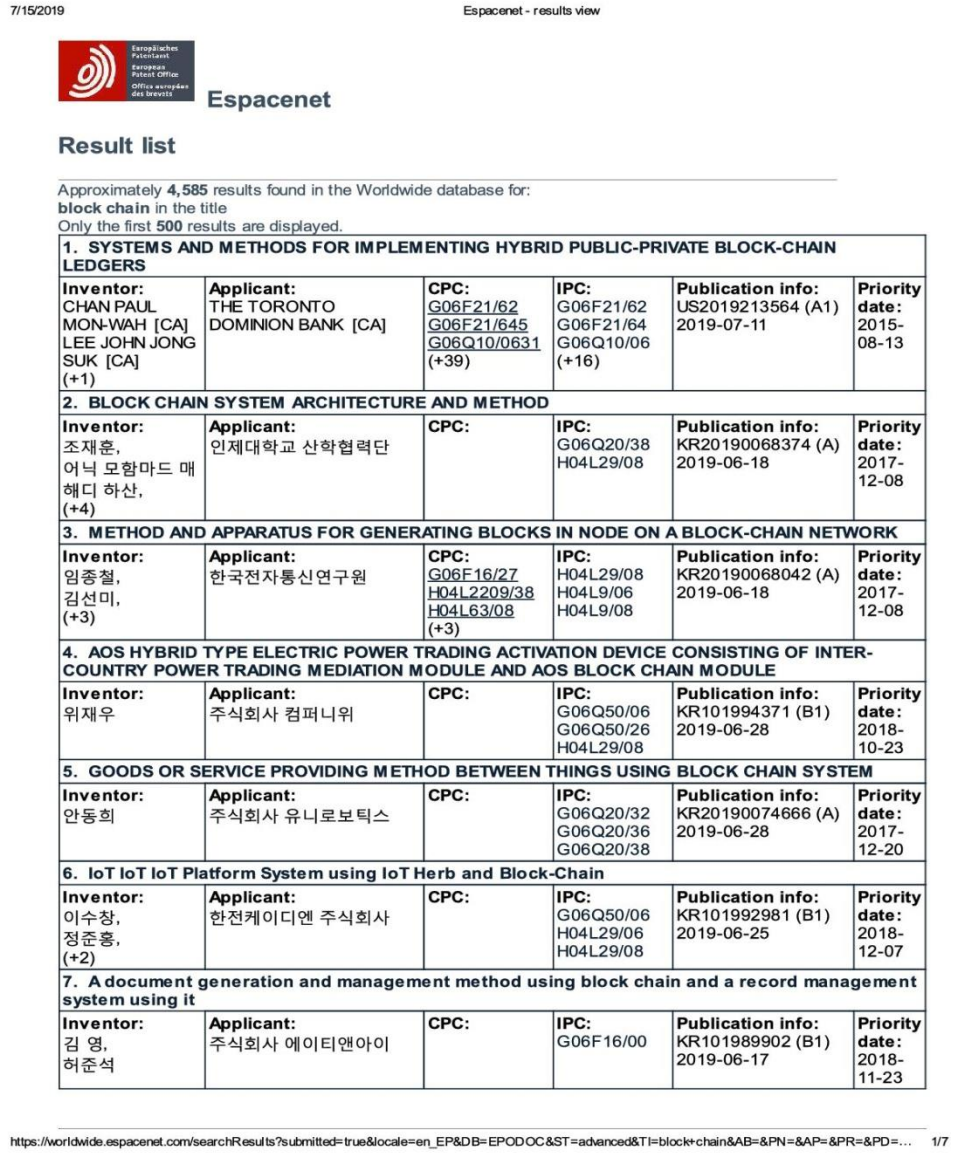
Block chain was invented by a person using the name Satoshi Nakamoto in 2008 to serve as the public transaction ledger of the cryptocurrency bitcoin. The invention of the block chain for bitcoin made it the first digital currency to solve the double-spending problem without the need of a trusted authority or central server. The first work on a cryptographically secured chain of blocks was described in 1991 by Stuart Haber and W. Scott Stornetta. They wanted to implement a system where document timestamps could not be tampered with. In 1992, Bayer, Haber and Stornetta incorporated Merkle trees to the design, which improved its efficiency by allowing several document certificates to be collected into one block. In August 2014, the bitcoin block chain file size, containing records of all transactions that have occurred on the network, reached 20 GB in January 2017, the bitcoin block chain grew from 50 GB to 100 GB in size. In May 2018, Gartner found that only 1% of CIOs indicated any kind of block chain adoption within their organizations, and only 8% of CIOs were in the short-term 'planning or [looking at] active experimentation with block chain'. To the end of July, 2019 the system of patent search worldwide Espacenet shows 4585 patent application and issued patent for Block chain.

The first application for BCH was dated of 1976 year.

Table 3: The number of application for BCH per year.

Year	Number of patent appl.
1980-1989	8-10
1990-1999	22-95
2000	22
2001-2009	Between 22-28
2010	28
2013	–
2014	–
2015	95
2016	167
2017	594
2018	1596

The last not least applications shown on the epo.org site are the following:



7/15/2019 Espacenet - results view

Espacenet

Result list

Approximately **4,585** results found in the Worldwide database for:
block chain in the title
Only the first **500** results are displayed.

1. SYSTEMS AND METHODS FOR IMPLEMENTING HYBRID PUBLIC-PRIVATE BLOCK-CHAIN LEDGERS					
Inventor: CHAN PAUL MON-WAH [CA] LEE JOHN JONG SUK [CA] (+1)	**Applicant:** THE TORONTO DOMINION BANK [CA]	**CPC:** G06F21/62 G06F21/645 G06Q10/0631 (+39)	**IPC:** G06F21/62 G06F21/64 G06Q10/06 (+16)	**Publication info:** US2019213564 (A1) 2019-07-11	**Priority date:** 2015-08-13
2. BLOCK CHAIN SYSTEM ARCHITECTURE AND METHOD					
Inventor: 조재훈, 어닉 모함마드 매해디 하산, (+4)	**Applicant:** 인제대학교 산학협력단	**CPC:**	**IPC:** G06Q20/38 H04L29/08	**Publication info:** KR20190068374 (A) 2019-06-18	**Priority date:** 2017-12-08
3. METHOD AND APPARATUS FOR GENERATING BLOCKS IN NODE ON A BLOCK-CHAIN NETWORK					
Inventor: 임종철, 김선미, (+3)	**Applicant:** 한국전자통신연구원	**CPC:** G06F16/27 H04L2209/38 H04L63/08 (+3)	**IPC:** H04L29/08 H04L9/06 H04L9/08	**Publication info:** KR20190068042 (A) 2019-06-18	**Priority date:** 2017-12-08
4. AOS HYBRID TYPE ELECTRIC POWER TRADING ACTIVATION DEVICE CONSISTING OF INTER-COUNTRY POWER TRADING MEDIATION MODULE AND AOS BLOCK CHAIN MODULE					
Inventor: 위재우	**Applicant:** 주식회사 컴퍼니위	**CPC:**	**IPC:** G06Q50/06 G06Q50/26 H04L29/08	**Publication info:** KR101994371 (B1) 2019-06-28	**Priority date:** 2018-10-23
5. GOODS OR SERVICE PROVIDING METHOD BETWEEN THINGS USING BLOCK CHAIN SYSTEM					
Inventor: 안동희	**Applicant:** 주식회사 유니로보틱스	**CPC:**	**IPC:** G06Q20/32 G06Q20/36 G06Q20/38	**Publication info:** KR20190074666 (A) 2019-06-28	**Priority date:** 2017-12-20
6. IoT IoT IoT Platform System using IoT Herb and Block-Chain					
Inventor: 이수창, 정준홍, (+2)	**Applicant:** 한전케이디엔 주식회사	**CPC:**	**IPC:** G06Q50/06 H04L29/06 H04L29/08	**Publication info:** KR101992981 (B1) 2019-06-25	**Priority date:** 2018-12-07
7. A document generation and management method using block chain and a record management system using it					
Inventor: 김 영, 허준석	**Applicant:** 주식회사 에이티앤아이	**CPC:**	**IPC:** G06F16/00	**Publication info:** KR101989902 (B1) 2019-06-17	**Priority date:** 2018-11-23

https://worldwide.espacenet.com/searchResults?submitted=true&locale=en_EP&DB=EPODOC&ST=advanced&TI=block+chain&AB=&PN=&AP=&PR=&PD=... 1/7

Figure 6:
Information of application for BCH
Source: Espacenet

General conclusions from the patent analyses: Most of the applicants in these 3 top subfields of the digital technologies are from the following countries: Korea, China and USA. Weak participation and presence are identified by the applicants from countries of Europe.

III. The national digital competitiveness as a brief concept and the IMD report of it for 2018

The author's point of view for the concept of digital competitiveness of a country also called national digital competitiveness is a concept of the specified country competitiveness beyond the general country competitiveness including main economic

and financial indicators and the digital competitiveness and is regarded to the following main aspects:

- innovations of the natural persons and of the companies based on digital technologies (ICT) and situated in this country;
- IPR for the innovations in ICT, especially patents as applications on the national, European and/or world level[19];
- organizational and technological infrastructure of this country based on digital technologies (ICT) and intended for the application and use of the digital technologies/achievement in this country;
- talent capacity (labor in digital/ICT field) as a number, education and skills.

The IMD World Digital Competitiveness Ranking[20] for 2018 year studies 63 countries and their economies in over 340 criteria measuring different aspects of competitiveness. The new Digital Competitiveness Ranking, however, introduces several new criteria to measure countries' ability to adopt and explore digital technologies leading to transformation in government practices, business models and society in general.

The IMD World Competitiveness Yearbook is divided into five sections: competitiveness rankings, competitiveness country profiles, digital competitiveness rankings, digital competitiveness country profiles and statistical tables.

In 2018 year the majority of countries in the study (29) experienced an improvement in their level of digital competitiveness. About 40% of the sample (26 countries) shows a decline while only eight economies remain in the same position. These changes are not geographically focused. Improvements and declines occur across continents.

The IMD World Competitiveness Center is publishing a separate report ranking countries' digital competitiveness. Indicators for technology and scientific infrastructure are already included in the overall rankings. The new Digital Competitiveness Ranking, however, introduces several new criteria to measure countries ability to adopt and explore digital technologies leading to transformation in government practices, business models and society in general.

[19] European patent application for innovations in ICT based on EPC – European patent convention with 38 countries-members, world patent applications for innovations in IPC based on Patent cooperation treaty with 152 contracting states.

[20] The IMD metrics for the digital competitiveness is complex and similar to the author's main point of view for digital competitiveness. The national competitiveness ranking also called country competitiveness is cited directly by the IMD record for 2018.

The USA leads the ranking in 2018 followed by Singapore, Sweden, Denmark and Switzerland.

Figure 7:

IMD World Digital Competitiveness Ranking Top 15 of 2018

Source: IMD World Competitiveness Center

These infographics show that at the top countries are USA, Singapore, Korea, Taiwan, Hong Kong SAR, Israel and Australia and European countries such Sweden, Denmark, Norway, Finland, Switzerland, UK, Austria and Germany.

IV. Conclusion

In the conditions of 4 IR and especially in subfields of 4 IR we identified a multiple rise of the patent applications from the natural and juridical persons for the last 5 years. In the last as statistical information in IPR 2018 year the remarkable rise as innovations with economic and social influence is shown in fields of AI, SDV and BCH. In 2018 the countries with main patent applications are the countries on the top 20 of IMD annual record for the world digital competitiveness. The top countries applicants of the top 3 subfields of the 4 IR are at the top of the digital competitiveness rank list of IMD record.

Each business cycle is preceded by the inner cycles of the science and technological development. Science and technology in their interaction are topic and a base for the next cycle. They form the level of a development of the self inter and the interactions between the two define a future development and their economic and social widespread and influence. Science may drive technological development, by generating a demand for new approaches and instruments to address a scientific question, or by illustrating technical possibilities previously unconsidered. In turn, technology may drive scientific investigation, by creating demand for technological improvements that can only be produced through research, and by raising questions about the main principles that a new technology based on.

This analysis completely proves the author's thesis presented at the beginning of this article for a correlation between the national digital competitiveness and the place of this country as a world place as patent applications for technological innovations in the 3 top subfields of 4 IR. In addition, more conclusions and relations are identified:

- Innovations in ICT sector protected as IPR are valuable factor for obtaining and for sustaining the digital competitiveness of the country;
- Research on the IPR/ patent research/ for patent applications may reveal new trends and new areas of the scientific and technological progress;
- European countries should invest more resources and creative efforts in the identified top 3 subfields of the 4 IR;
- The IMD researchers may include in their metrics of the assessment the digital competitiveness of countries an additional indicator of IPR for innovations in the top fields of the 4 IR.

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Policy Recommendations for Higher Access to the Healthcare while Addressing Intellectual Property Rights and an Individual Case: Cancer Care for Azibun Nessa

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Abstract

The author reports the last few days of his mother's life who was battling with non-small cell lung cancer and lost her life to the disease. The healthcare crisis in Bangladesh, the author experienced in the cancer treatment of his mother Azibun Nessa, motivated him to look for the answer of a fundamental question: "how access to healthcare can be increased in low and mid income countries". The article argued that "human rights based approach" in IPR (Intellectual Property Right) protection of medicine can contribute to increase the level of access to the healthcare. Indian legal responses to "intellectual property protection in medicine" and their arguments on "right to healthcare" can be useful for other countries in similar social-economic conditions to increase access to the healthcare by their patient population. The article explores the possible costs of a medicine and makes recommendation on "how access to healthcare can be increased in low and mid income countries". Furthermore, the role of IPR in medicine and IPR's direct connection with the accessibility of healthcare, were at the core of discussion.

Keywords: Healthcare, Intellectual Property, Medicine, Cancer, Azibun Nessa

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I. Introduction

"I wish I could've burnt alive instead", she said in her last days of life. The monstrous battle for life was intense, long and slow for the patient, as her cancer treatment continued with bleak results. The patient had no problem in embracing death, but she did not want the long, painful, difficult, outrageous and suffocating end of life. The experience as family member of an advanced stage cancer patient's treatment, inspired me to explore the difficulties involved in "access to healthcare" in Bangladesh. The patient was not privileged and she dedicated her life in educating the underprivileged children at a suburb in Bangladesh. In this writing, I reported the condition of the "cancer treatment" and "cancer care" in Bangladesh. Thereafter, I explained how "right to healthcare" deserves more attention and how directly the Intellectual Property (IP) protection in medicine is linked to the accessibility of the therapy. The article explored the costs that a manufacturer might incur in the process of the drug development. The article makes several policy recommendations in the light of the findings.

II. Cancer care for Azibun Nessa

Azibun Nessa founded a school for the underprivileged children in the 70s at her home premises on the outskirts of Habiganj town in Bangladesh. The school she founded was named as *Teghoria Zamina Primary School,*[21]later nationalized and continued as a Government primary school. Nessa continued teaching the primary school children throughout her life. In November2018, she was diagnosed with advanced stage non-small cell lung cancer. Based on a blood biopsy report, she was recommended "*targeted therapy*" that prescribed a medicine called *Alectinib*.[22] The clinical trial of the medicine was conducted, rather, on a small number of subjects (patients/participants)[23] and multiple studies are recruiting the subjects at the time of this writing.[24] After 3 months of medication (8 capsules per day) her health condition deteriorated and a core biopsy was conducted. The core biopsy analyzed the affected cell of the lung and the report did not find the *marker* based on which she was prescribed *Alectinib*. The doctor decided to apply *chemotherapy*. By then, it was too late to explore other treatment options. Azibun Nessa[25] lost her battle for life. She passed away on 08 March 2019,[26] after painful last few months of her life. Death

[21] Named after her eldest daughter Zamina Akter.

[22] It is a very expensive medicine. The price of the drug is completely out of reach for the common people in countries like Bangladesh. DRUGS.COM, *Alecensa Prices, Coupons and Patient Assistance Programs*, https://www.drugs.com/price-guide/alecensa (last visited Dec.10, 2019). "The cost for Alecensa [Alectinib] oral capsule 150 mg is around $15,614 for a supply of 240 capsules, depending on the pharmacy you visit. Prices are for cash paying customers only and are not valid with insurance plans."

[23] 253 patients. Erin Larkins et al., *FDA Approval: Alectinib for the Treatment of Metastatic, ALK-Positive Non-Small Cell Lung Cancer Following Crizotinib*, 22(21) CLIN CANCER RES. 5171, 5171-5176 (2016). "On December 11, 2015, the FDA granted accelerated approval to alectinib (Alecensa; Genentech) for the treatment of patients with anaplastic lymphoma receptor tyrosine kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC)."

[24] U.S. NATIONAL LIBRARY OF MEDICINE, https://pubchem.ncbi.nlm.nih.gov/compound/Alectinib#section=ClinicalTrials-gov (last visited Dec. 12, 2019).

[25] She is the mother of the author.

[26] Moulvibazar, *Azibunnesa passes away*, THE DAILY STAR (March 09, 2019), https://www.thedailystar.net/city/news/azibunnesa-passes-away-1712470.

came as a relief and freedom, as life was so unbearable to her, for the pain, for the breathing difficulties, for the sufferings caused by the disease and the treatment procedures.

Throughout the entire treatment procedure, the recurring questions the family members had to face are:

- How can we buy more time for the patient, meaning "longer life"?
- How can the sufferings (caused by the disease and of the treatment protocol) be reduced?
- As it was privately funded, where would the enormous cost of the treatment come from?

It is pertinent to mention here that the medicine Alectinib has three US patents,[27] i.e., US9126931,[28] US9440922,[29] US9365514[30] whose *assignee*(patent owner) is Chugai Seiyaku Kabushiki Kaisha but the FDA (the US Food and Drug Administration) applicant is Hoffmann-La Roche.[31] Alectinib's IP ownership history appears to be associated with three entities. i.e., Chugai Seiyaku Kabushiki Kaisha, Genentech and Hoffmann-La Roche; the commercial value of the patents are apparent.

However, Azibun Nessa was a Bangladesh Government's primary school teacher. She devoted her life to educate underprivileged children. In the end stage of her life, she had to face the bitter reality of the developing countries, where healthcare is largely private. Her income from the teaching job was low and she had a very little pension. When we talk about cancer treatment, we talk about large sum of money, which is beyond the capacity of the people with normal income level in the countries like Bangladesh. Her eldest daughter spent all her savings in the treatment of her mother. Nessa lost her battle for life to cancer but the price of the medicine that she took for three months, ineffective in her case though, was totally unaffordable for the low income population. If it were effective and if she had continued to live with that medicine, how would a "*retired primary school teacher*" in Bangladesh afford the

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[27] U.S. NATIONAL LIBRARY OF MEDICINE, https://pubchem.ncbi.nlm.nih.gov/compound/Alectinib (last visited Dec. 12, 2019).

[28] United States Patent and Trademark Office, *USPTO Patent Full – Text and Image Database*, UNITED STATES PATENT AND TRADEMARK OFFICE (Sep. 08, 2015), http://patft.uspto.gov/netacgi/nph-Parser?d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=9126931.PN.&OS=PN/9126931&RS=PN/9126931. (Assignee of the patent is Chugai Seiyaku Kabushiki Kaisha (Tokyo, JP).)

[29] United States Patent and Trademark Office, *USPTO Patent Full – Text and Image Database*, UNITED STATES PATENT AND TRADEMARK OFFICE (Sep. 13, 2016), http://patft.uspto.gov/netacgi/nph-Parser?d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=9440922.PN.&OS=PN/9440922&RS=PN/9440922. (Assignee of the patent is Chugai Seiyaku Kabushiki Kaisha (Tokyo, JP).)

[30] United States Patent and Trademark Office, *USPTO Patent Full – Text and Image Database*, UNITED STATES PATENT AND TRADEMARK OFFICE (Jun. 14, 2016), http://patft.uspto.gov/netacgi/nph-Parser?d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=9365514.PN.&OS=PN/9365514&RS=PN/9365514. (Assignee of the patent is Chugai Seiyaku Kabushiki Kaisha (Tokyo, JP).)

[31] U.S. NATIONAL LIBRARY OF MEDICINE, https://pubchem.ncbi.nlm.nih.gov/compound/Alectinib#section=FDA-Orange-Book-Patents (last visited Dec. 12, 2019).

monthly expenses of a patented drug that costs around $15,614 per month.[32] So I ask this question: "do the poor people have to die early"? Azibun Nessa was only 69 years old at the time of her death.[33]

In the last week of her life, she asked me: "what will you do with me?". I took few minutes and replied: "we will continue with the treatment". It was an emotionally overwhelming conversation between a dying mother and as son.[34] Her eldest son came with this conclusion: "if we have 1% chance of life, we will go for it". Her children put all resources at stake.[35]But she left next week for ever.

The treatment protocol was very painful. Multiple biopsies were conducted. The "core biopsy" was so painful that I could hear her screams from the outside of an apparently sound proof door. Should we have done nothing and have done only palliative care? The most of the physicians thought that her treatment outcome would be very gloomy. The oncologist who was in charge of her treatment, believed that if the medicine (Alectinib) had worked, she would have 3-5 years of life more. So as family members, we thought, we must go for it. But the medicine was either inaccurate in her case or ineffective. So all the painful biopsies had just added sufferings to her final days of life. What could the family members have chosen for her? She was not able to breath. What choices she would have made for her? Making an informed choice in such a critical condition, is not easy for an individual. She was relying on the choices her children made for her. Her children made those choices that they could afford and thought "scientifically and ethically" best for her.

Before her diagnosis confirmed cancer, she was admitted to the respiratory care unit, with her lung filled with fluid. She had enormous breathing difficulties, pain and sufferings. She told her husband (my father): "these doctors are not good, this hospital is not good, take me to a hospital in Shillong". Shillong is a hilly place in Meghalaya, India. You can see the lights of the mountainous regions of Shillong from her parent's home, where she spent her early life. She was married at a very young age. Shillong is not known to be a healthcare destination. Why she wanted to go to Shillong? I was standing quiet on the other side of her bed and thought: "did they travel to Shillog for healthcare in the old days or it's just a hope". She was buried next to the school she founded. Her healthcare was conducted entirely in Bangladesh.[36]

III. Right to health care

Healthcare is a right of every individual, as he/she has duty to the State as good citizen.[37]Article 25 of the Universal Declaration of Human Rights, 1948 recognized the right to healthcare. Article 25(1) of the Universal Declaration of Human Rights reads as follows:

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[32] *Supra* note 2.

[33] Her cancer care was administered at a private hospital in Dhaka, Bangladesh. Her last days were very painful, though she did not die a lonely death. She did not make the choices of her treatment protocols on her own. Her elder son made the choices in consultation with the physicians. However, all the family members were informed.

[34] The author of the article is her youngest child. She had four children. i.e., 2 daughters and 2 sons.

[35] I was willing to sell my inheritance.

[36] The possibility of taking her to Mumbai was explored. The financial issues and other complications did not allow that to happen.

[37] It is also a right of those who fled war and persecution and living as refugees or as a stateless person.

> "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and *medical care* and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."[38]

Article 12of the International Covenant on Economic, Social and Cultural Rights (ICESCR) 1966 states:

1. The States Parties to the present Covenant recognize the *right of everyone to the enjoyment of the highest attainable standard of physical and mental health*.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

   (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
   (b) The improvement of all aspects of environmental and industrial hygiene;
   (c) The *prevention, treatment and control of epidemic, endemic, occupational and other diseases*;
   (d) The creation of conditions which would *assure to all medical service and medical attention in the event of sickness*.[39]

During my Doctoral study (from 2012 to 2016), I lived in Germany, Italy and Lithuania. I visited public and private healthcare facilities of these countries and closely observed their conditions. Except the time (nearly 4 years) I spent for studies and research in the continental Europe, I have lived in Bangladesh. I observed that notable disparity exists between and among countries, when it comes to free healthcare by the State. The coverage of free care or a standard and basic healthcare service depends on the country and varies from country to country. There are common goals in the European States to offer universal healthcare to the citizens. Arif Jamil observed:

> Both the public and private service providers exist in the countries revisited (Germany, Italy, Lithuania, Spain, UK and the USA). The social insurance and private insurance also exist at the same time. Consumers of the health care services are free to exercise their choice with respect to receiving their health care service channel. Certain countries have been able to provide adequate service coverage to the citizens through the public channel and public funding and some have not. There are plenty of reasons to believe that the quality of care may vary depending on the affordability of a patient in some countries. It is often true that the private services cost a lot more for the patients.

[38] Universal Declaration of Human Rights art. 25, Dec. 10, 1948. (Accessed on Dec. 18, 2019 from http://www.un.org/en/documents/udhr.)
[39] International Covenant on Economic, Social, and Cultural Rights art. 12, Dec. 16, 1966. (Accessed on Dec. 18, 2019 from http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx.)

> Despite right to health as can be found in the constitution of some countries, e.g., Italy, Spain and Lithuania, it cannot be found as a right guaranteed by the constitution in some others, e.g., UK, USA and Germany. Few countries recognize the access to health care as the right of the citizen and prescribes means to avail it, while making it the duty of the State, e.g. Italy and Lithuania.[40]

The illegal immigrants, undocumented inhabitants (or migrants) and unemployed adults are the most disadvantaged, when it comes to State sponsored healthcare services. The services available in most of the countries as healthcare provided by the State are basic, i.e., the essential ones. Aesthetic, experimental medical treatments, unproven therapeutic application, "not recommended as essential" by the physician employed by the Government, is not covered by the State's free care. In some countries, hospitals of the universities enroll patients for clinical trial of unproven therapies. Quality of healthcare service in the UK and USA has been a core issue during the recent election campaigns. America is divided over the insurance expansion of *Obama care*. The question of "quality of service" provided by the NHS in England has divided the political parties during the election campaign. However, the USA is the only wealthy country without universal healthcare coverage for its citizens and as a result, "28 million Americans […] have no coverage".[41]

Kimberly Amadeo observed:

> Out of the 33 developed countries, 32 have universal health care. They adopt one of the following three models.
>
> In a single-payer system, the government taxes its citizens to pay for health care. Twelve of the 32 countries have this system. The United Kingdom is an example of single-payer socialized medicine. Services are government-owned and service providers are government employees. Other countries use a combination of government and private service providers.
>
> Six countries enforce an insurance mandate. It requires everyone to buy insurance, either through their employer or the government. Germany is the best example of this system.
>
> The nine remaining countries use a two-tier approach. The government taxes its citizens to pay for basic government health services. Citizens can also opt for better services with supplemental private insurance. France is the best example.[42]

Some developing countries are also trying to protect the right to health through constitutional interpretation by Court cases, e.g., India. Section 3(d) of the Patents Act, 1970, as amended by the Act of 2005 of India prevents patenting for incremental changes in the invention/innovation or getting a new patent for already existing patent

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[40] Jamil, *infra* note 43 at 65.

[41] Kimberly Amadeo, *Universal Health Care in Different Countries, Pros and Cons of Each: Why America Is the Only Rich Country Without Universal Health Care***,** THE BALANCE (Dec. 14, 2019), https://www.thebalance.com/universal-health-care-4156211. "Despite some similarities, Obamacare is not universal health care. It is simply a program that offers subsidies to participants to purchase insurance. U.S. programs that are more similar to universal health care are Medicaid and Medicare."

[42] *Id.* (FN omitted).

by showing insubstantial inventive step.[43] This provision will work against what is typically known as "evergreening of patent."India has already set example of rejecting patent for "insubstantial changes" or for failure to fulfill the "inventive step" requirement. The patent for *Gleevec/Glivec*[44] was finally rejected by the Indian Supreme Court[45] on this ground and the generic of the drug is being sold by local manufacturers (e.g., Cipla Ltd.) at around one-tenth of the patented price.[46] This decision will allow higher access to this essential medicine by the poor population, as "cancer" cases are fast rising in low and mid-income countries. The decision was criticized by the pharmaceutical industry and applauded by the "public-health advocacy and rights groups".[47]

For allowing compulsory licenses, the judicial interpretation connecting "*right to life* with *right to health*" has to be invoked, as Indian Constitution does not guarantee the "right to health" and "access to healthcare" as an enforceable right, i.e., fundamental right. There are commitments in the Constitution for the State as "duty to raise the level of standard of public health" under Part IV ("Directive Principles of State Policy"), the realization of which will depend on the ability of the State.[48]

In the case of *Paschim Banga Khet Mazdoor Samity & Ors v. State of West Bengal & Anor* (1996)[49] the Supreme Court of India considered that, "not providing emergency medical treatment on time" is a violation of the "right to life" as embodied in the Article 21[50] of the Indian Constitution, and therefore, the Government hospitals are under obligation to protect this right. Therefore, when the health of the citizen is a "human rights concern", Indian Courts responded in a manner that made room for protecting its citizens. In *Bandhua Mukti Morcha v. Union of India and Ors. (1983)*[51] the Supreme Court's judgment was intended to protect health of the workers in extremely adverse working conditions like "sites of stone crushing and mines". The Court established a link between "right to life" (Article 21), which is fundamental right guaranteed by the Constitution (of India) and articles 39(e)(f), 41 and 42 (all "Directive Principles of State Policy"),[52] for which the enforcement is supposed to depend on the economic ability of the State. This case invoked the concept of "*human dignity*" to rationalize the move to guarantee "healthy working condition" and

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[43] Section 3(d) explained what are "not patentable inventions" for the purpose of the Act as following: "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant." Patents (Amendment) Act, 2005, No. 15, Act of Parliament, 2005 (India), *available at* http://www.wipo.int/wipolex/en/text.jsp?file_id=128116.

[44] A cancer drug, Swiss Company Novartis AG owns the patent in other countries.

[45] Novartis v. Union of India & Others, Civil Appeal No. 2706-2716 of 2013.

[46] R. Jai Krishna, & Jeanne Whalen, *Novartis Loses Glivec Patent Battle in India*, THE WALL STREET JOURNAL (Apr. 01, 2013), https://www.wsj.com/articles/SB10001424127887323296504578395672582230106.

[47] *Id*. This case also showed how polarized we are as human society. Innovation, incentive and society's need are at a confrontational position, instead of a harmonized co-existence.

[48] INDIA CONST. art. 47, *amended by* The Constitution (Ninety-Sixth Amendment) Act, 2011, *available at* http://indiacode.nic.in/coiweb/welcome.html.

[49] A.I.R. 1996 S.C. 2426 / (1996) 4 S.C.C. 37 (India).

[50] It is ensured as the fundamental right, enforceable through Courts.

[51] A.I.R. 1984 S.C. 802 (India).

[52] All of these provisions referred have connection with the protection of the health of the workers and health issues related to work.

"protection of the workers' health". In *Mohinder Singh Chawla v. The State of Punjab and Ors.* (1996)[53] declining reimbursement of payment for the room rent for "post-operative stay" in the hospital was found against the spirit of Article 14 of the Indian Constitution (fundamental right guarantees the "equal protection of law"), and the reimbursement was ordered to be allowed along with the main medical costs.[54]

Therefore, it is evident that India would be a complex and different reality for the marketing and commercialization of healthcare commodities by foreign patentees. In India, there is strong support from the judicial institutions to protect the "right to life" and "human rights" in one hand, have big market of its own and is a signatory to TRIPS on the other hand. Other developing countries and LDCs lack strong judiciary and substantial market of their own. Therefore, Indian example could be cited to show that despite being signatory to TRIPS, countries still try to maneuver to evade the "TRIPS' IP protection obligations" and can ensure "healthcare rights" through tools of "human rights protection".

Among other causes that reduce access to healthcare, one is, denial of access to essential medicine. The crisis of the developing countries in accessing the essential medicine and their complex relation with the "IPR shielded pharmaceutical industry" is undeniable. Allowing to breach a patent for the excessive price of the drug and authorizing the local manufacturer to produce it at a cheaper cost, *will enhance access to the therapy by the wider number of population* for sure, but this rejection of "patent monopoly" is a choice that requires two things:

- substantial strength for the country to oppose the strong "international IP framework" (which favors patent owners only); and
- legal maneuvering, i.e., providing a justification for granting the compulsory licenses to work in its favor.

Therefore, being the "signatory to TRIPS" and "rejecting a patent" to reduce the cost of the therapy at the same time, is not the reality of all the poor and weaker nations. It is not envisaged in the "TRIPS framework" that "excessive drug price" would be considered as a reason for "compulsory licensing" by the poor countries.

Jamil commented:

> "[T]he *right based approach* in access to medicine has taken the forefront of the discussion on health care. Merger of "access to medicine and/or health care" with the notions of human rights recognized in the national context through constitution may make way for higher access to medicine and health care in many countries."[55]

The constitutional recognition alone will not guarantee "access to the healthcare", unless a country achieves the economic strength and learns how to manage its healthcare resources. Population size and resources have to be in balance to be able to provide right kind of healthcare. In countries like Bangladesh, population size is an enormous challenge on way to providing free healthcare; there are simply too many

[53] (1996) 113 P.L.R. 499 (India).
[54] The two years of delay in payment was mentioned as "inhuman approach." Mohinder Singh Chawla v. The State of Punjab and Ors. (1996) 113 P.L.R. 499 (India).
[55] Jamil, *infra* note 43 at 62.

people. So, "population reduction" and "population stabilization" are also very important (in Bangladesh's context) along with constitutional guarantee (as fundamental human right) of right to healthcare.

IV. Healthcare concerns

D. IPR issues that impact access to the essential medicine

The countries can be classified into the following economic groups: "high, upper-middle, lower-middle, and low".[56] Bangladesh is grouped as lower-middle income economy ($1,026 to $3,995).[57] Cost of the therapy depends on multiple factors but cost of the medicine has direct connection with the IPR over the medicine owned by the assignee (patent owner). IPR contributes to the higher price of the medicine, as it eliminates competitions and generic does not exist in the market until the patent and Data Exclusivity Right (hereinafter DER) expires. Local manufacturing of foreign drugs (patented ones) is not possible without exercising the provision on "compulsory licensing". Use without permission of the right holder (assignee) or invoking of "compulsory licensing" cannot be arbitrarily exercised by the country in desperate need of a medicine. They must comply with the TRIPS Agreement[58] and Doha Declaration.[59] Only few diseases (HIV/AIDS, Malaria and Tuberculosis) are recognized exceptions. Paragraph 5(c) of the Doha Declaration states : "Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to *HIV/AIDS, tuberculosis,*[60] *malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency* (italics added)." If a country has outbreak of a disease (or "other epidemics"[61]) that justifies "circumstances of extreme urgency"[62], and issues "compulsory licensing" following the legal recourses mandated by the Doha Declaration, it is still likely to face the backlash and retaliatory measures or trade sanctions from the patent owners, powerful lobbies and countries that support tough IPR.[63]Therefore, the windows of hope created by the Doha Declaration are undermined by the continuous *dodging-games* of some of the industrialized countries and lobbying groups that

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[56] WORLD BANK BLOGS, *New country classifications by income level: 2018-2019*, https://blogs.worldbank.org/opendata/new-country-classifications-income-level-2018-2019 (last visited Dec. 12, 2019).

[57] *Id.* ; THE WORLD BANK, *World Bank Country and Lending Groups*, https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups (last visited Dec. 12, 2019).

[58] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994). Hereinafter TRIPS Agreement.

[59] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, WT/MIN(01)/DEC/2, also *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. Hereinafter Doha Declaration.

[60] There is very little research on the issue of antibiotic resistance in the treatment of tuberculosis, therefore, it became one of the top terminal diseases globally.

[61] Doha Declaration, para. 5(c).

[62] Doha Declaration, para. 5(c).

[63] Arif Jamil, Patent Framework for the Human Stem Cells in Europe and the USA: Innovation, Ethics and Access to Therapy ch.3.4, Ph.D. diss, University of Bologna (2016). *available at* http://amsdottorato.unibo.it/id/eprint/7739.

support extremely tough IPR. Patent tenure and period of DER together delays the entry into the market of the generic drugs, hence, the price of the medicine remains monopolistic, i.e., much higher than the competitive price. The monopolistic price of the IPR protected medicine, in consequence, excludes large number of patient population in poor countries and also those that have no insurance (irrespective of the country's economic status) for accessing the available medicine, which might be the "state-of-the-art" treatment. Furthermore, in recent times, the US is engaged in a practice of bilateral Free Trade Agreement (hereinafter FTA) where tough IPR is imposed on poor nations.[64] Once a country grants a special favor (granting higher standard of IPR) to a (any) country, according to the principle of "*Most Favoured Nation Treatment"* in the TRIPS Agreement (hereinafter MFN), the same facility has to be made available to all the member States of the Agreement.[65]Therefore, granting tough IPR on medicine by Chile, for example, to the USA means, the same standard (which is a higher standard than TRIPS would have asked for) of IP will have to be made available to the other member States and Chile would compromise its access to the "state-of-the-art" medicines for its population. Strictly enforced *patents on medicine*, *DER on the clinical trials data*, and *MFN as a result of the FTA* will, in combination, undermine the spirit of the Doha Declaration and contribute to the shrinking of the access to essential medicine by the poor populations who cannot afford the monopolistic price of the medicine and "not insured" and do not have free healthcare from the State.

E. Cost of the medicine

Price of a patented drug depends on various factors. Depending on the country where the drug is marketed, there could be some variations in the final costs. Many different kinds of costs, expenditures and burdens comprise of the "drug price" for the consumers to bear. Cost of the drug borne by the patient may include the following:

- **R&D (Research and Development):** Investment for *research and development* of the whole project.
- **The prescribed fees for the Government/ Ethics Committee approval:** For clinical trial there are Government requirements to be fulfilled and approved. There is likely to be an Ethics Committee, the approval of which is would be necessary to obtain in a biomedical research.
- **Patent Application fees, approval and maintenance of the patent:** How many countries are chosen for patent protection might influence the costs, as each country has patent's procedural and maintenance fees.
- **Litigation and Marketing:** All legal notices and litigation costs for IP protection (both for defending and enforcing), marketing of the new product/branding cost, attorney and expert's fees, etc.

[64] FREDERICK ABBOTT, THOMAS COTTIER, & FRANCIS GURRY, INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY 5, 57, & 632 (1st ed. 2007).

[65] TRIPS Agreement art. 4. "With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members."

- **Near Future Threat:** *Deterioration of the scientific value* caused by a better and more effective medication or treatment in the market, *time lost* in patent's bureaucratic/procedural process, *time lost* from granting of patent till regulatory approval for human application and apprehension of *generic in the market sooner than expected* either for compulsory licenses to local manufacturer or being *unsuccessful to utilize the invention as faster as desired*.
- **Incentive for future R&D and making profit:** Keeping an *incentive for the future research* projects and a *high profit* margin (unless the anti-trust laws are exercised by a country)determined by the manufacturer (patent owner).

Arif Jamil observed:

> The patent has implications for the price of the invented goods. After the expiry of the patent, the *generic* enters the market and the drug price goes down, as the competitors start selling the copy version. The typically used approaches by some of the countries for reducing the cost of the medicine has been issuing the "compulsory licenses to the local manufacturer," allowing "parallel import," and preventing "evergreening of patent". There is very limited leeway to avoid the spirit of the TRIPS Agreement (Chandra 2010, 401), once the country has signed it. The TRIPS spirit is to ensure an effective mechanism for the enforcement of the IPR.[66]

V. Recommendations and conclusion

- Azibun Nessa's "*bleak cancer battle results*" clearly indicate that there were certain flaws in the prognosis. Success rate of medicines approved by the regulatory authorities based on studies of "low sample size" remain entangled in questionable results. If effective, they are weighing too expensive. If ineffective, the patient may run out of critical time and fail to explore other treatment options. To have the best results in critical and terminal illness, *right prognosis* and *opting the right treatment option* are the most important things that may increase the chances of living longer. How affordable these cutting edge medical treatments are, if privately funded, remains a question. How many people in the developed world are insured against cancer? Therefore, *if public healthcare provides cancer treatment, there are high chances that the patients will live longer*.

- Right to healthcare can be found in multiple international legal instruments. Unfortunately their enforcement is limited. On the contrary, instruments that regulates "trade" have higher enforcement mechanisms. Those trade treaties provide increasingly tough IPR to the pharmaceutical manufacturers. Many of the countries in need (for the patient population) cannot or do not offer free healthcare in one hand, tough IP reduces accessibility to medicine (that one would buy from the pocket), on the other hand.

[66] Jamil, *supra* note 43 at 60.

Therefore, if trade instruments have enforcement mechanisms, *"human rights' legal instruments" should also be enforceable to protect the "right to healthcare"*.

- Right to healthcare should be *guaranteed in the constitution* of a country as fundamental human right and should be enforceable as such.

- The *universal healthcare or free healthcare* may have some criticisms but the benefits are overwhelming. A healthy nation is a wealthy nation! Healthy population can positively contribute to the welfare and development of the country. Art, culture, science, quality of life thrives in countries where the State provides healthcare to the citizens.

- Indian laws and justice system have higher degree of support for fostering access to medicine and healthcare; though healthcare in India is also largely private. The *Judiciary should stand for the society*, when manufacturers demand excessive and unrealistic reward for the invention. Otherwise, the low income societies will be excluded from the benefits of the inventions having application in healthcare.

- Access to healthcare will also depend on how the following matters are managed, addressed or dealt with by a country:

    - Needs and circumstances (priorities in general) of a country or community;

    - Health problems that have higher frequency;

    - Channels (public, private, insurance) used to access the healthcare services, healthcare infrastructure (roads, hospitals, ambulance services) and healthcare resources (doctors, nurses, staff);

    - Constitutional guarantee of right to "health/healthcare";

    - IP protection framework;

    - Regulatory framework (authority of the Court to upheld compulsory licenses);

    - Capacity to produce/manufacture drug products domestically;

    - Capacity of the Government to negotiate the drug price;

    - Accountability and transparency in the healthcare resources' management;

    - Size of the healthcare market of the country (small markets are not lucrative to the generic drug manufacturer);

- Research "funding approach"[67]and the availability of the research fund;
- International treaty obligation and translation of those treaties into reality; etc.

➢ The *"right based approach" may foster wider access to healthcare* in some countries,[68]particularly low income economies, i.e., poor nations and those that have "no real" public healthcare services for the mass population. Increase of "co-pay" in the industrialized nations, who in the past provided free healthcare, will reduce the access to healthcare. Many welfare nations, at present, put corporate interest before the interest of the citizens and environment.[69] This is an alarming trend of our time! Political and economic *ideologies and philosophies that are already proven to be failed or those that demonstrate the danger of expediting extinction of "weak", need to be abandoned*.

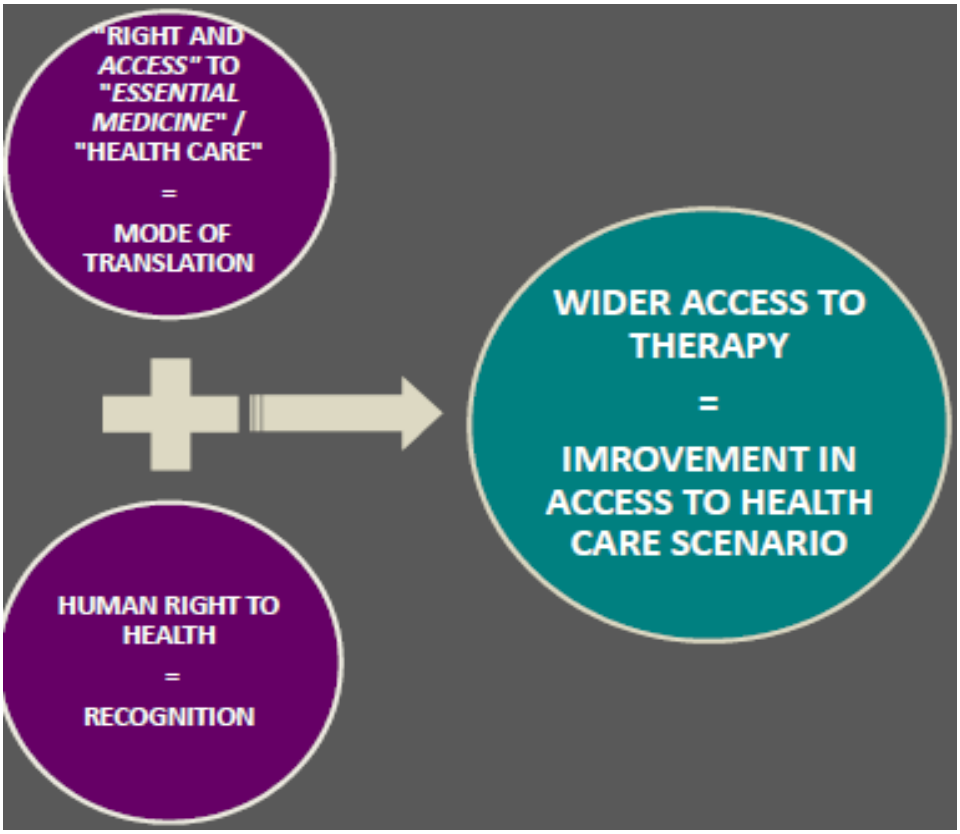

Figure 1:
Degree of access to healthcare depends on recognition of the right to healthcare and the translation of the right.
Source: Author's Concepts

[67] Rare disease, poor man's disease and "diseases that do not show promising commercial incentive", e.g., "antibiotic resistance", usually do not get "research investment" by the private manufacturers.
[68] Jamil, *supra* note 43 at 140.
[69] Air, water and soil pollution is directly linked to the public health, e.g., poor air quality standard will increase the burden of respiratory diseases and cost associated to it.

Hence, “healthcare for all” is one valid demand, largely disregarded by pursuing ill-conceived priorities. To blame “population size”, corruption and resource mismanagement for not providing the right healthcare is so lame, as all of them can be addressed by population stabilization and through good governance and rule of law. It is the *“political will”, which is most important for ensuring “good quality public healthcare”.* The international communities need to stand by the principles adopted to protect human dignity. There no limit of making profit for a private investor or manufacturer, unless the legal mechanisms adequately address the issue of finding a balance between the “*incentive for invention*” and “*benefits of the society*”.

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Analysis of Supplementary Protection Certificate (SPC) and Certificate of Supplementary Protection (CSP) Manufacturing Waivers and Their Impact on Pharmaceutical Industry※

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Abstract

Supplementary Protection Certificate (SPC) is a type of Intellectual Property Right which extends the patent term and is applicable to approved specific pharmaceutical and plant protection products in European Union (EU). On 01 July 2019, Regulation (EU) 2019/933 of 20 May 2019 concerning SPC came into force. It is also referred as "the SPC manufacturing waiver" Regulation and was published in the Official Journal of the EU on 11 June 2019. Similarly, Canada also introduced Certificate of Supplementary Protection (CSP) Regulations on 21 September 2017. It is governed by provisions in the Canadian Patent Act and the CSP Regulations. These developments would have impact on global pharmaceutical industry including United States of America (US). US being the largest pharmaceutical market, policy making in US has direct and indirect impact on global pharmaceutical industry. Thus, it is important to study SPC or CSP manufacturing waiver in light of the developments in the USA. On 30 October 2019, United States Food and Drug Administration (USFDA) released a report on Drug Shortages. Apart from identifying root causes for drug shortages, the Report also recommended enduring solutions to maintain or enhance the quality of medicines and manufacturing facilities.

This research work compares EU and Canadian SPC/CSP manufacturing waiver developments with each other. In-depth analysis of the impact of these SPC/CSP manufacturing waivers on competition amongst pharmaceutical companies, economic impact on patients and pharmaceutical companies, swifter access to generic medicines, rise of new generic companies has been carried out. The impact of suggestion from USFDA to create a rating system for manufacturing facilities in light of these SPC/CSP manufacturing waiver is also studied. It was observed that there are few important differences between these manufacturing waivers of EU and Canada. These waivers would have an impact on the manufacturing facilities of pharmaceutical product. It could change the manufacturing clusters like China and India, which exists today and would increase the competition amongst the pharmaceutical manufactures.

※ The views expressed in this article are those of the authors' and not of Lupin Limited and Manipal Academy of Higher Education.

It is likely to help reduce the cost of generic medicines especially in USA and EU region.

Keywords: Certificate of supplementary protection, Manufacturing waiver, Patent term extension, Supplementary protection certificate, USFDA

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I. Introduction

Under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, the current available term of patent protection expires no earlier than twenty years from the date of first filing. Although, the topic of Patent Term Extension (PTE) to compensate for regulatory delays was raised in the Uruguay Round of negotiations, the TRIPS Agreement does not contain an obligation to introduce such an extension. Supplementary Protection Certificate (SPC) is a type of Intellectual Property Right which extends the patent term and is applicable to approved specific pharmaceutical and plant protection products in European Union (EU).In September 2017, Canada allowed similar type of extension known as CSP.

II. SPC and Related Recent Developments in European Union

On 28 May 2018, the European Commission (EC) proposed amending the Regulation (EC) No.469/2009 concerning the SPC for medicinal products to create a new exception to the infringement of SPC.[1] On 01 July 2019, Regulation (EU) 2019/933 of 20 May 2019 came into force. Term of the SPC remains unchanged. It is up to five years with further extension possible up to six months if paediatric studies are performed. It is also referred as "the SPC manufacturing waiver" Regulation and was published in the Official Journal of the EU on 11 June 2019. The new exception is known as the "SPC manufacturing waiver", since it would permit manufacturing a protected technology with the exclusive aim of either exporting to third countries or entering the market right after the expiry date of the SPC. This proposal was welcomed and at the same time was criticized also (especially by USA based pharmaceutical giants). This change will now allow European pharmaceutical companies to access the USA market as well as the European market earlier than before. Prior to Regulation (EU) 2019/933, SPC Regulation (EC) No. 469/2009 had two unintended consequences: It had prevented EU based manufacturers from manufacturing medicinal products, even for the purpose of (i) exporting and (ii) to enter the EU market immediately after expiry of the SPC, given that manufactures were notable to build up the production capacity. This was leading to a significant competitive disadvantage. Although, the 'Bolar' provision has allowed activities necessary for securing Marketing Authorization prior to expiry of such protection, however any commercial activities would invite the infringement of patent or SPC protection. Regulation (EU) 2019/933 will enable European manufacturers to be competitive abroad and in the European territory after the expiry of an SPC because it will now allow the production of a medicine for which a Marketing Authorisation has been obtained in a third country despite the existence of an SPC in the country of manufacture in EU.[2] The proposal to amend the SPC regulation to include the export exception was put forth many times since 2003, but it was not accepted by the European Commission (EC). The 'Comprehensive Economic and Trade Agreement' (CETA) and the findings of studies commissioned by the EU lead to the recent Proposal of amendment. Charles River Associates conducted a study to assess the economic impact on the EU pharmaceutical industry, at the directions of the DG

[1] Regulation (EU) 2019/933 of The European Parliament and of The Council of May 20, 2019. (Accessed on Dec. 20, 2019 from https://eur-lex.europa.eu/eli/reg/2019/933/oj)

[2] Roche Products, Inc. Appellant, v. Bolar Pharmaceutical Co., Inc., Appellee, 733 F.2d 858 (Fed. Cir. 1984). (Accessed on Dec. 20, 2019 from https://law.justia.com/cases/federal/appellate-courts/F2/733/858/459501/)

(Directorate-General) Internal Market, Industry, Entrepreneurship and (Small Medium Enterprises) SMEs.[3] Similar conclusions were drawn in Copenhagen Economics' Study and Max Planck Institute for Innovation and Competition study.[4] The opinion was issued in February 2016 and published by the EC on 05 October 2017 with the title of "Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe". It was clear that the SPC export waiver and the day-1 launch would benefit the EU pharmaceutical industry i.e. increase in exports of the EU pharmaceutical industry between 6 to 18% and, if the day-1entry were introduced, savings on pharmaceutical expenditure between 1 to 4%.[5] The objectives of this amendment were: (a) to ensure that EU based manufacturers (makers) were able to compete effectively in third-country markets where supplementary protection is not granted, or had successfully challenged or had expired; (b) to put EU based manufacturers (makers) in a better position to enter the Union market immediately after expiry of the relevant SPC; and (c) to serve the aim of fostering access to medicines. After 15 years since it was first proposed this manufacturing exception clause was accepted, although limiting its application to SPCs.

This SPC manufacturing waiver is not violation of TRIPS agreement. TRIPS do not apply to SPCs. The SPC is an extension of Patent Term based on local effects of the delay in obtaining a Market Authorisation for a medicament. It is established in the TRIPS Agreement that the term "intellectual property" refers to (1) Copyright and Related Rights; (2) Trademarks; (3) Geographical Indications; (4) Industrial Designs; (5) Patents; (6) Layout-Designs(Topographies) of Integrated Circuits; and (7) Protection of Undisclosed Information.[6] Thus, SPCs are not the object of regulation in the TRIPS Agreement.Thus, the TRIPS Agreement does not extend to SPCs or patent restoration terms and the member states are free to decide on whether they are regulated or not and with what terms and limitations.Countries that approved an extension for patents are USA in 1985, South Korea in 1987, Japan in 1988, Australia in 1990, Taiwan in1994, Israel in 1998, Ukraine in 2000, Belarus in 2002, Russia in 2003, Commonwealth of Independent States (CIS) in 2004, Singapore in 2004, and Canada in 2017.[7]

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[3] RAPHAËL DE CONINCK, ELINA KOUSTOUMPARDI, ROMAN FISCHER, & GUILLAUME DÉBARBAT, ASSESSING THE ECONOMIC IMPACTS OF CHANGING EXEMPTION PROVISIONS DURING PATENT AND SPC PROTECTION IN EUROPE (2016). (Accessed on Dec. 31, 2019 from https://publications.europa.eu/en/publication-detail/-/publication/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1/language-en)

[4] COPENHAGEN ECONOMICS, STUDY ON THE ECONOMIC IMPACT OF SUPPLEMENTARY PROTECTION CERTIFICATES, PHARMACEUTICAL INCENTIVES AND REWARDS IN EUROPE (2018). (Accessed on Jan. 31, 2020 from https://op.europa.eu/en/publication-detail/-/publication/8ffeb206-b65c-11e8-99ee-01aa75ed71a1/language-en)；Max Planck Institute for Innovation and Competition, *Study and annexes on the legal aspects of Supplementary Protection Certificates in the EU*, EUROPEAN COMMISSION (May 28, 2018), https://ec.europa.eu/docsroom/documents/29524.

[5] EUROPEAN COMMISSION, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS - UPGRADING THE SINGLE MARKET: MORE OPPORTUNITIES FOR PEOPLE AND BUSINESS (2015). (Accessed on Feb. 01, 2020 from https://ec.europa.eu/transparency/regdoc/rep/1/2015/EN/1-2015-550-EN-F1-1.PDF)

[6] Articles 9 to 39 of the Agreement on trade-related aspects of intellectual property rights (TRIPS), 15 Apr. 1994.

[7] Miguel Vidal-Quadras, *Analysis of EU Regulation 2019/933 on the SPC Manufacturing Waiver*

F. Activities Permissible Under the SPC Manufacturing Waiver for Export Purpose[8]

Article 5(2)(a) provides protections for certain acts against infringement of an SPC under the exception. Article 5(2) states that "By way of derogation from paragraph 1, the certificate referred to in paragraph 1 shall not confer protection against certain acts which would otherwise require the consent of the holder of the certificate ('the certificate holder'), if the following conditions are met".

1. the acts comprise: (i) the making or any related act necessary for export of a product to third countries and (ii) no earlier than six months before the expiry of the certificate, the making or any related act necessary for the stockpiling for day-1 entry purpose;

2. the maker notifies the authority of concerned member state and informs the certificate holder no later than three months before the start date of the making in that member state, or no later than three months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by a certificate, whichever is the earlier;

3. if the information as per above point 2 changes, the maker notifies the authority of concerned member state and informs the certificate holder, before those changes take effect;

4. for the purpose of export to third countries, the maker ensures that a logo is affixed to the outer packaging of the product, or where feasible, to its immediate packaging.

Subsection (a) covers the acts which comprise the making of a product, or a medicinal product containing that product for the purpose of export to third countries or of storing it in the member state of making for day-1 entry the SPC expiry. It implies not only that the acts carried out by the maker are included in the exception, but also those acts carried out by the maker itself or by third parties that are required either to enable the making or the export of the product made.Recital 9 of the amended regulation relates to the examples of activities that would be covered by the exceptions to SPC rights. Such activities include: (i) Possessing, supplying, offering to supply, importing, using or synthesising an active ingredient for the purpose of making a medicinal product containing the product; (ii) Temporary storing or advertising for the exclusive purpose of exporting to third-country destinations; and (iii) Related acts performed by third parties who are in a contractual relationship with the maker. Recital 11 of the amended regulation relates to the examples of activities that would not be covered by the exceptions to SPC rights. Such activities are: (i) Placing a product or a medicinal product containing that product on the market of a member state, which is made for the purpose of export to third countries whenever an SPC has not been extended or is not in force in that country; (ii) Storing a product or a medicinal product containing that product with a view to EU day-1entry on the

Exception, 50(8) IIC INT REV IND PROP COPYR Law 971, 971-1005 (2019). ; Communication from European Commission, *EU-Canada trade agreement enters into force*, EUROPEAN COMMISSION (Sep. 20, 2017), http://trade.ec.europa.eu/doclib/press/index.cfm?id=1723.

[8] Article I of Regulation (EU) 2019/933 of The European Parliament and of The Council of May 20, 2019. (Accessed on Dec. 20, 2019 from https://eur-lex.europa.eu/eli/reg/2019/933/oj)

market of a member state where a certificate is in force, either directly or indirectly after export; (iii) Re-importation of such a product or a medicinal product containing that product into the market of member state in which a certificate is in force; (iv) Any act or activity for the purpose of import of products or medicinal products containing those products into the Union merely for the purposes of repackaging and re-exporting; and (v) Any storage of products or medicinal products containing those products for any purposes other than those set out in the Regulation.

G. Activities Permissible Under the SPC Manufacturing Waiver for Day-1 Entry[9]

In absence of Amended Regulations, the Commission stated that the EU industry is "at a significant competitive disadvantage compared with manufacturers based in third countries that offer less or no protection" from export and day-1 entry point of view.[10] The combined effects of an SPC export waiver and a stockpiling exemption are likely to be mutually reinforcing, as EU based generic and biosimilar producers that have already set up large scale production to supply export markets will also be able to prepare stocks for timely entry upon domestic SPC protection expiry.[11] In the initial proposal for amending the SPC regulation, it was proposed that Stockpiling should be allowed with a limitation on its applicability to two years before the expiry of the SPC, but the limitation was finally reduced to six months by the European Council without any justification. This limitation of six months may not be helpful in all cases e.g. producers of biosimilars wherein the preparedness generally requires time more than six months. Many complexities are involved in manufacturing of a biosimilar product. The European Council also made a provision regarding the evaluation, of usefulness of manufacturing waiver and related amendments, to be carried out after five years.[12]

H. Requirements for Taking Benefit of SPC Manufacturing Waiver for Export as well as Day-1 Entry

Apart from the manufacturing exception, the amendment also establishes a specific regimen of safeguards, "in order to increase transparency, to help the holder of a certificate to enforce its protection in the Union and check compliance with the conditions set out in this regulation and to reduce the risk of illicit diversion onto the Union market during the term of the certificate". It requires: (a) a special labelling of the product manufactured for export; (b) an obligation to inform clients; and (c) the obligation to make a communication to the certificate holder as well as to the corresponding patent offices with certain information of the maker that will be

[9] *Id.*
[10] European Commission - Press release, *Pharmaceuticals: Commission refines intellectual property rules*, EUROPEAN COMMISSION (May 28, 2018), https://ec.europa.eu/commission/presscorner/detail/en/IP_18_3907.
[11] Recital 8 of Regulation (EU) 2019/933 of The European Parliament and of The Council of May 20, 2019. (Accessed on Dec. 20, 2019 from https://eur-lex.europa.eu/eli/reg/2019/933/oj)
[12] *supra* note 8.

published.[13]

1. Labelling Requirement

The amended regulation imposes labelling requirements on the maker in order to facilitate, by means of a logo, identification of such products or such medicinal products as being exclusively intended for the purpose of export to third countries.[14]

Article5(2)(d) states that "the maker ensures that a logo, in the form set out in Annex I, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging". The logo as per Annex I is reproduced below:[15]

Products not labelled as indicated in the Regulation will not fall under the exception, unless an appropriate reason is given by the manufacturer (for instance, if the product has not been packaged yet or the outer packaging is commissioned to a third company).

2. Client Notification Requirement

The amended regulation establishes that the makers will have to inform persons within its supply chain in the Union, including the exporter and the person carrying out the storing, through appropriate and documented means, in particular contractual means, that the product, or the medicinal product containing that product, is covered by the exception provided for in this regulation and that the making is intended for the purpose of export or storing. The obligation of information established in the regulation is aimed at informing those within the supply chain of the maker or downstream. Failure to do so could result in infringement and thus would not be able to take the benefit of manufacturing exception. Thus, the SPC holder may take necessary action.

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[13] *supra* note 1.
[14] *supra* note 8.
[15] Annex I of Regulation (EU) 2019/933 of The European Parliament and of The Council of May 20, 2019. (Accessed on Dec. 20, 2019 from https://eur-lex.europa.eu/eli/reg/2019/933/oj)

3. State/(s) Authorities and SPC Holder Notification Requirement

The amended regulation requires that the maker should provide certain information to the state or states authorities like industrial property office, or another designated authority, which granted the certificate in state where making is to take place and the SPC holderno later than three months before the start of making or of the first related act.Failure to do so may result in infringement of an SPC. The state or states authorities shall publish the information as soon as possible.[16] According to Recital 15, the information notified is limited to what is "necessary and appropriate" for the SPC holder to assess if its rights are respected, and "should not include confidential or commercially sensitive information", which is consistent with EU Directive 2016/943.

I. Date of Application of Regulation (EU) 2019/933

The amended regulation stated the date of application as02 July 2022 and to any certificate that takes effect as from the entry into force, which was 01 July 2019, therefore being effective three years after the entry into force of the Regulation.[17]

III. CSP and Related Recent Developments in Canada

In October 2016, the European Union (EU) and Canada signed 'Comprehensive Economic and Trade Agreement' (CETA).[18] Under CETA, in order to bring Canadian patent practice more in line with European practice, Canada agreed to make number of important changes to intellectual property protection for pharmaceutical patents.[19] Canada amended its *Patent Act 1985* and introduced CSP for pharmaceutical and veterinary products on 21 September 2017.[20] This is a significant development as Canada has lagged behind other industrialized countries in the protection of pharmaceutical and veterinary patents, since no extension of patent term was previously available.

The rights provided by Canadian Patent Act with respect to patents, give patent owner the exclusive right to use the invention for typically up to 20 years from the date of first patent filing. CSP can further extend this term. The Canadian CSP regime

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[16] *supra* note 11.
[17] Recital 26 of Regulation (EU) 2019/933 of The European Parliament and of The Council of May 20, 2019. (Accessed on Dec. 20, 2019 from https://eur-lex.europa.eu/eli/reg/2019/933/oj)
[18] Communication from European Commission, *supra* note 7.
[19] Jennifer Ledwell, *Update on implementing CETA in Canada - What pharmaceutical companies need to know*, LEXOLOGY (May 10, 2017), https://www.lexology.com/library/detail.aspx?g=66437b46-9961-455e-aacf-572f930796f2.
[20] Canadian 'Patent Act 1985' amended on Sep. 21, 2017.

has been created with the aim of meeting obligations under Article 20.27 of CETA, which requires parties to provide an additional period of protection for patent-protected pharmaceutical products, while continuing to balance the interests of stakeholders and the public within the Canadian Patent Act. Amendment to Canadian Patent Act introduced CSP regime. Various timelines, requirements and procedures regarding CSP regime are defined in Sections 104 – 134 of the Canadian Patent Act. Both generic and innovative industry members were involved in the consultations.[21]

A. Scope of Supplementary Protection in Canada[22]

The issuance of a CSP grants the certificate holder and their legal representatives, during the certificate term, the same rights, privileges and liberties that are granted by the patent set out in the certificate. But these rights, privileges and liberties are granted only with respect to the making, constructing, using and selling of any drug that contains the medicinal ingredient, or combination of medicinal ingredients, set out in the certificate, by itself or in addition to any other medicinal ingredient. These rights, privileges, and liberties granted by CSP are transferable only if the patent is transferred. If these rights are violated by anyone then an action for the infringement of a CSP can be brought similar to an infringement of a Canadian patent. Canada Government may apply to use invention protected by a CSP. It is not an infringement of the CSP for any person to make, construct, use or sell the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada.

Section 115(2) of Canadian Patent Act states that with the title of "No infringement – export", "Despite subsection (1), it is not an infringement of the CSP for any person to make, construct, use or sell the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada". Subsection (1) states that "The issuance of a CSP grants the certificate's holder and their legal representatives, during the certificate's term, the same rights, privileges and liberties that are granted by the patent set out in the certificate, but only with respect to the making, constructing, using and selling of any drug that contains the medicinal ingredient, or combination of medicinal ingredients, set out in the certificate, by itself or in addition to any other medicinal ingredient."

B. Term of the Canadian CSP[23]

The term of CSP is determined by subtracting five years from the period

[21] Certificate of Supplementary Protection Regulations, Canada Gazette Part II, Extra Vol. 151, No. 1, Sep. 07, 2017.
[22] *supra* note 20.
[23] *supra* note 20.

beginning on the filing date of the patent application and ending on the day on which the authorization for sale is issued, but in any event is not more than two years.

CSP Term = [Notice of compliance date – Patent filing date] – five years, with a cap of two years.

Notice of compliance (NOC) is a notice issued by Government of Canada (Ministry of Health) to a manufacturer following the satisfactory review of a submission for a new drug and signifies compliance with the Food and Drug Regulations of Canada. Notice of compliance date is the date that a therapeutic product was granted market authorization by receiving a NOC. Canadian Minister of Health may reduce the term of the CSP if unjustified delay in obtaining the authorization for sale is found. The CSP takes effect only if the patent remains valid until, and not void before, the expiry of that term. A CSP issued never takes effect if the calculation of its term produces a result of zero or a negative value.

Table 1: Comparison between Manufacturing Waiver during SPC and CSP Period

S. No.	Description	EU	Canada
1	Term of extension	Up to five years	Up to two years
2	Paediatric extension	Six months of extension due to paediatric studies is possible, thus total term up to five and a half year[24]	Not allowed
3	Manufacturing waiver for export purpose	Allowed	Allowed
4	Manufacturing for export purpose can start	Anytime during the term of SPC, not before SPC comes in force	Anytime during the term of CSP, not before CSP comes in force
5	Manufacturing waiver for stockpiling	Allowed	Not allowed
6	Manufacturing for stock piling can start	Not before 6 months from the expiry of SPC term	Not allowed
7	Manufacturing waiver for export of Generic and Biosimilar	Allowed	Allowed
8	Special labelling requirements for export purpose	Yes	No

IV. Impact of SPC/CSP Manufacturing Waiver on Global Pharmaceutical Market

A. Impact on Global Manufacturing Sector

Study of impact of SPC/CSP manufacturing waiver on global pharmaceutical industry is one of the objectives of this research work. Since, the demand for medicines is increasing mainly because of aging population, it could be an opportunity for pharmaceutical manufactures to expand the manufacturing capacities and thus expand the business globally. Demand for medicines in developed and developing countries like China, India, and other Asian countries is in uptrend.EU or Canada based manufactures can cater to medicinal needs of many emerging markets as well. EU or Canada based manufacturers can also ride onto the wave of expanding pharmaceutical market now. Along with the volume of manufacturing, it is also important to maintain the quality of medicines and maintain the quality of manufacturing facilities high and compliant to global standards. Looking into the past,

[24] Article 13 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of May 6, 2009.

it is possible for EU or Canada to achieve such high degree of quality compliance and thus gain the competitive advantage.

US is the largest pharmaceutical market in the world. Thus, any development in US has impact on global pharmaceutical industry. Thus, it is important to study SPC or CSP manufacturing waiver in light of the developments in the USA. Since, these waivers are related to manufacturing and thus related to manufacturing facilities, it is significant to study the impact of manufacturing facility inspections carried out by USFDA. Inspections of manufacturing locations are regularly done by USFDA. Recently, in December 2019, United States Government Accountability Office published a report. According to the report, USFDA inspects foreign manufacturing facilities to a large extent. Figure 1 below depicts domestic (within US) and foreign inspections conducted by USFDA year-wise.[25]

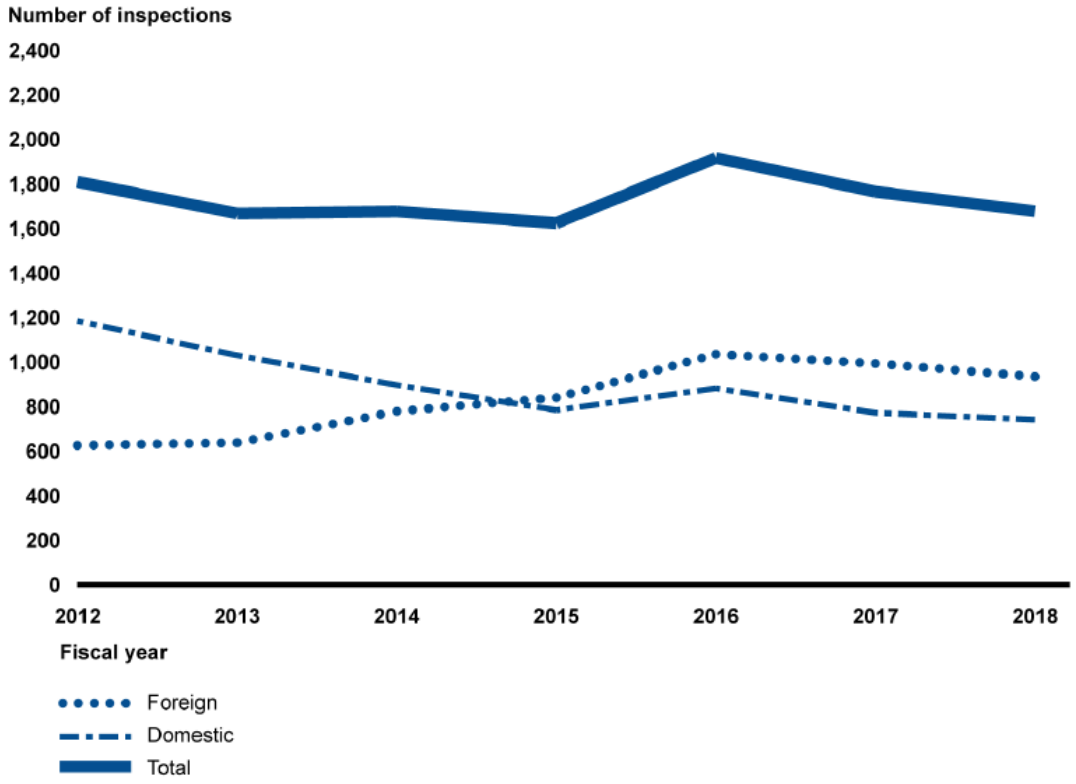

Figure 1:
Total Number of FDA Inspections of Foreign and Domestic Drug Establishments, Fiscal Year 2012 Through 2018
Source: United States Government Accountability Office

Table 2 below depicts that establishments in India were the most frequently inspected, followed by ones in China and Germany. The report also states that large number of manufacturing facilities are located outside US, mostly in India and China.

[25] MARY DENIGAN-MACAULEY, DRUG SAFETY - PRELIMINARY FINDINGS INDICATE PERSISTENT CHALLENGES WITH FDA FOREIGN INSPECTIONS (2019). (Accessed on Dec. 20, 2019 from https://www.gao.gov/assets/710/703078.pdf)

Drugs sold in the United States are manufactured across the world.[26]

Out of the total 935 foreign inspections, 252 inspections were carried out in India alone and 153 in China.

Table 2: Total Number of FDA Foreign Drug Inspections, By Country, Fiscal Year 2012 Through 2018

Country	2012	2013	2014	2015	2016	2017	2018
India	140	110	114	204	207	219	252
China	59	74	113	127	173	165	153
Germany	59	60	72	68	72	69	68
Canada	49	51	39	52	56	72	48
Italy	38	45	50	41	69	46	45
Japan	49	28	47	31	65	46	43
South Korea	4	7	8	5	13	56	40
France	25	37	44	45	55	42	36
Switzerland	23	23	37	31	37	25	32
United Kingdom	29	27	33	43	41	40	12
All Other Countries	150	175	222	193	247	213	206
Total Foreign	625	637	779	840	1,035	993	935
Total Domestic (USA)	1,184	1,030	897	784	882	772	742

As of March 2019, India and China had the most manufacturing establishments shipping drugs to the United States, with about 40 percent of all foreign establishments. Most of these USFDA approved manufacturing facilities are situated outside EU for multiple reason, one of which was SPC bar for manufacturing products for export to third countries where such protection is either not granted or is expired or is successfully challenged and immediate entry after the expiry of SPC i.e. day-1

[26] *Id.*

entry in member states. Since, these SPC waiver are introduced, EU based manufactures can now compete with non-EU manufactures. Out of 32 warning letters issued by the Office of Manufacturing Quality, USFDA till November 2019, 15 warning letters were issued for Indian Pharmaceutical Manufactures. This is an alarming situation for Indian Pharmaceutical Industry. EU and Canada based manufactures can take benefit of current situation of warning letters to non-EU manufactures and can flourish the manufacturing sector based in EU or Canada. USFDA's suggestion given in October 2019 report on drug shortages regarding creating a rating system to measure and rate the manufacturing facilities could further give advantage to EU or Canada based manufactures. Apart from identifying root causes for drug shortages, the report also recommended enduring solutions to maintain or enhance the quality of medicines and manufacturing facilities.[27] The report identifies three root causes for drug shortages: (i) Lack of incentives for manufacturers to produce less profitable drugs; (ii) The market does not recognize and reward manufacturers for "mature quality systems" that focus on continuous improvement and early detection of supply chain issues; and (iii) Logistical and regulatory challenges make it difficult for the market to recover from a disruption. The report also recommends enduring solutions: (i) Developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and (ii) Promoting sustainable private sector contracts. USFDA stated that the market does not recognize and reward mature quality management. It suggested creating a rating system to measure and rate the quality management maturity of individual manufacturing facilities based on specific objective indicators to incentivize drug manufacturers to invest in achieving quality management system maturity. No such rating system currently exists for drug manufacturing facilities. A rating would state the quality of compliance at a manufacturing facility and thus, could be useful for purchasers and group purchasing organizations (GPOs) to know about the state of, and commitment to, the quality management of the facility making the drugs they are buying. It also stated that Pharmaceutical companies could disclose the rating of the manufacturing facilities. GPOs and purchasers may ask Pharmaceutical companies about the rating that has been awarded to the manufacturing facility related to the manufacturing facility where the concerned drug is getting manufactured. Contracts between pharmacy benefit managers (PBMs), insurers, wholesalers, and pharmacies decide financial exchange in terms of fees, chargebacks, discounts, and rebates.[28] Since, the top-rated producers will get a

[27] DRUG SHORTAGES TASK FORCE, DRUG SHORTAGES: ROOT CAUSES AND POTENTIAL SOLUTIONS (2019). (Accessed on Mar. 14, 2020 from https://www.fda.gov/media/131130/download)

[28] Neeraj Sood, Tiffany Shih, Karen Van Nuys, & Dana P. Goldman, *Follow The Money: The Flow of Funds In The Pharmaceutical Distribution System*, HEALTH AFFAIRS (Jun. 13, 2017),

competitive advantage and thus would be motivated to achieve highest level of rating as these rating would be helpful for manufactures to negotiate better financial terms and also the assurance that chances of supply disruption due to warning letter/import alerts is minimum. This rating system would: (i) Communicate the value of quality management maturity so it can be adopted by manufacturers and priced into contracts by purchasers; (ii) Promote the adoption of better tools to measure manufacturing performance to allow earlier detection of potential problems that could lead to shortage; and (iii) Incentivize improvements to manufacturing infrastructure that enhance reliability of manufacturing and thus supply. Thus, looking into current scenario of rate of warning letters issued by USFDA for manufacturing facilities, EU based manufacturer can emerge as an alternate manufacturer with high quality compliant facilities and securing high rating for such facilities from USFDA. Since, SPC and CSP manufacturing waiver is now in place, EU or Canada based manufacturers could benefit by exporting products to USA market for day-1 entry. In July 2019, EU and US fully implemented the mutual recognition agreement (MRA) for inspections of manufacturing sites for certain human medicines in their respective territories. Under the MRA, EU and US regulators will now rely on each other's inspections for human medicines in their own territories and hence avoid duplicative work. As a result of the MRA, both the EU and the US will be able to free up resources to inspect facilities in other countries. Particularly in light of the USFDA's suggestion of creating such rating system for manufacturing facilities, the SPC/CSP manufacturing waivers of EU and Canada appears to have potential to shift the pharmaceutical manufacturing significantly from Asian countries like China and India and to slighter extent from the United States of America (USA) to Europe or Canada especially considering the compliance issues being faced by Indian and Chinese manufacturing facilities.[29] It would also add additional responsibility on existing generic players to maintain or improve the quality of the generic medicines and manufacturing facilities. In addition, it is likely to increase the competition for current generic players as new generic players from EU and Canada would emerge in near future.

B. Impact on Competition and Pricing of Medicines

The probable change as mentioned above is likely to enhance the competition and thus reduce the cost of generics further. Medicines price depends on stakeholders across the developed and developing world. According to IQVIA Institute report of

https://www.healthaffairs.org/do/10.1377/hblog20170613.060557/full/.

[29] Timo Minssen, Aaron S. Kesselheim, & Jonathan J. Darrow, *An export-only exception to pharmaceutical patents in Europe: should the United States follow suit?*, 37(1) Nat. Biotechnol. 21, 21-22 (2019).

2019, the global pharmaceutical market is expected to exceed $1.5 trillion by 2023 growing at 3–6% compound annual growth rate. Since, 18 of the current top-20 branded drugs will be facing generic or biosimilar competition by 2023, the impact is expected to be $121 billion between 2019 and 2023, mostly in the US. Global growth of medicine spending through 2023 will primarily be driven by developed markets and their adoption of a wave of newly launched innovative products.

According to "Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices" report of USFDA published in December 2019: (i) Single generic producer, the generic average manufacturer prices (AMP) is 39% lower than the brand drug price before generic competition, compared to a 31% reduction using invoice-based drug prices; (ii) Two competitors, AMP data show that generic prices are 54% lower than the brand drug price before generic competition, compared to a 44% reduction using invoice-based drug prices; (iii) Four competitors, AMP data show that the generic prices are 79% less than the brand drug price before generic entry, compared to a 73% reduction using invoice-based drug prices; and (iv) Six or more competitors, generic prices using both AMP and invoice-based drug prices show price reductions of more than 95% compared to brand prices before generic entry.[30]

V. Conclusion

It was found that on one hand, this new European regulation provides exemption to Europe based generic and biosimilar companies to manufacture products for export and stockpiling purpose during the SPC period and on the other hand, it reduces the period of indirect unintended exclusive rights of innovators. It has opened a door for European medicine manufactures to (i) enter the market on day-1 after expiry of SPC and (ii) export their products to such countries where SPC is not in force or is not awarded. It was observed that there are few important differences between these manufacturing waivers of EU and Canada. The manufacturing waiver periods are not enough for certain type of products e.g. biological products. Also, particularly in light of the USFDA's suggestion of creating a rating system for manufacturing facilities, these manufacturing waivers have potential to shift the pharmaceutical manufacturing significantly from Asian countries like China and India and to slighter extent from the United States of America (USA) to Europe or Canada. In addition, it is likely to increase the competition for current generic players as new generic players from EU and Canada would emerge in near future. This probable change in current generic scenario is likely to enhance the competition and thus reduce the cost of generics further. It would also add addition responsibility on existing generic players to maintain or improve the quality of the generic medicines and manufacturing facilities.

[30] RYAN CONRAD, & RANDALL LUTTER, GENERIC COMPETITION AND DRUG PRICES: NEW EVIDENCE LINKING GREATER GENERIC COMPETITION AND LOWER GENERIC DRUG PRICES (2019). (Accessed on Feb. 14, 2020 from https://www.fda.gov/media/133509/download)

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Combining Brand Equity Questionnaire with Weighted Average Cost of Capital

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Abstract

Brand is a multi-dimensional type of intangible asset, that has a significant effect on success of a corporation in market. So, measuring the amount of its strength, would help managers and marketers to find out the potential value of their brand. Also, a more valuable brand can generate more cash. In the leading research, a new approach for evaluating value of a brand according to its strength is presented. The new approach is structured based on Brand Equity Strength concept and Weighted Average Cost of Capital (WACC). In order to making this method, 5 phases were taken. First structured literature of brand equity was reviewed. 136 main parameters with effect on brand equity strength were gained in this part. Second 426 business experts were interviewed. Third, a Brand Equity Strength (BES) questionnaire was introduced (according to literature review and interview result). fourth, WACC formula was changed and improved (according to experts' opinion). At last, the BES questionnaire and improved WACC were integrated so that a new quantitative-qualitative method for brand evaluation was generated. 40 public companies' brands were evaluated by the new approach and 2 other existing approaches. By comparing the results of them, accuracy of the new approach was approved.

Keywords: Brand Equity, Brand Equity Strength, Weighed Average Cost of Capital, Intangible Asset, Brand Equity Valuation

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I. Introduction

Twenty first century is age of new form of competition among businesses. Companies should pay more attention on different potentials of their own. Assets are one of these potentials. Mostly, assets can be divided into one of two categories: tangible and intangible. Traditionally, physical assets are considered as tangible assets and intellectual properties like trademarks, copyrights and brands are taken into account as intangible assets. Today, more and more of business enterprises' worth are tied up in intangible assets. Most intangible assets generate premium returns for the business that owns them, either through an increase in revenues or through a reduction in costs.[1] It is increasingly important to correctly value these assets in order to properly represent it to an owner that owns the asset, a creditor with an interest in the asset, or a buyer that wants to buy the asset.[2]

The primary intangible capital of many businesses is their brands. A strong brand can help customers to choose the best product or service in the market.[3] This kind of purchasing decision from customers' perspective, leads to market competition for different enterprises that are working in a specific market.[4] The idea that a brand has an equity that exceeds its conventional asset value was developed by financial academic and practical experts. The escalation of new product development costs, and the high rate of new product failure, has led manufacturers to engage in brand extension.[5] A growing body of evidence supports the importance of brands and brand management for B2B and B2C marketers across multiple industries.[6]

As far back as 5000BC, identity marks were used on pottery. However, these ancient marks identified the owners of the goods rather than the manufacturer. In the twelfth century, the use of trademarks became widespread. Craft guilds required that members mark their goods so that the quantity and quality of products could be controlled. Branded products usually guarantee that products of a unique brand will be of uniform quality. Usually, the value of a brand is indicated by the money that customers are willing to pay for the products; but, it's not an accurate method.

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Whenever customer, believes that a product or service form a specific brand, has high quality or a specific feature, he/she would pay even more than usual to buy that product or use that service.

There are various methods of valuing brand equity, some of which are more robust than others. Unfortunately, there is a lack of global consensus as to which methods are preferred and this in turn leads to a lack of confidence in the area. Improving the existing approaches may lead to wider acceptance of these methods.

This paper provides valuable insight into the measurement of brand equity in viewpoint of different kind of stakeholders and offers a foundation for future brand equity evaluation researches. This paper has several objectives. First, concept of Brand Equity Strength (BES) is used to measure the potentials of a company according to its brand. Second, a new form of Weighted Average Cost of Capital (WACC) formula is introduced which is improved by splitting the equities, adding risk, inflation and tax into it. At last, a new approach in order to evaluating brand equity is indicated through integrating BES and WACC. Major innovation of this study is that not only the introduced method can represent the financial value of a brand, but also, it can indicate the qualitative strengths and weaknesses of that brand. This quality measurement includes internal stakeholders' (like shareholders, managers, etc.) viewpoint, as well as, external stakeholders' (like customers, consumers, etc.) opinion.

II. Literature Review

The research method used in this study is a combination of systematic review and meta-synthesizes methodology. 821 articles from scientific databases IEEE, Science Direct, Emerald Insight, ProQuest, Taylor and Francis, Scientific, Sage and Wiley. In order to extract these articles, the following keywords were used: Pricing Models, Intellectual Property Valuation, Intangible Asset Valuation, Brand Evaluation, Brand Equity. The period in which articles were searched was between 1980 and 2018.

By reviewing the articles, 136 significant parameters from 361 related papers were identified that have effect on brand equity. These parameters have been introduced by various researchers as influential parameters on the brand equity and value. All these parameters effect on brand equity had been proved in main articles. Below, these parameters are given along with their number of uses in various articles. At first the name of the parameter is written, then in the parentheses the number of times which that parameter was used by researchers is shown. Then the articles which contain this parameter are written in bracket. Every number is related to an article in the reference part. (1) **Perceived Quality of Brand (132[7])**[8] ; (2) **Customer's Loyalty**

[7] Number of uses in different articles.

[8] Those articles are: Reference [2], [4], [11], [12], [15], [17], [20], [25], [35], [36], [41], [43], [44], [45], [48], [50], [51], [53], [56], [57], [58], [60], [61], [63], [65], [66], [67], [68], [69], [70], [72], [79], [80], [81], [83], [84], [88], [89], [91], [96], [101], [102], [104], [109], [113], [114], [115], [116], [117], [127], [131], [133], [136], [139], [144], [151], [153], [159], [162], [163], [164], [165], [167], [174], [179], [182], [184], [185], [186], [189], [195], [199], [200], [202], [208], [210], [212], [213], [215], [216], [220], [222], [224], [226], [228], [233], [237], [239], [240], [242], [245], [247], [248], [251], [254], [255], [256], [260], [262], [265], [273], [275], [276], [277], [279], [280], [284], [289], [294], [301], [302], [303], [304], [307], [310], [311], [312], [313], [314], [318], [320], [324], [329], [333], [335],

to the Brand (119)[9]; (3) **Awareness/Mental Association of Brand (82)**[10]; (4) **Brand Image (62)**[11]; (5) **Emotional Relationship with Brand (39)**[12]; (6) **Customer Satisfaction (33)**[13]; (7) **Trust to Brand (31)**[14]; (8) **Marketing and sales' advertising (29)**[15]; (9) **Credit of Brand (27)**[16]; (10) **Experience Gained from Brand (25)**[17];(11) **Product Features (24)**[18]; (12) **Attitude to Brand (22)**[19]; (13) **Purchasing Goals (20)**[20]; (14) **Brand Position in Social Media (19)**[21]; (15) **Communications Brand (18)**[22]; (16) **Brand Associations (16)**[23]; (17) **Brand Identity (Brand Personality) (15)**[24]; (18) **Company and Reputation Image (15)**[25]; (19) **Popularity, Credit,**

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[341], [342], [344], [347], [350], [359], [360].

[9] Those articles are: Reference [1], [4], [6], [11], [15], [17], [19], [23], [35], [37], [43], [45], [54], [55], [57], [65], [66], [67], [68], [71], [81], [83], [89], [90], [92], [96], [97], [102], [113], [114], [115], [116], [124], [127], [131], [135], [136], [144], [147], [149], [150], [151], [161], [162], [164], [165], [166], [170], [171], [172], [174], [179], [182], [183], [184], [185], [189], [193], [196], [202], [203], [204], [210], [211], [213], [216], [222], [223], [224], [225], [228], [230], [232], [239], [241], [244], [245], [247], [248], [251], [254], [260], [262], [269], [273], [274], [275], [276], [279], [280], [286], [287], [291], [293], [296], [298], [302], [303], [304], [305], [306], [309], [310], [312], [313], [315], [316], [317], [318], [320], [329], [338], [341], [347], [350], [352], [356], [358], [360].

[10] Those articles are: Reference [2], [7], [10], [11], [15], [17], [19], [20], [24], [35], [43], [44], [45], [50], [55], [57], [58], [66], [67], [102], [113], [114], [115], [124], [125], [127], [132], [134], [144], [151], [154], [159], [161], [163], [168], [172], [178], [179], [183], [184], [189], [190], [204], [207], [209], [210], [216], [222], [224], [225], [228], [239], [245], [247], [248], [249], [251], [252], [262], [268], [269], [271], [272], [276], [279], [280], [286], [293], [294], [301], [309], [310], [311], [313], [318], [320], [324], [329], [340], [347], [348], [360].

[11] Those articles are: Reference [5], [17], [24], [25], [31], [33], [35], [46], [50], [56], [66], [67], [68], [79], [89], [97], [102], [114], [124], [133], [144], [155], [159], [161], [162], [164], [168], [173], [178], [179], [182], [183], [185], [189], [202], [208], [209], [210], [212], [224], [227], [228], [237], [248], [255], [269], [272], [273], [274], [275], [286], [287], [293], [298], [301], [302], [303], [317], [319], [340], [347], [353].

[12] Those articles are: Reference [12], [13], [23], [26], [59], [76], [81], [84], [89], [92], [95], [105], [109], [120], [137], [139], [141], [155], [159], [165], [168], [170], [178], [215], [223], [232], [235], [240], [244], [250], [270], [274], [288], [292], [313], [317], [348], [351], [360].

[13] Those articles are: Reference [16], [31], [34], [66], [92], [102], [114], [118], [126], [131], [135], [143], [145], [152], [170], [171], [174], [193], [210], [215], [222], [241], [262], [269], [281], [305], [306], [311], [315], [316], [317], [328], [344].

[14] Those articles are: Reference [15], [20], [31], [37], [90], [92], [93], [109], [127], [134], [135], [136], [148], [170], [171], [181], [193], [203], [213], [215], [223], [225], [232], [270], [274], [284], [298], [301], [305], [315], [338].

[15] Those articles are: Reference [8], [21], [25], [41], [44], [53], [55], [62], [79], [81], [100], [101], [103], [111], [123], [124], [141], [142], [147], [186], [203], [242], [250], [276], [290], [299], [314], [351], [357].

[16] Those articles are: Reference [10], [46], [62], [68], [76], [88], [96], [100], [104], [130], [131], [134], [158], [174], [212], [221], [240], [251], [253], [258], [277], [298], [307], [317], [319], [334], [353].

[17] Those articles are: Reference [23], [25], [40], [70], [77], [90], [95], [109], [127], [141], [154], [166], [191], [220], [232], [235], [282], [301], [308], [317], [328], [346], [356], [358], [362].

[18] Those articles are: Reference [11], [14], [25], [72], [74], [97], [121], [122], [142], [168], [177], [191], [194], [196], [208], [214], [244], [252], [262], [282], [283], [319], [330], [333].

[19] Those articles are: Reference [7], [44], [46], [57], [79], [89], [95], [99], [126], [128], [200], [227], [231], [242], [261], [285], [296], [305], [306], [315], [340], [362].

[20] Those articles are: Reference [2], [4], [26], [74], [77], [82], [109], [115], [121], [151], [153], [168], [178], [194], [235], [261], [296], [300], [306], [336].

[21] Those articles are: Reference [33], [108], [124], [130], [156], [175], [184], [213], [221], [232], [252], [258], [270], [286], [287], [307], [337], [351], [353].

[22] Those articles are: Reference [2], [11], [29], [63], [126], [134], [159], [172], [216], [230], [239], [249], [280], [308], [315], [318], [347], [352].

[23] Those articles are: Reference [15], [36], [43], [45], [46], [113], [131], [161], [245], [251], [279], [294], [304], [313], [320], [334].

[24] Those articles are: Reference [29], [39], [112], [123], [212], [217], [225], [294], [295], [302], [314],

Image and Brand Role of the Country of Origin (15)[26]; (20) **Branding Strategy (13)**[27]; (21) **Price of Products (13)**[28]; (22) **Quality of Services and Products (11)**[29]; (23) **Innovations in Brand (9)**[30]; (24) **Social responsibility of the organization and stakeholders (9)**[31]; (25) **Word of Mouth Communications (8)**[32]; (26) **Brand Management (7)**[33]; (27) **Premium Payments (Insurance) (7)**[34]; (28) **Brand Knowledge (7)**[35]; (29) **Corporate Responsiveness Services (After Sales Service) (6)**[36]; (30) **Brand Strength (6)**[37]; (31) **Brand Identification (5)**[38]; (32) **Business Crises (5)**[39]; (33) **Investment (5)**[40]; (34) **Brand Culture (4)**[41]; (35) **Environmental Liability of the Company (4)**[42]; (36) **Organization Responsibility (4)**[43]; (37) **Understanding Risk (4)**[44]; (38) **Market Performance (4)**[45]; (39) **Intergenerational Communication (4)**[46]; (40) **Customer Relation Management (4)**[47]; (41) **Symbols and Slogans of the Organization (4)**[48]; (42) **The Role and Behavior of Staff (4)**[49]; (43) **Product Innovation (4)**[50]; (44) **Fake Goods - Gray Market (4)**[51]; (45) **Corporate Financial Value (4)**[52]; (46) **Consumer Behavior (4)**[53]; (47) **Consumer Characteristics (3)**[54]; (48) **Staff Loyalty (3)**[55]; (49) **Ability to Serve (3)**[56]; (50) **Promotion of Research and Development (3)**[57]; (51) **Customer Recognition Level of The Brand (3)**[58]; (52) **The quality of brand communication (3)**[59]; (53) **Partner**

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[315], [328], [352], [363].

[25] Those articles are: Reference [32], [34], [73], [95], [143], [145], [158], [176], [181], [186], [255], [261], [281], [321], [332].

[26] Those articles are: Reference [9], [19], [21], [39], [133], [137], [157], [169], [180], [201], [248], [257], [268], [347], [354].

[27] Those articles are: Reference [8], [10], [29], [55], [106], [123], [148], [196], [227], [267], [345], [349], [351].

[28] Those articles are: Reference [2], [5], [14], [74], [98], [106], [154], [166], [179], [214], [244], [289], [330].

[29] Those articles are: Reference [13], [14], [27], [105], [139], [150], [162], [219], [226], [236], [313].

[30] Those articles are: Reference [30], [34], [41], [71], [118], [208], [230], [256], [355].

[31] Those articles are: Reference [3], [147], [156], [158], [176], [228], [240], [264], [322].

[32] Those articles are: Reference [22], [194], [126], [136], [198], [239], [318], [346].

[33] Those articles are: Reference [42], [122], [191], [205], [256], [311], [319].

[34] Those articles are: Reference [36], [37], [117], [162], [238], [331], [360].

[35] Those articles are: Reference [24], [89], [128], [212], [230], [293], [317].

[36] Those articles are: Reference [109], [179], [236], [262], [284], [304].

[37] Those articles are: Reference [71], [251], [267], [268], [285], [308].

[38] Those articles are: Reference [225], [241], [291], [356], [359].

[39] Those articles are: Reference [84], [87], [261], [321], [339].

[40] Those articles are: Reference [12], [35], [105], [147], [174].

[41] Those articles are: Reference [28], [132], [189], [361].

[42] Those articles are: Reference [112], [128], [240], [337].

[43] Those articles are: Reference [240], [286], [307], [337].

[44] Those articles are: Reference [58], [136], [149], [188].

[45] Those articles are: Reference [179], [219], [229], [246].

[46] Those articles are: Reference [36], [47], [146], [260].

[47] Those articles are: Reference [80], [332], [335], [343].

[48] Those articles are: Reference [75], [79], [122], [289].

[49] Those articles are: Reference [27], [28], [241], [256].

[50] Those articles are: Reference [34], [78], [243], [278].

[51] Those articles are: Reference [69], [160], [263], [319].

[52] Those articles are: Reference [1], [10], [96], [325].

[53] Those articles are: Reference [48], [80], [113], [340].

[54] Those articles are: Reference [146], [215], [227].

[55] Those articles are: Reference [2], [13], [271].

[56] Those articles are: Reference [5], [129], [355].

[57] Those articles are: Reference [30], [278], [299].

[58] Those articles are: Reference [89], [316], [327].

and Joint venture Organizations' Brands (3)[60]; (54) **Customer Participation (3)**[61]; (55) **Integrated Marketing Communication (IMC) (3)**[62]; (56) **Sound Icon (3)**[63]; (57) **Corporate Governance Behavior (2)**[64]; (58) **Production, Circulation, Distribution, Marketing and Services (2)**[65]; (59) **Relations, Interactions and Social Identity in the Media Environment (2)**[66]; (60) **Quality of Electronic Services (2)**[67]; (61) **The Overall Ability of a Company or Organization (2)**[68]; (62) **Organization `s Performance (2)**[69]; (63) **Geographical Customer Attributes (2)**[70]; (64) **Consumer Gender (Female or Male) (2)**[71]; (65) **Brand Reputation (2)**[72]; (66) **Competency Supplier (2)**[73]; (67) **Culture, Ideology and Customer Values (2)**[74]; (68) **Information (2)**[75]; (69) **Trade Mark (2)**[76]; (70) **Information and Communication Technology ICT (2)**[77]; (71) **Brand Distinctions (2)**[78]; (72) **Customizing Services and Products (2)**[79]; (73) **Staff Satisfaction (2)**[80]; (74) **Behavioral Brand Citizenship (2)**[81]; (75) **Employee Commitment (2)**[82]; (76) **Brand Similarities (2)**[83]; (77) **Relationship Between Shareholders (2)**[84]; (78) **Ideal Self-Test (1)**[85]; (79) **Geographical Location of Companies and Service Providers (1)**[86]; (80) **Brand Rights (1)**[87]; (81) **Brand position in trade (1)**[88]; (82) **Penetration of the brand (1)**[89]; (83) **Individual Customer Knowledge of the Organization (1)**[90]; (84) **Stakeholder Interactions (1)**[91]; (85) **The Motivations of Decision Making in the Organization (1)**[92]; (86) **Personnel development (1)**[93]; (87) **Rival brand value**

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[59] Those articles are: Reference [55], [70], [282].
[60] Those articles are: Reference [52], [65], [219].
[61] Those articles are: Reference [82], [150], [212].
[62] Those articles are: Reference [217], [273], [275].
[63] Those articles are: Reference [94], [140], [363].
[64] Those articles are: Reference [138], [359].
[65] Those articles are: Reference [30], [236].
[66] Those articles are: Reference [117], [325].
[67] Those articles are: Reference [64], [171].
[68] Those articles are: Reference [324], [343].
[69] Those articles are: Reference [120], [346].
[70] Those articles are: Reference [25], [39].
[71] Those articles are: Reference [206], [146].
[72] Those articles are: Reference [3], [134].
[73] Those articles are: Reference [118], [135].
[74] Those articles are: Reference [132], [173].
[75] Those articles are: Reference [5], [125].
[76] Those articles are: Reference [2], [172].
[77] Those articles are: Reference [273], [275].
[78] Those articles are: Reference [20], [248].
[79] Those articles are: Reference [64], [329].
[80] Those articles are: Reference [18], [187].
[81] Those articles are: Reference [57], [187].
[82] Those articles are: Reference [119], [311].
[83] Those articles are: Reference [108], [167].
[84] Those articles are: Reference [49], [326].
[85] The article is Reference [241].
[86] The article is Reference [297].
[87] The article is Reference [266].
[88] The article is Reference [323].
[89] The article is Reference [358].
[90] The article is Reference [240].
[91] The article is Reference [359].
[92] The article is Reference [120].
[93] The article is Reference [30].

(1)[94]; (88) **Learning Ability (1)**[95]; (89) **Influence of Messaging (1)**[96]; (90) **Brand Content (1)**[97]; (91) **Strategic Intelligence Model (1)**[98]; (92) **Determine the brand name for a product (1)**[99]; (93) **Role Overlapping Behaviors (1)**[100]; (94) **Symbolic Value (1)**[101]; (95) **Value of The Role (1)**[102]; (96) **Adaptation value (1)**[103]; (97) **Understanding Between the New and Old Product (1)**[104]; (98) **B2B transactions internationally (1)**[105]; (99) **Acceptance and consumer interaction (1)**[106]; (101) **Sports Sponsorship (1)**[107]; (102) **Relational Marketing (1)**[108]; (103) **Shared values and empathy (1)**[109]; (104) **Online and Offline Media (1)**[110]; (105) **Social Media Marketing (1)**[111]; (106) **Attitude Towards Website Owners (1)**[112]; (107) **Customer Expectations (1)**[113]; (108) **Anti-Brand Factors (1)**[114]; (109) **Invalid service and after sales service (1)**[115]; (110) **Consumer Hope (1)**[116]; (111) **Consumer and Seller Interactions (1)**[117]; (112) **Brand Skill (1)**[118]; (113) **Private Brands (1)**[119]; (114) **The use of Celebrities (1)**[120]; (115) **Functional Aspects of the Brand (1)**[121]; (116) **Expresses its value (1)**[122]; (117) **Consumer Preferences (1)**[123]; (118) **Brand origin (1)**[124]; (119) **Communication Management (1)**[125]; (120) **Consumer Types (1)**[126]; (121) **Worth buying (1)**[127]; (122) **Product Producer Company (1)**[128]; (123) **Product Designer Country (1)**[129]; (124) **Customer involvement (1)**[130]; (125)

[94] The article is Reference [297].
[95] The article is Reference [361].
[96] The article is Reference [82].
[97] The article is Reference [82].
[98] The article is Reference [5].
[99] The article is Reference [342].
[100] The article is Reference [359].
[101] The article is Reference [258].
[102] The article is Reference [328].
[103] The article is Reference [328].
[104] The article is Reference [227].
[105] The article is Reference [72].
[106] The article is Reference [213].
[107] The article is Reference [56].
[108] The article is Reference [352].
[109] The article is Reference [352].
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[111] The article is Reference [272].
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[118] The article is Reference [230].
[119] The article is Reference [85].
[120] The article is Reference [100].
[121] The article is Reference [317].
[122] The article is Reference [258].
[123] The article is Reference [25].
[124] The article is Reference [133].
[125] The article is Reference [275].
[126] The article is Reference [197].
[127] The article is Reference [135].
[128] The article is Reference [73].
[129] The article is Reference [73].
[130] The article is Reference [211].

Internal Marketing (1)[131]; (126) **Brand Structure (1)**[132]; (127) **Business Ethics (1)**[133]; (128) **Public Relations (1)**[134]; (129) **Employee Participation (1)**[135]; (130) **Employee Identification (1)**[136]; (131) **Intellectual Capital (1)**[137]; (132) **Interacting with the Brand (1)**[138]; (133) **Brand Popularity (1)**[139]; (134) **Brand Charm (1)**[140]; (135) **Perceptual Similarity (1)**[141]; (136) **Brand Performance (1)**[142].

These 136 parameters can be placed in terms of semantic and functional similarities in larger categories. Each of these categories itself can be selected as a parameter affecting brand value that is composed of a number of other sub-parameters. Bottom table illustrates this grouping.

131 The article is Reference [18].
132 The article is Reference [57].
133 The article is Reference [229].
134 The article is Reference [8].
135 The article is Reference [311].
136 The article is Reference [311].
137 The article is Reference [345].
138 The article is Reference [312].
139 The article is Reference [336].
140 The article is Reference [293].
141 The article is Reference [259].
142 The article is Reference [12].

Table 1 Categorization of the parameters affecting the brand value in terms of semantic and functional relationship

No	Category title	Sub-set parameters
1	Quality	Perceived Quality of Brand - Credit of Brand - Product Features - Branding Strategy - Price of Products - Quality of Services and Products - Innovations in Brand - Brand Management - Premium Payments (Insurance) - Corporate Responsiveness Services (After Sales Service) - Brand Strength - Business Crises – Investment - Brand Culture - Organization Responsibility - Understanding Risk - Market Performance - Product Innovation - Corporate Financial Value - Ability to Serve - Promotion of Research and Development - The quality of brand communication - Partner and Joint venture Organizations' Brands - Corporate Governance Behavior - Production, Circulation, Distribution, Marketing and Services - Quality of Electronic Services - The Overall Ability of a Company or Organization - Organization `s Performance - Ideal Self-Test - Brand Reputation - Competency Supplier - Customizing Services and Products - Geographical Location of Companies and Service Providers - The Motivations of Decision Making in the Organization - Personnel development - Rival brand value - Learning Ability - Brand Content - Strategic Intelligence Model - Role Overlapping Behaviors - Symbolic Value - Value of The Role - Adaptation value - Customer Expectations - Anti-Brand Factors - Invalid service and after sales service - Brand Skill - Functional Aspects of the Brand - Expresses its value - Brand origin - Worth buying - Product Producer Company - Brand Structure - Business Ethics - Employee Identification - Intellectual Capital - Brand Performance
2	Loyalty	Customer's Loyalty to the Brand - Emotional Relationship with Brand - Customer Satisfaction - Trust to Brand - Attitude to Brand - Customer Relation Management - Consumer Behavior - Consumer Characteristics - Staff Loyalty - Customer Participation - Relations, Interactions and Social Identity in the Media Environment - Geographical Customer Attributes - Consumer Gender (Female or Male) - Culture, Ideology and Customer Values - Staff Satisfaction - Behavioral Brand Citizenship - Employee Commitment - Relationship Between Shareholders - Stakeholder Interactions - B2B transactions internationally - Acceptance and consumer interaction - Shared values and empathy - Attitude Towards Website Owners - Consumer Hope - Consumer and Seller Interactions - Communication Management - Consumer Types - Customer involvement - Employee Participation - Interacting with the Brand - Brand Popularity

No	Category title	Sub-set parameters
3	Awareness	Awareness/ Mental Association of Brand - Marketing and sales' advertising- Purchasing Goals - Brand Position in Social Media - Communications Brand - Word of Mouth Communications - Brand Knowledge - Brand Identification - Intergenerational Communication - Fake Goods - Gray Market - Customer Recognition Level of The Brand - Integrated Marketing Communication – Information - Information and Communication Technology ICT - Brand Rights - Brand position in trade - Penetration of the brand - Individual Customer Knowledge of the Organization - Influence of Messaging - understanding Between the New and Old Product - Sports Sponsorship - Relational Marketing - Online and Offline Media - Social Media Marketing - Private Brands - Consumer Preferences - Internal Marketing - Public Relations
4	Image	Brand Image - Experience Gained from Brand - Brand associations - Brand Identity (Brand Personality) - Company and Reputation Image - Popularity, Credit, Image and Brand Role of the Country of Origin - Social responsibility of the organization and stakeholders - Environmental Liability of the Company - Symbols and Slogans of the Organization - The Role and Behavior of Staff - Sound Icon - Trade Mark - Brand Distinctions - Brand Similarities - Determine the brand name for a product - The use of Celebrities - Product Designer Country - Brand Charm - Perceptual Similarity

III. Structuring Brand Equity Measuring Methodology

In order to measuring brand equity, brand equity strength (BES) questionnaire was suggested and combined with improved form of weighted cost of capital.

A. BES Structure

In order to extracting main criteria of BES questionnaire, 426 business experts were interviewed. 13 main criteria were extracted. The authors designed 222 questions which were related to these 13 parameters. Once again, these 426 experts were interviewed in order to checking the validity and reliability of the designed questionnaire. According to their oral comments and also the result of Cronbach's Alpha test (which was 0.8), the validity and reliability of the questionnaire was obtained. Then One-Way T- Student test via SPSS was performed on the experts score to each question. Result of this test is shown in table 2.

Table 2 Results of One-Way T- Student test

Criterions	Test Value = 3					
	t	Df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Leadership and Ownership	10.737	425	.000	.89453	.7274	1.0617
Strategy	16.288	425	.000	1.13075	.9914	1.2701
Customers and Their Outcomes	18.953	425	.000	1.33774	1.1961	1.4794
Social Responsibility	7.408	425	.000	.69585	.5074	.8843
Other Beneficiaries	10.741	425	.000	.98604	.8018	1.1703
Human Resources	7.880	425	.000	.78075	.5819	.9796
Technology and Innovation	13.118	425	.000	1.12830	.9557	1.3009
Main Processes	13.206	425	.000	1.12509	.9541	1.2960
Support Processes	8.392	425	.000	.76981	.5857	.9539
Finance	4.885	425	.000	.74585	.4395	1.0522
Risk	5.905	425	.000	.60585	.4000	.8117
Inflation	.951	425	.346	.11151	-.1238	.3469
Tax	-2.754	425	.008	-.34491	-.5962	-.0936

By summing up the experts' opinions, examining the scores of each criterion, as well as the output of the One-Way T- Student, it is proved that, the Tax parameter should be omitted.

B. Financial Formula Structure

The basic formula for the WACC is as follows:

$$WACC = \frac{D}{D+E} \times K_{\mathrm{d}} + \frac{E}{D+E} \times K_{\mathrm{e}}$$ [143]

Where in D: Total Debt, E: Total Equity, K_d: Debt Value and K_e: Shareholder Value.

In order to optimizing the structure of the formula, the mentioned experts were asked to count different known types of Inflation, Tax and Risk. By summing up their comments, three factors including inflation, tax and risk were identified as the main

[143] EUGENE F. BRIGHAM & JOEL F. HOUSTON, FUNDAMENTALS OF FINANCIAL MANAGEMENT (2017).

factors. The result of this question is presented in table 3.

Table 3 Different types of Inflation, Tax and Risk

No.	Inflation	Tax	Risk
1	Pseudo inflation	Income Tax	Strategic Risk
2	Absolute inflation	Value Added Tax	Mandatory Rules Risk
3	Creeping Inflation	Securities Transaction Tax	Financial Risk
4	Walking Inflation	Sale Tax	Operational Risk
5	Galloping Inflation	Service Tax	Credit Risk
6	Hyperinflation	Customs Duty Tax	Business Risk
7	Core Inflation	Tax on Inside Manufactured Goods	Country Risk
8	Wage Inflation	Anti-Damping Tax	Commercial Risk
9	Asset Inflation	Municipal Taxes	Tax Risk
10	Import Inflation	Road Tolls	Risk of Changes in Government Rules
11	Demand-Push Inflation	Stamp Tax	Risk of Changes in Macro Managers
12	Cost-Push Inflation	Consuming Tax	Political Instability Risk
13	Investment-Push Inflation	---	Economic Risk
14	Stagflation	---	Market Risk
15	Deflation	---	Liquidation Risk
16	---	---	Inflation and Reducing Purchasing Power Risk
17	---	---	Risk of Losing Money Due to Investment Focus
18	---	---	Reinvestment Risk

Also, with the suggestion of experts, individuals (both real and legal) who can take part in an investment project, divided into four categories including ordinary shareholders, preferred shareholders, suppliers (or buyers) and the bank.

1. Splitting Equities

In this step, we developed the base formula in such a way that ordinary stock, preferred stock, supplier/buyer and bank are included. Thus, the formula is:

$$WACCopt.B = \frac{\sum_{i=1}^{I(ES)} MVES_i \times R_i}{MV} + \frac{\sum_{j=1}^{J(PS)} MVPS_j \times R_j}{MV} + \frac{\sum_{i=1}^{K(SC)} MVSC_k \times R_k}{MV} + \frac{\sum_{i=1}^{L(BL)} MVBL_l \times R_l}{MV} \quad (1)$$

Where in:
MV: total market value of resources (debt and equity of stockholders)
$MVES_i$ = i = 1,2,3, ... I (ES): Market value of ordinary stock returns
$MVPS_j$ = j = 1,2,3, ... J (PS): The market value of the preferred stock market
$MVSC_k$ = k = 1,2,3, ... K (SC): Value of supplier/seller delivery
$MVBL_l$ = l = 1,2,3, ... L (BL): The value of the bank loan

If the parameter 1/MV is factorized in the whole formula, the following simplified formula is obtained.

$$WACC_{opt.B} = \frac{1}{MV}\left(\sum_{i=1}^{I(ES)} MVES_i \times R_i + \sum_{j=1}^{J(PS)} MVPS_j \times R_j + \sum_{i=1}^{K(SC)} MVSC_k \times R_k + \sum_{i=1}^{L(BL)} MVBL_l \times R_l\right) \quad (2)$$

2. Adding Tax

In the next step, the tax is added to the optimized formula.

$$WACC_{opt.B} = \frac{1}{MV}\left(\sum_{i=1}^{I(ES)} MVES_i \times R_i + \sum_{j=1}^{J(PS)} MVPS_j \times R_j + (1 - t_{ck}) \sum_{i=1}^{K(SC)} MVSC_k \times R_k + (1 - t_{cl}) \sum_{i=1}^{L(BL)} MVBL_k \times R_k\right) \quad (3)$$

In this formula, t_{ck} is the tax (supplied) by the supplier or buyer and t_{cl} is the tax charged by the bank.

3. Adding Inflation:

If the inflation is optimized in the formula, the formula is as follows:

$$WACC_{opt.F} = \sum_{t=0}^{T}\sum_{i=1}^{I(ES)} \frac{MVES_{it}\times(1+fR_{it})^{-t}\times R_i}{MV} + \sum_{t=0}^{T}\sum_{j=1}^{J(PS)} \frac{MVES_{it}\times(1+fR_{jt})^{-t}\times R_j}{MV} + \sum_{t=0}^{T}\sum_{k=1}^{K(SC)} \frac{(1-t_{ck})\times MVES_{it}\times(1+fR_{kt})^{-t}\times R_k}{MV} + \sum_{t=0}^{T}\sum_{k=1}^{L(BL)} \frac{(1-t_{cl})\times MVES_{it}\times(1+fR_{lt})^{-t}\times R_l}{MV} \quad (4)$$

In this formula, the parameter fR_{it} denotes the ordinary shareholder's inflation, fR_{jt} denotes the inflation of the preferred shareholder, fR_{kt} denotes the inflation of the supplier or the buyer and fR_{lt} represents the inflation of the bank.

4. Adding Risk

If the desired risk level is optimized in the WACC formula, the formula is as follows.

$$WACC_{opt.R} = \frac{1}{MV} \times [\sum_{i=1}^{I\ (ES)} MVES_i \times \left(R_{Loci} + \beta_i \times (R_{mi} - R_{Loci})\right) + +$$

$$\sum_{j=1}^{J(PS)} MVES_j \times (R_{Locj} + \beta_j \times \left(R_{mj} - R_{Locj}\right)) + (1 - t_{ck}) \times$$

$$\left(\sum_{k=1}^{K(SC)} MVSC_k \times R_k\right) + (1 - t_{cl}) \times \left(\sum_{l=1}^{L(BL)} MVSC_l \times R_l\right)] \qquad (5)$$

In the formula above, $R_{mi,\ j}$ is equal to the risk rate of the preferred ordinary or preferred investor, $R_{f.Ref}$ is equal to the risk-free return rate in a reference country, and $R_{f.Loc}$ is the risk-free return rate in the source country, which is calculated by the following formula:

$$R_{f.Loc} = \left(1 + R_{f.Ref}\right) \times \left(\frac{(1+inflation_{Loc})}{(1+inflation_{Ref})}\right) - 1 + \frac{Country\ Risk\ of\ the\ Local\ Country}{Country\ Risk\ of\ the\ Reference\ country} \qquad (6)$$

In this formula, $inflation_{Loc}$ represents inflation in the country of origin and $inflation_{Ref}$ represents inflation in the reference country. Country Risk of the Local Country means the country's risk in the country of origin and the country Risk of the Reference Country indicates the country's risk in the reference country.

The β coefficient represents the systematic risk through the following:

$$\beta = \frac{Cov(r_i, r_m)}{\sigma^2(r_m)} \qquad (7)\ ^{144}$$

In this formula, R_i represents rate of return of equity, and r_m represents the rate of return of the market.

5. Final WACC Formula

Finally, the following general formulation is obtained by combining the above-mentioned parameters:

$$WACC_{opt.F.R.Tc} = \frac{1}{MV} \times [\sum_{i=1}^{I\ (ES)} MVES_i \times \left(R_{Loci} + \beta_i \times (R_{mi} - R_{Loci})\right) \times (1 +$$

$$fR_{it}) + + \sum_{j=1}^{J(PS)} MVES_j \times (R_{Locj} + \beta_j \times \left(R_{mj} - R_{Locj}\right)) \times \left(1 + fR_{jt}\right)^{-t} +$$

$$(1 - t_{ck}) \times \left(\sum_{k=1}^{K(SC)} MVSC_k \times R_k\right) \times (1 + fR_{kt})^{-t} + (1 - t_{cl}) \times$$

$$\left(\sum_{l=1}^{L(BL)} MVSC_l \times R_l\right) \times (1 + fR_{lt})^{-t}] \qquad (8)$$

144 *Id.*

C. Final Evaluation Formula

Finally, in order to add the output of the questionnaire to the optimized WACC formula, the output of the formula $WACC_{opt.F.R.Tc}$ is multiplies with BES output:$Brand\ Value = WACC_{opt.F.R.Tc} \times\ (BES) \times Profit$

IV. Case Study

In order to examining the generated method, 40 enterprises among public companies in various fields were chosen. These enterprises are working in bank, petrochemical, automobile manufacturing, pharmaceutical, investing and development, food, tourism, telecommunication, Aluminum, zinc, copper and oil industry. Average of 5 years of their brand equity was calculated. Besides, the 5-year average brand value of these companies was calculated via 2 other existing methods that were introduced in (Yu & Yan, 2010)[145] and (Bagna et al, 2017)[146]. As told before, these samples (companies) are among public companies; so, in order to preventing from any impact on their stock value, name of them are omitted. The results are shown in table 4.

Table 4 Result of calculating brand equity (Numbers are in Million Rials[147])

NO.	Industry	New Method	Yu, Yan, 2010	Bagna et al, 2017
1	***Bank***	-	-	-
2		151,602	-	199,684
3		-	68	4,848,439
4		-	2,667	-
5		-	37	8,809,052
6	**Petrochemical**	670,810	14,173	114,624
7		1,653,070	45,772	517,264
8		123,435	735	4,103,906
9		3,610,304	-	-
10		1,229,706	73,501	-
11		835,757	43,712	156,320
12	**Car Manufacturing**	-	31,056	546
13		-	-	6,355
14		-	-	-
15		-	1,351	8,162
16		-	-	-

[145] Bai Yu & Wang Bai Yan, *How to Value the Brand Valuation of an E-Commerce Enterprise*, 2010 International Conference on E-Business and E-Government, Institute of Electrical and Electronics Engineers, 1815–1818 (May 2010).
[146] Emanuel Bagna, Grazia Dicuonzo, Andrea Perrone & Vittorio Dell'Atti, *The value relevance of brand valuation*, 49(58) APPL ECON 5865, 5865–76 (2017).
[147] Islamic Republic of Iran Currency.

NO.	Industry	New Method	Yu, Yan, 2010	Bagna et al, 2017
17	**Pharmaceutical**	-	-	53,566
18		228	-	648
19	**Investing and Development**	18,843	-	
20		15,703	2,157	231
21		-	0.22	655
22		-	503	-
23		1,632	1,166	-
24		381,155	39,818	8,125
25		4,465	1,567	618
26	**Food**	892.91	-	2,691
27		-	1,696	5,781
28	**Tourism**	16,729	401	-
29		-	6	12
30	**Telecommunication**	225,739	-	34,880,220
31		-	561	-
32	**Aluminum**	-	33,675	-
33		-	3,592	-
34	**Zinc**	48,635	38,438	1,074,350
35		1,375	-	20,962
36		62,191	113,994	-
37	**Copper**	-	12,757	-
38		-	-	-
39	**Oil**	236,510	2,651,815	61,048
40		**-**	**6,934,097**	**7,233,470**

According to table (4), some brand's equity values are 0; it is because of that companies' financial operation in their fiscal year. The result of R^2 for new formula was: 99.94% based on (Yu & Yan, 2010) and 99.75% based on (Bagna et al, 2017). It shows the accuracy of the formula. Also, it was found out statistically significant more valuable brands in oil and its derivatives industries, because the main source of Islamic republic of Iran GDP is based on producing and selling oil and its derivates. Also, because of the accessibility of raw material and low price of processing in these sections, the total sale and marginal profit of these companies are higher. These would directly impact on their brand equity strength and value. On the other hand, in banking and car manufacturing industries, because of constructional and technical limitations and constraints, the overall sale and so the marginal profit is so less or even non. So that, their brand is worth less or non (although they are large scale enterprises in their field).

V. Conclusions

The main purpose of this study was to introduce a new method to evaluate brand equity. For this reason, a new form of WACC and brand equity strength questionnaire was used. According to the literature review, previous brand equity evaluation methods had some defects. Most of them didn't use qualitative and quantitative approaches at the same time. Not including these two together would lead to misunderstanding about real quality and value of brand. Counting monetary value of brand without knowing its qualitative position, doesn't let managers to know the weaknesses and strengths of their brand, so, they might make incomplete decisions. Also, if managers only focus on measuring the quality of their brand without counting its financial value, they cannot understand the effect of their decisions on their brand as well. So, we decided to combine these 2 main approaches in order to giving managers a better picture of their brand.

Also, most of previous qualitative researches only contained the viewpoint of either internal stakeholder of a business or external stakeholder. It can proceed to an imperfect picture of a brand. By only focusing on external stakeholders' opinion like customers, managers might weight less on their employees' needs as companies' internal stakeholders. As well if they concentrate on internal stakeholders' opinion, they cannot understand value of their brand in mind of their customers. So, we decided to include viewpoint of both groups of stakeholders in order to bringing a wider and more precise picture of the brand.

There are some limitations for this research which will be resolve in future works. First of all, brand is a multi-dimensional asset. So, studying various aspects of it is important. Brand equity is one of many. Therefore, in future works we'll focus on other aspects of brand. Secondly, BES can directly show the impact rate of brands effect in a company. Thus, by combining it with other financial tools, monetary amount of brands effect on enterprise's cash flow and p/l statement can be measured. Hence, for future works, we will apply it to other financial tools to find out more about importance of brand in generating cash. At last, by using this methodology, impact of other intangible assets can be measured.

This research was conducted to identify the parameters affecting the brand value. A total of 367 articles in English are among the most prestigious research related to the subject matter of the research, which gained credible international databases between 1980 and 2018. According to the survey, brand perceived quality criteria, customer loyalty to brand, and brand awareness / affinity are the most commonly used parameters in determining brand value. Another result of this study is the classification of the parameters into four main categories of brand image, brand quality, brand loyalty and brand awareness. The other factors affecting brand value can be classified into these four groups according to their semantic and functional relationship.

A new brand equity strength (BES) questionnaire was suggested based on the findings and experts' opinions. It contains 12 main parameters that are: Leadership and Ownership, Strategy, Customers and Their Outcomes, Social Responsibility, Other Beneficiaries, Human Resources, Technology and Innovation, Main Processes, Support Processes, Finance, Risk and Inflation. A total of 210 questions were produced for this questionnaire.

After that, 2 brand valuation formula from (Yu, Yan, 2010) and (Bagna et al, 2017) were chosen in order to optimizing them with BES questionnaire. 40 public companies were used as case study. The brand equity value of these companies was obtained by main (Yu, Yan, 2010) and (Bagna et al, 2017) methods and also with the combinations of each method with BES questionnaire. Results showed that the output of (Bagna et al, 2017) that is mixed with BES is more reliable and accurate.

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Artificial Intelligence, A new frontier for intellectual property policymaking

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Abstract

The emergence, growth and sophistication of artificial intelligence (AI) and computer-generated works (CGW), have opened the discussion towards the property and accountability of creations made by machines. These creations, founded on algorithms and learning-processes based on large data analysis may become instrumental, or even independent, in the creative processes. The ownership of these creations comprises a challenge for intellectual property (IP) regulations as, traditionally, the concept of author has been associated to human inventions. This paper attempts to analyse the state-of-the-art and expand the literature regarding AI's copyright protection. For this purpose, through an extensive literature review, we identify the main concepts regarding AI's copyright protection in order to establish an analytic framework to study current regulations at an international and domestic level. This allows us to set the parameters to compare if, and how, these key concepts have been incorporated or interpreted in policymaking. The absence of an international consensus regarding the authorship concept -leaving it to domestic interpretation- may lead to contradictory norms causing uncertainty in terms of their protection. We propose the recognition of Artificial Intelligence Generated Works (AIGW) as a new conceptual category, and its protection through a new sui generis legislation.

Keywords: Artificial Intelligence, Intellectual Property, Copyrights, CGW, AIGW

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I. Introduction

The emergence, growth and sophistication of artificial intelligence (AI), and therefore computer-generated works (CGW), have opened the discussion towards the property and accountability of creations made by machines.[247] Even though there is not a generally accepted AI definitions, it can be understood as "the processes of human intelligence simulated by computers [which aim is to] achieve human-level intelligence and finally to make computers solve problems by itself".[248]

When a new work is created by AI, questions as the following arise, whether who can be considered the "composer", "author" or "inventor"; or if software-programmers or machine-owners have rights over the outcome; as well as, the responsible for possible violation of rights, or even damages caused by these creations.

The ownership of AI generated works comprises a challenge for intellectual property (IP) regulations. Founded on algorithms and learning-processes based on large data analysis, machines may become instrumental, or even independent, in the creative processes. What happens when AI creates a novel piece of art? If copyrights may be understood as incentives to creativity[249], it can be possible that AI is conceived in the same way. According to authors such as Abbot (2017), this could not be part of what is being protected under current IP regulations as AI are not considered humans, and therefore, its creations are not result of human creativity.[250]

In 2016, Dutch financial company ING partnered with Amsterdam based J. Walter Thompson marketing agency to look for a way to innovate and stand out amongst its competitors, deciding that "art" became the natural playground for the brand's venture into innovation.[251] In this context, using the advances in technologies and artificial intelligence, they decided to generate a new Rembrandt masterpiece. For this venture, they brought collaboration of Microsoft, TU Delft, Mauritshuis, and Rembrandthuis, to set a team of data scientists, engineers and art historians to analyse Rembrandt's painting techniques, style and subject matter. They then transferred that knowledge into the software. [252]

In order to generate this work, 346 known Rembrandt paintings were analysed, gathering 150 GB of data through high resolution 3D scans and digital files, which were

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[247] WIPO Magazine, *Artificial intelligence and intellectual property: an interview with Francis Gurry*, WIPO (Sep. 2018), www.wipo.int/wipo_magazine/en/2018/05/article_0001.html. ; United States Patent and Trademark Office, *Artificial Intelligence: Intellectual Property Policy Considerations*, USPTO (2019), www.uspto.gov/about-us/events/artificial-intelligence-intellectual-property-policy-considerations.

[248] Jiachao Fang, Hanning Su, & Yuchong Xiao, *Will Artificial Intelligence Surpass Human Intelligence?*, SSRN (Jun. 03, 2018), https://ssrn.com/abstract=3173876.

[249] Ana Ramalho, *Will Robots Rule the (Artistic) World? A Proposed Model for the Legal Status of Creations by Artificial Intelligence Systems*, 21(1) JOURNAL OF INTERNET LAW 12, 12-25 (2017).

[250] Ryan Abbott, *Artificial intelligence, big data and intellectual property: protecting computer-generated works in the United Kingdom*, in RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY DIGITAL TECHNOLOGIES, (J. Phillips ed., 2017) ; Ralph D. Clifford, *Intellectual property in the era of the creative computer program: Will the true creator please stand up*, 71 TUL. L. REV. 1675, 1675-89 (1996).

[251] JWT, *The Next Rembrandt - ING*, www.jwt.com/en/work/thenextrembrandt (last visited Nov. 12, 2019).

[252] Steve Schlackman, *Who holds the Copyright in AI Created Art*, ARTREPRENEUR ART LAW JOURNAL, https://alj.artrepreneur.com/the-next-rembrandt-who-holds-the-copyright-in-computer-generated-art/ (last visited Oct. 20, 2019).

upscaled by deep learning algorithms to maximize resolution and quality.[253] After the analysis of the data, the team planned the painting should be a portrait of a Caucasian male, with facial hair, between 30-40 years old, wearing dark clothing, a collar and a hat, and facing to the right.[254] With these parameters, a facial-recognition algorithm learned Rembrandt's techniques. This software was designed to understand Rembrandt based on his use of geometry, composition and painting materials. These elements were used to replicate the painter's style to generate the "New Rembrandt".[255]

As stated by Yanisky-Ravid, once the program "learned" the style of the painter, it created a new, creative, independent and original work of art of the genuine Rembrandt. Finally, pixel data helped the computer mimic brushstrokes; and an advanced 3D printer brought the painting to life using 13 layers of ink.[256] The portrait consists of 148 million pixels and is based on 168,263 fragments from Rembrandt's portfolio.[257] The final work was unveiled on April 5, 2016 in Amsterdam, opening a series of question regarding the authorship of the Next Rembrandt, which motivates this research.

As shown in the previous example, the present state of AI forces us to challenge existing definitions and legislations. Although the debate on AI copyright protection itself is not novel, being already stated in the 1970s, when the UK´s Whitford Committee on Copyright Designs and Performers Protection raised the question on the authorship of computer generated works[258], the rapid evolution of AI in the last years has made clear and urgent the need to understand its policy dimension within IP rights. Some difficulties may have already been overcome under the current IP frameworks. For instance, the discussion that machine owners or AI programmers are the ones who build and feed AI in order to produce new works; or the fact that AI could not be capable of producing new works without data. The challenge now is the recognition of AI as responsible for new creations. Authorship has developed close to the breaking point, and we face a moment in which we should decide whether this paradigm (human authorship) should be retained[259], or if a new one should be adopted that moves away from the concept of personal authorial creation.

While patents may protect the AI itself, copyrights do not protect the results they could embrace, therefore a disincentive towards the use and creation of new and more sophisticated AI programs may be generated. The evolution of AI has led to a state in which the algorithms created by humans allow the AI to produce its own creative process; therefore humans are not responsible for the actual outcome. AI is capable of learning from both data and previous experimentation, emulating the human creative process. This generates novel works which may not be attributable to programmers or users, but to the AI itself, due to its capacity to generate and express new ideas.

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253 THE NEXT REMBRANDT, *Gathering the Data: Building an extensive pool of data*, www.nextrembrandt.com (last visited Aug. 19, 2019).

254 The Next Rembrandt, *The Next Rembrandt*, YOUTUBE (Apr. 05, 2016), www.youtube.com/watch?v=IuygOYZ1Ngo.

255 Schlackman, *supra* note 6.

256 Shlomit Yanisky-Ravid, *Generating Rembrandt: Artificial Intelligence, Copyright, and Accountability in the 3A Era: The Human-like Authors Are Already Here: A New Model*, 2017(4) MICH. ST. L. REV. 659, 659-726 (2017).

257 JWT, *supra* note 5.

258 Collin Davies, *An evolutionary step in intellectual property rights–Artificial intelligence and intellectual property*, 27(6) COMPUT. LAW SECUR. REV. 601, 601-19 (2011).

259 Sam Ricketson, *The 1992 Horace S. Manges Lecture-People or Machines: The Bern Convention and the Changing Concept of Authorship*, 16 COLUM.-VLA J.L. & ARTS 1, 1-37 (1991).

This paper attempts to expand the literature regarding AI copyright protection. For this purpose, first, through an extensive literature review, we identify the main concepts under debate, establishing an analytic framework for current regulations. After, using these concepts, we study regulations state-of-play in International Agreements, as well as key international actors such as the United States, the United Kingdom and the European Union. This allow us to analyse and compare if these key concepts are incorporated in policymaking, and (if so) to what extent, identifying potential existing gaps. The absence of an international consensus regarding the concept of authorship, left to domestic interpretation, may lead to contradictory norms that cause uncertainty when referring to their IP protection. We propose the recognition of Artificial Intelligence Generated Works (AIGW) as a new conceptual category, and therefore, its protection through a new sui generis legislation that goes beyond the copyright debate.

II. Copyright protection for AI, a literature review

The development of new technologies has constantly challenged intellectual property regulations. Since Napoleon Sarony's photography of Oscar Wilde was subject to the US Supreme Court in 1884[260], different litigations and interpretations have risen from technology derived works, and its possible copyright protection. For years, the discussion on technology aiding creation process was dominated by the conception that these technologies were inert, in this sense, a typewriter or a camera could be comparable to a pen or a brush.[261] The digital revolution comprised by computer development challenged this conception, as Prof. Ricketson anticipated, Computed Generated Works (CGW) will generate a problem because the absence of "any human whose participation in the computer's output would be sufficiently proximate and original to constitute authorship".[262] Today elements such as 3D maps, songs and sculpture design can be created by AI and, at the same time, are part of the Bern Convention definition of "work" (Art. 2).[263]

Whether AI should be recognized as the author of a copyrightable work is one of the most puzzling problems in copyright law.[264] In the 1970s the issue of authorship of computer-generated works was analysed by the US National Commission on New Technological Uses of Copyrighted Works (CONTU), which in its Final Report stated that the capabilities of computers, and whether to classify them as inert "still is an open question"[265]. Nevertheless, Farr states that this analysis is based on the general requirement of copyright, and if users, programmers or computers fill them. In general terms, in order to qualify as a "work of authorship," a work must evidence some intellectual creativity. Therefore, it must be determined whose idea is being expressed when referring to computer-created works.[266] When analysing who should be the owner

[260] Michael D. Sherer, *Copyright and Photography: The Question of Protection*, 8(6) COMM. & L. 31, 31-40 (1986).
[261] Andrew J. Wu, *From video games to artificial intelligence: Assigning copyright ownership to works generated by increasingly sophisticated computer programs*, 25 AIPLA Q. J. 131, 131-56 (1997).
[262] As cited in James Grimmelmann, *There's No Such Thing as a Computer-Authored Work and It's Good Thing, Too*, 15 Cornell Law Faculty Publications 133, 133-46 (2016).
[263] Concepción Saiz Garcia, *Las obras creadas por sistemas de inteligencia artificial y su protección por el derecho de autor*, 1 INDRET; REVISTA PARA EL ANÁLISIS DEL DERECHO 1, 45 (2019).
[264] Wu, *supra* note 15, at 131.
[265] National Commission on New Technological Uses of Copyrighted Works (CONTU), *Final Report on the National Commission on New Technological Uses of Copyrighted Works*, 3 COMPUTER L.J. 53, 53-104 (1981).
[266] Evan Farr, *Copyrightability of computer-created works*, 15 RUTGERS COMPUTER & TECH. L.J. 63,

of the copyrights, Farr reviews three different scenarios: programmer as author; user as author and computer as author, arguing that only programmers can be authors. In this case, programmers exercise originality when first conceiving what the created work will "look" like, and therefore, entitled for protection. Users would not meet the originality requirement as they just use what the programmer preconceived. In the case of the machine, the author claims that giving authorship rights to a computer would be absurd, because the computer would be incapable of enforcing such rights and would imply that a computer can have ideas. The author concludes that under the US Copyright Act, computer-created works can be copyrighted only by the programmer, as even though the works created may be different each time the program is executed, the programmer's idea is expressed.

This preconception of the programmer as the sole copyrighter holder has been challenged. The balance of inputs towards new creations delivered by the programmer (fixed input) and user (progressive input) have changed. Authorship between programmer and user can be distinguished as people use programs created by someone else, for example, to compose a musical work.[267] In other cases, users do not have copyright claim because "the program would have generated the same output no matter which human user caused the output to be generated".[268] Therefore, we need to differentiate between users who are authors from those who just push a button.

In order to distinguish the contribution made by programmer and user in the creative process, a two-axis diagram was proposed (Figure 1)[269]. On the x-axis the contribution made by the programmer (software creator) is noted (fixed input), and on the y-axis, the contribution made by the user is represented (progressive input).

63-80 (1989).

[267] Grimmelmann, *supra* note 16, at 133.

[268] *Ibid*.

[269] Bruce E. Boyden, *Emergent Works*, 39 COLUM. J.L. & ARTS 377, 377-94 (2015).

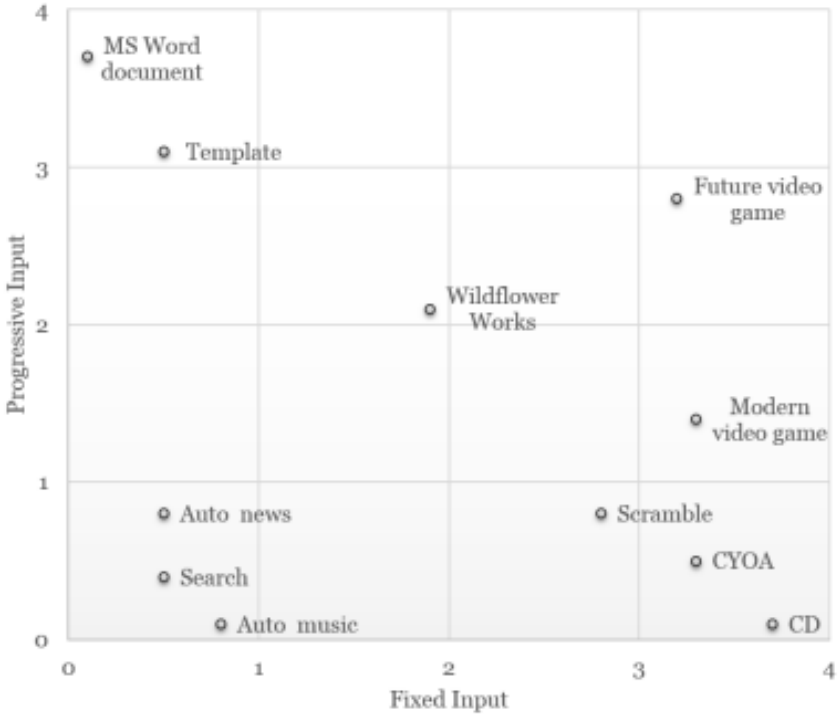

Figure 1:
Examples of fixed vs. progressive input to a work
Source: Bruce Boyden 'Emergent Works'[270]

Boyden's approach leaves no space for AI as part of the creative process, as it divides the creation between the inputs made by the programmer (embodied in the AI) and the user. This leaves us with the need to expand this binary diagram into a multi-actor model, which acknowledges AI contribution as presented in Figure 2. Here we recognize that AI may play an independent and autonomous role in creative processes. Authors state that it must be considered that the majority of works created by machines have been someway assisted or validated by a human staff (software programming, selecting the correct data, etc.). In these cases, AI systems serve human creativity, as the final creation could not have been achieved without the human staff.[271]

However, we distinguish that there is a threshold in which originality and creativity can be mainly attributed to AI processes (Figure 2). The notions of conception and execution are part of the possible author's role. From here, if the programmer/user is actively participating in the response, his or her originality will be present in the creation. On the contrary, we can refer to AI creations if the instructions given to the AI system are not explanatory enough and the system learns and spontaneously creates the outcome. In this situation, the contributions made by the programmer and user will not be as evident as to be considered responsible for the result.

[270] *Id*. at 386.
[271] Saiz, *supra* note 17, at 45.

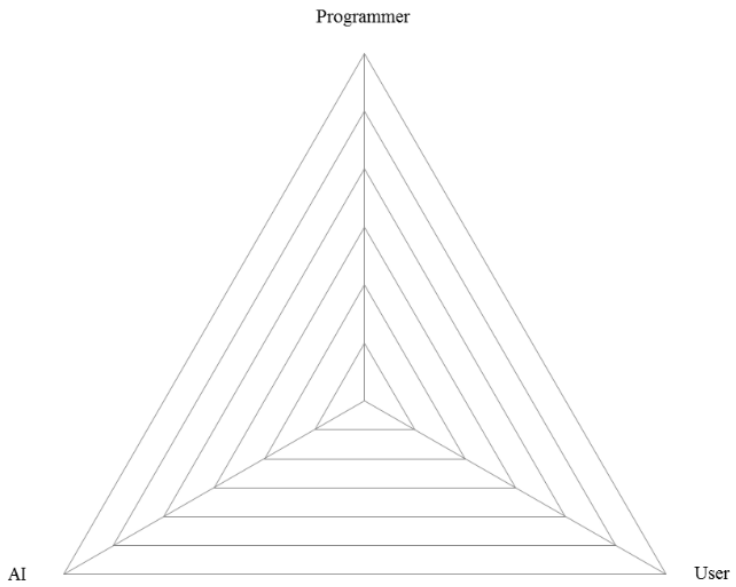

Figure 2:
Creative process three-axis contribution
Source: Authors' elaboration

Having stated that AI contributes in the creative process, we turn into how to determine it, and particularly, to set the threshold where a new creation is resulted from AI. Andrew Wu proposes a five-step approach to establish authorship[272]. First, it is important to identify whether the output of the program is repetitive and predictable. If the program generates the same output regardless of the user's input, then the programmer may claim to have fixed the work in a tangible medium of expression (computer program). Second, whether the user's input meet the test in *Feist*[273] for minimum standards of creativity. Third, if both programmer and user meet the requirements of fixation and originality (i.e., if the first two inquiries are both "yes"), then it must be examined whether the programmer and user intend to be joint authors. Fourth, determine whether the computer-generated work contains blocks of expression attributable neither to the programmer not the user; in which case the author may be the computer program (the AI) itself. Finally, if the AI itself authored a work, it must be reviewed whether it has the sophistication to make decisions regarding the generation of future works. If so, copyright protection should be awarded to the AI, which will stimulate future creations. If AI cannot generate future works, copyrights should be assigned to the owner of the computer program, under the Fictional Human Author Theory.[274]

Yanisky-Ravid explains the concept of Machine Learning. She argues that: (1) the algorithm is nurtured using several examples, (2) "the algorithm breaks the data down

[272] Wu, *supra* note 15, at 131.

[273] In March 1991, the US Supreme Court decision in *Feist Publications v. Rural Telephone Service Company Inc.* resolved a definitional tension determining that there was a constitutional requirement of creativity. Daniel J. Gervais, *Feist goes Global: A Comparative Analysis of the Notion of Originality in Copyright Law*, 49(4) JOURNAL OF THE COPYRIGHT SOCIETY OF THE USA 949, 949-81 (2002).

[274] Under this theory, copyrights are assigned to whoever owns the copyright of the computer program as neither the user nor the programmer meet the requirements of authorship. This theory requires courts to modify the language of the Copyright Act. Wu, *supra* note 15, at 131.

into "tiny" electronic signals, undetectable by humans, and tries to identify hidden insights, similarities, patterns and connections, without being explicitly programmed on where to look".[275] Therefore, the similarities found may not be understood by the programmers (in fact the trainer can be human or other AI system). (3) Performance will improve and evolve with the new data.

She also identified 10 features of AI systems' algorithm for the accountability discussion.[276] First creativity, which understands that AI systems can operate as creative devices as they are able to create new and original works. Then, AI can be autonomous and independent when it accomplishes a high-level task on its own, working with minimum human intervention. AI can have unpredictable and new results and it is capable of data collection and communication with outside data. Besides, AI has the ability to process data through feedback (learning capability), and it can evolve by constantly finding new patterns and change the outcome. Referring to other features, AI can be a rational-intelligent system, as it is capable of perceiving data and making decisions about the activities that would maximize its probabilities of success. Finally, AI is capable of rapidly processing a large amount of data (beyond human brain ability); it can choose between different activities to reach the best outcome; and it is goal-oriented.

Based on these features, it seems clear that AI systems can create works autonomously and therefore copyright laws available are not responding to the current technological developments. Now, we cannot only refer to human creativity because AI is constantly evolving. Yanisky-Ravid goes further and discuss whether "AI systems should own the products they produce".[277]

It is clear that the originality threshold, which refers to the author's own creativity in producing the original work, and how this could be applied to AI becomes one of the most controversial issues. When talking about AI, it is hard to narrow down the concept of authorship to who simply pushes the button and does not actively participate in the process.[278] In a general definition, original works must reflect "author's own intellectual creation".[279] Traditionally referred as a human value, creativity may also be found in AI, when understood as original (novel, surprising and unexpected) and adaptive, hence it may be materialized.[280] de Cock Buning also shows that creativity could manifest in three ways: as a mental process that yields adaptive and original ideas; as a type of 'person' who exhibits creativity; and third, it can be analysed in terms of the concrete products that result from the creative process. The latter possess a challenge to current regulations, as creations made by AI could fulfil this creativity requirement. If courts no longer assess the author, but rather the work created, regardless of the creative process, the result of machine creativity could be compared to the result of human creativity objectively, without "prejudice".

In terms of legal authorship, Grimmelmann analyses six possible outcomes for authorship: infringing copy, unlawful derivative work, lawful derivative work, joint

[275] Yanisky-Ravid, *supra* note 10, at 659.
[276] *Ibid.*
[277] *Ibid.*
[278] Iegor Bakhariev, *The Changing Concept of Authorship: Case of a Monkey Selfie*, Lund University, Lund, Sweden (2015).
[279] Saiz, *supra* note 17, at 45.
[280] Madeleine de Cock Buning, *Autonomous Intelligent Systems as Creative Agents under the EU framework for Intellectual Property*, 7(2) EUR J RISK REGUL 310, 310-22 (2016).

work, sole-authored work and no copyright.[281] The author argues that if the day comes that AI is unpredictable enough that we cannot tell it what to do, it will be because we have made decisions in law and other areas of life to treat it as people, so copyright law will adjust to this reality. Saiz state that AI created works can be protected by using a system of "collective works", which has been introduced in the IP regulations of some countries, such as Spain and Italy.[282] In this case, a group of individuals participate in the creative process. However, the authorship will belong to the coordinator of the project. Besides, authors such as Sorjamaa discusses other theories whether the owner of AI should be the programmer, user, AI itself, or it should be granted under joint authorship, a fictional human author category or public domain.[283]

Pearlman discusses possible AI owners, but also refers to other issues for AI systems, such as not being human, not having a soul, no consciousness, no feelings, and no free will.[284] Hence, he first identifies the user who sees machines as merely tools to create a work. In this case, it is believed that the user applies its originality and creativity in the process. However, when users do not provide guidance for the creation and, as it was mentioned, originality and creativity will depend on the type of CGW and user's contribution. Second, as programmers invest time, energy and creativity in the process, they should be the owners. Nevertheless, this assumes that the programmer instructed the AI with step-by-step indications, but in many cases the program improves, changes and learns by its own. Finally, Pearlman also presents the option of AI as the owner, arguing that it should only be granted ownership when "it achieves similar capabilities to natural persons, completely ignoring analogous legal personhood as is found in corporations and government entities".[285]

Regarding the framework for AI ownership, Pearlman states that law courts should recognize sufficiently creative AIs as authors, matching AI intellectual property rights to that of natural or legal persons. In fact, Pearlman presents a Test for AI authorship with questions such as: is the creation original? Was it developed independently from mere instructions? The objective is to prove creativity independence, with minimum human directions, nor merely instrumental.[286]

III. Overview of current regulations of copyright protection for AI

AI reflects the problem that current legal frameworks do not match the development of technological advances.[287] While AI rapidly develops, regulations tend to be static. In this section we analyse current legislations in order to assess how AI could be embraced by these regulations, and how legislations have been interpreted to fit AI. Acknowledging the relevance of international agreements as frameworks for domestic regulations, our analysis begins with the main international treaties relatives to copyright, and follows with the analysis of United States, United Kingdom and the

[281] Grimmelmann, *supra* note 16, at 133.
[282] Saiz, *supra* note 17, at 45.
[283] Tuomas Sorjamaa, I, Author - Authorship and Copyright in the Age of Artificial Intelligence, doctoral thesis, Hanken School of Economics (2016).
[284] Russ Pearlman, *Recognizing Artificial Intelligence (AI) as Authors and Investors under US Intellectual Property Law*, 24 RICH. J.L. & TECH.1, 1-38 (2017).
[285] *Id*. at 24.
[286] *Id*. at 24.
[287] World Intellectual Property Organization, *WIPO Technology Trends 2019: Artificial Intelligence*, WIPO (2019), www.wipo.int/edocs/pubdocs/en/wipo_pub_1055.pdf.

European Union regulations. These actors had been selected for two reasons. First, they may be considered within the state of the art in AI development, and second, their legal frameworks serve as a basis for other legislations both on continental and common law.

J. International agreements

As part of the analysis, the following international agreements were compared: Berne Convention[288], Universal Copyright Convention[289], TRIPS Agreement[290], WIPO Copyright Treaty[291] and CPTPP[292]. Table 1 presents the summary of the comparison based on the following elements: subject matter and scope of copyright, concept of author, authorship, the direct reference to AI or CGW, the originality threshold, the degree of creativity, and fixation.

[288] Berne Convention for the Protection of Literary and Artistic Works, September 9, 1886, revised at Paris July 24, 1971 25 U.S.T. 1341. ; 1161 U.N.T.S. 3.
[289] Universal Copyright Convention, as revised at Paris, July 24, 1971 25 U.S.T. 1341. ; TIAS 7868; 943 U.N.T.S. 178.
[290] Agreement on Trade-Related Aspects of Intellectual Property Rights (Marrakesh, Morocco, 15 April 1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of The Uruguay Round of Multilateral Trade Negotiations 321 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994). [hereinafter TRIPS Agreement].
[291] WIPO Copyright Treaty, Dec. 20, 1996 S. Treaty Doc. No. 105-17 (1997). ; 2186 U.N.T.S. 121; 36 I.L.M. 65 (1997).
[292] Comprehensive and Progressive Trans-Pacific Partnership (CPTPP), 21 February 2018.

Table 1: Comparison of AI reference in current selected international agreements

Treaty	**Subject matter and scope of copyright**	**Concept of author**	**Authorship**	**Direct reference to AI or CGW**	**Originality threshold (work)**	**Degree of creativity** **(author's creative choices)**	**Fixation**
Berne Convention	Literary and artistic works	Lack of definition	Lack of definition	None	Minimum, left to domestic regulations	Minimum, left to domestic regulations	Any form of expression Open to domestic legislation
Universal Copyright Convention	Literary, scientific and artistic works	Lack of definition	Lack of definition	None	No reference	No reference	Reproduction in tangible form and the general distribution to the public of copies of a work from which it can be read or otherwise visually perceived.
WTO's TRIPS	Literary and artistic works (refers to Berne Convention)	Lack of definition (refers to Berne Convention)	Lack of definition (refers to Berne Convention)	None	Lack of definition (refers to Berne Convention)	Lack of definition (refers to Berne Convention)	Tangible expressions, not ideas, procedures, methods of operation or mathematical concepts.
WIPO Copyright Treaty	(i) computer programs, whatever the mode or form of their expression; and (ii) compilations of data or other material (databases)	Lack of definition (refers to Berne Convention)	Lack of definition (refers to Berne Convention)	None	Refers to intellectual creations	Lack of definition (refers to Berne Convention)	Any form of expression
CPTPP	work, performance or phonogram	Lack of definition	Lack of definition	None	Lack of definition (refers to Berne Convention)	Lack of definition (refers to Berne Convention)	Lack of definition (refers to Berne Convention)

The fundamental base for copyright protection is the Berne Convention for the Protection of Literary and Artistic Works. There are different interpretations as to what is required for "authorship" and who an "author" is, and it is left to states to determine these concepts. It seems that there is a general conclusion among countries that author's intellectual participation is the most important element when referring to authorship.[293] The concept is not directly defined in the Berne Convention, but it can be derived that it refers to only a natural person, for example, when the term of protection is considered, as it refers to the life of the author and the concept of moral rights. However, legal person can also be considered author. Nevertheless, as stated by Abbot, "nothing in these, or any other binding international instrument, explicitly authorizes, or prohibits, protections for CGWs".[294] The lack of "author" definition in the Berne Convention may allow countries to protect AI/CGW. Indeed, the Berne Convention commitment to human authorship wavers with respect to cinematographic works, since Art. 14bis(2) permits vesting copyright in the "maker" of a cinematographic work.

The reasons behind the lack of definition have generated serious debates. Ricketson argued that despite overlooking the definition of "author," there was a basic agreement regarding the meaning of the term between the contracting states.[295]The Berne Convention is based on two pillars, whose respective widths vary in common law and civilian systems. The first one (generally attributed to civil law states) is the natural rights of the author, a rationale that roots exclusive rights in personal creativity and that largely underpins the Berne Convention. The second (most frequently associated with common law countries), incentives to create, invest in creativity, and to disseminate works for the general benefit of society.[296] These pillars reflect the reality faced back in the 1880s. Hence, it can be argued that human authorship was embodied in the original spirit of the Convention, not being able to currently acknowledge that circumstances have evolved since this moment.

As stated by Ricketson, this evolutionary approach was present in the Berne Convention, specifically in cinematographic copyrights, as films' rights are granted to the "maker" of the film.[297] This special treatment of cinematographic works serves to underscore the general principle that authorship of works is limited to natural persons.

In the 1982 recommendation by WIPO and UNESCO, computer generated copyrights were mentioned. Copyright ownership was recommendable given to the user of the program, while the programmer is considered an author or co-author if they had a creative contribution.[298] Still, as technologies evolve, the need to include AI as a possible author is stressed. Ihalainen states that any future legislation around AI and copyright would therefore have to distinguish between computer created works and works created with the assistance of computers. This in order to protect the interests of active, computer-assisted

[293] Bakhariey, *supra* note 32.
[294] Abbott, *supra* note 4, at 1675.
[295] Ricketson, *supra* note 13, at 1.
[296] Jane C. Ginsburg, *People Not Machines: Authorship and What It Means in the Berne Convention*, 49 INT. REV. INTELLECT. PROP. COMPET. LAW 131, 131-135 (2018).
[297] Ricketson, *supra* note 13, at 1.
[298] Sorjamaa, *supra* note 37, at 724.

creators, but restraining the rights in passive AI-created works in the absence of clear and substantial human input.[299]

When reviewing other international agreements, we find a similar diagnosis. First, most of international regulations refers to Berne Convention in terms of definition, and most of the differences are set up in protection timeframes and enforcement mechanisms. Second, most of the agreements had been negotiated in a context where AI was not capable of generating new works, and therefore, human authorship was not challenged. In the case of the Universal Copyright Convention, as an alternative to the Berne Convention for developing economies, the definitions of author or authorship were not addressed, leaving it to domestic legislations. Its main purpose was to establish a universal copyright system not affecting existing national regulations, through the promotion of national treatment amongst the members, and a less restrictive policy than the proposed by the Berne Convention.[300]

In the case of the TRIPS Agreement, as stated by Story "Berne's provisions do provide a central element of the overall TRIPS package, as Berne's key assumptions and ideology infuse the copyright agenda of both TRIPS and of the World Trade Organization that enforces its provisions".[301] The TRIPS Agreement in its article 1 refers to "the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits" leaving the definition of author to these international agreements. Due to TRIPS national treatment, if any member state recognize the protection of AI works, it should become available in other members.[302]

It must be highlighted that during the discussion of the WIPO's Model Copyright Law, AI/CGW were considered. The Model stated that "the original owner of the moral and economic rights in such a work would be either the entity by whom or by which the arrangements necessary for the creation of the work are undertaken, or the entity at the initiative and under the responsibility of whom or of which the work is created and disclosed".[303] Nevertheless, the Model was never adopted as further study was needed. Therefore, no multilateral commitments have been installed, leaving regulations at a domestic level.

K. Domestic regulations

As reviewed above, international agreements have set a framework regarding some aspects of copyrights protection, through the establishment of minimum requirements and protections. However, these agreements have left open important aspects to domestic

[299] Jani Ihalainen, *Computer creativity: artificial intelligence and copyright*, 13(9) JOURNAL OF INTELLECTUAL PROPERTY LAW PRACTICE 724, 724-28 (2018).
[300] Alberto Cerda, *Evolución histórica del derecho de autor en América Latina*, 22(1) IUS ET PRAXIS 19, 19-58 (2016).
[301] Alan Story, *Burn Berne: Why the Leading International Copyright Convention must be Repealed*, 40(3) HOUS. L. REV. 763, 763-801 (2003).
[302] TRIPS, *supra* note 44.
[303] Abbott, *supra* note 4, at 1675. ; Clifford, *supra* note 4.

legislations to define, such as author, authorship, creativity, originality and how those ideas should be expressed. Therefore, in order to completely understand the treatment of AI works, we need to examine national legislations. For this purpose, we analysed the norms in three relevant actors in the international system, the United States, United Kingdom and European Union. The first two are based on common law, while the latter is based con continental law. Table 2 summarizes the comparison among these actors, considering elements such as subject matter and scope of copyright, concept of author, authorship, any direct reference to AI or CGW, the originality threshold, the degree of creativity and fixation.

Table 2: Comparison of AI reference in current selected domestic regulations

	Law	Subject matter and scope of copyright	Concept of author	Authorship	Direct reference to AI or CGW	Originality threshold (work)	Degree of creativity (author's creative choices)	Fixation
United States	**US Copyright Act of 1976 and future amendments**	(1) literary works; (2) musical works, including any accompanying words; (3) dramatic works, including any accompanying music; (4) pantomimes and choreographic works; (5) pictorial, graphic, and sculptural works; (6) motion pictures and other audio-visual works; (7) sound recordings; and (8) architectural works.	Not defined	Human author	Yes	Original works of authorship, own intellectual effort.	creative choices	Reproduction in tangible medium
United Kingdom	**Copyright, Designs and Patents Act 1988**	Literary, dramatic, musical or artistic work	"the person who creates it"	Programmers	Yes	Not consistent and determined by courts	Not consistent and determined by courts	Fixation is not an element of authorship
European Union	**Eleven directives[304] & two regulations[305]**	Depends on each Directive	Not defined Left to national legislatures and courts.	Lack of clarity	Adapt copyright legislations to new technological developments	Not defined: "author's own intellectual creation". Left to national legislatures and courts.	Defined for some type of works, but mostly left to national regulations	Defined for some works, but mostly left to national regulations

[304] Directive on the harmonisation of certain aspects of copyright and related rights in the information society; Directive on rental right and lending right and on certain rights related to copyright in the field of intellectual property; Directive on the resale right for the benefit of the author of an original work of art; Directive on the coordination of certain rules concerning copyright and rights related to copyright applicable to satellite broadcasting and cable retransmission; Directive on the legal protection of computer programs; Directive on the enforcement of intellectual property right; Directive on the legal protection of databases; Directive on the term of protection of copyright and certain related rights amending the previous 2006 Directive; Directive on certain permitted uses of orphan Works; Directive on collective management of copyright and related rights and multi-territorial licensing of rights in musical works for online use in the internal market; Directive on certain permitted uses of certain works and other subject matter protected by copyright and related rights for the benefit of persons who are blind, visually impaired or otherwise print-disabled.

[305] Regulation on the cross-border exchange between the Union and third countries of accessible format copies of certain works and other subject matter protected by copyright and related rights for the benefit of persons who are blind, visually impaired or otherwise print-disabled; Regulation on cross-border portability of online content services in the internal market.

In the United States, the human intervention in the creation process has become the fundamental piece to attribute copyright to a work. The Copyright Office has stated that "[the office] will not register works produced by a machine or mere mechanical process that operates randomly or automatically without any creative input or intervention from a human author".[1] For a work to be copyrightable, "it must owe its origin to a human being".[2] This interpretation has derived into the complaint that AI developers would not have incentives to improve their capabilities, and that the term "authorship" should be redefined to include both humans and non-humans authors.[3]

In the United Kingdom, the Copyright, Designs and Patents Act 1988 (CDPA) added a provision that allowed the authorship of computer-generated works (where the work is generated by a computer in such that there is no human author) to vest in "the person by whom the arrangements necessary for the creation of the work are undertaken", in many cases courts are expected to interpret these elements.[4] Section IX (3) of CDPA states that if a work meets the requirement in relation of the author or country –if it was first published in the UK- there is no consideration of human involvement.[5] The UK Act is not accurate in terms of originality, as each kind of work requires individual applications, leaving it to court interpretation. As it was mentioned, in order to determine the author of the AI-created work, the threshold for originality and author's definition must be considered.[6] Therefore, whether AI can produce copyrightable works is not clear. It must be highlighted that these provisions were included when AI did not challenge copyright regulations.

In the European Union (EU), the objective of constructing a single market has led to centralize and harmonize national IP laws. The cases ruled by the Court of Justice of the European Union (CJEU) established the doctrine of exhaustion and the specific subject matter. The European Union Computer Programs Directive does not specifically permit or refuse copyright protection for CGWs, but many member states have laws that restrict authorship to natural persons.[7] However the Directive states in Article 1(3) that "a computer program shall be protected if it is original in the sense that the author's own intellectual creation. No other criteria shall be applied to determine its eligibility"[8].

The Commission of the European Union addressed in the 1988 Green Paper on copyrights the new challenges posed by computer creations.[9] For the Commission, the idea of copyright protection is based on the "exercise of sufficient skill and labour", so the user is entitled the protection, and the computer is just a tool. Besides, as it was mentioned, the 2019 EU Directive on Copyright in the Digital Single Market does not address these issues, but it regulates the use of data, instrumental for AI

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1 Kalin Hristov, *Artificial intelligence and the copyright dilemma*, 57 IDEA 431, 431-54 (2016).
2 Davies, *supra* note 12, at 601. ; Clifford , *supra* note 4.
3 Gonenc Gürkaynak, Ilay Yılmaz, Türker Doygun, & Ekin İnce, *Questions of Intellectual Property in the Artificial Intelligence Realm*, 3(2) THE ROBOTICS LAW JOURNAL 9, 9-11 (2017). ; Hristov, *supra* note 60. ; Margot E. Kaminski, *Authorship, disrupted: AI authors in copyright and First Amendment Law*, 51 UCDL REV. 589, 589-616 (2017).
4 Sorjamaa, *supra* note 37, at 724.
5 Davies, *supra* note 12, at 601
6 Sorjamaa, *supra* note 37, at 724.
7 Abbott, *supra* note 4, at 1675. ; Clifford, *supra* note 4.
8 Sorjamaa, *supra* note 37, at 724.
9 *Ibid*.

progress. Some articles from the latest copyright reform were largely discussed before its approval. Particularly, Article 11 that give publishers a way to protect themselves when companies link to their stories, allowing them to demand paid licenses; Article 13 requires platforms to stop users from sharing unlicensed copyrighted material; and Article 3 regarding the exception for data mining.[10]

L. **Sui generis approach**

As reviewed, current regulations do not conceive AI as a possible author. Even though this possibility is not restricted by international commitments, national regulations have turned to the conception of human copyright holder. There was no other alternative when this conception was conceived in the Berne Convention, assuming authorship as a human characteristic. This doctrine must be challenged, as new technologies have proven that the copyright requirements may be fulfilled by non-human entities, such as AI.

Therefore, we propose the recognition of a new conceptual category for this type of creations: Artificial Intelligence Generated Works (AIGW). AIGW distinguished from other computer-related works, as it is based on the autonomy that AI has in the creative process (Figure 3). Current technological developments have made clear that AIGW cannot be necessarily considered inert in the creative process. From here, we face two possible outcomes when analysing the concession of copyright protection. On the one hand, and as reflected by the literature, when the AI creative process is not autonomous (human participation and creativity can be reflected in the final work), assigning copyrights will depend on the actual participation of the programmer or user[11]. On the other hand, AI entities can make autonomous decisions (not due to randomness or pre-established algorithms) in the creative process, due to the learning process and its capacity to generate and express new ideas. Hence, authorship of these works should be attributed to AI.

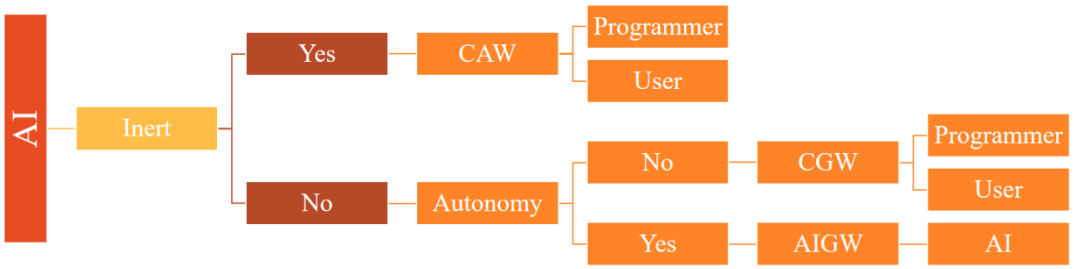

Figure 3:
Establishing AI autonomy
Source: Authors' elaboration

Under current legislations, AIGW would fall into public domain, or in the best-case scenario, copyrights would be attributed to "the person by whom the arrangements necessary for the creation of the work are undertaken"[12] as stated in the

[10] James Vincent, *EU approves controversial Copyright Directive, including internet 'link tax' and 'upload filter'*, THE VERGE (Sep. 12, 2018), www.theverge.com/2018/9/12/17849868/eu-internet-copyright-reform-article-11-13-approved.
[11] Boyden, *supra* note 23.
[12] UK Copyright, Designs and Patents Act 1988.

UK Law, and no recognition of authorship would be given. As technology evolves, stressing the limitations of the current framework, the gap between IP protection and AI development may increase.

In order to breach the gap, current IP regulations should adapt to incorporate AI. Although, as it was mentioned, these regulations are developed at the domestic level, international forums may be functional towards debating and achieving common definitions. Particularly, as international conventions (Berne) represent the framework of these regulations. For example, smaller forums, with non-binding characteristics, and comprising like-minded economies such as the Organization for Economic Co-operation and Development (OECD) and the Asia-Pacific Economic Cooperation (APEC) can help to identify best-practices and creating model laws and guidelines that may be used by member (and non-member) economies. While OECD membership is mainly driven by developed economies, APEC heterogeneity could become (as previously with other topics) a natural experiment laboratory.

Besides, due to the economic impact that technological changes could embrace, it would not be surprising that countries may begin to undertake this discussion through trade agreements. To this regard, close attention should be put on regulations derived from new preferential trade agreements such as Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)[13] or Agreement between the United States, the United Mexican States and Canada (USMCA)[14]. While concepts like authorship are not being part of these agreements, chapters on digital trade are ruling on data flows, which are vital for AI growth. These agreements are focused on promoting technological innovation and its dissemination to encourage social and economic welfare, as highlighted in the CPTPP IP chapter.

Based on the previous discussion and the need to recognize AI, we support the establishment of a sui generis protection system, with a proper definition and scope of protection, that could recognize the AI authorship as well as incentive the creation of both new AI and AIGW. First, as traditionally the distinction between ownership and authorship was not needed, it has not been fully addressed in the AI context. A sui generis system should be capable of recognizing the contribution of the AI as author. Second, it will grant the ownership to the employer, investor or other person for whom the work was prepared, or the person by whom the arrangements necessary for the creation are undertaken; generating the incentives to enhance the development of new AI and AIGW.

In this context, we recommend a protection expiring after fifteen years and the work will be available to the public. The idea is to recover investment and maintain the incentive for AI technology development, while recognizing AI as the author. In summary, the sui generis system should,

- Recognize the autonomous contribution of the AI as author and protect the investment, ensuring protection against unauthorized use.

[13] Hosuk Lee-Makiyama, *Biefing Note: AI & Trade Policy*, ECIPE (2018), https://ecipe.org/wp-content/uploads/2018/10/TDS2018-BriefingNote_AI_Trade_Policy.pdf. ; Susan Aaronson, *Artificial Intelligence is Trade Policy's New Frontier*, CIGI (Jan. 11, 2018), www.cigionline.org/articles/artificial-intelligence-trade-policys-new-frontier.

[14] Jesse Hirsh, *How Will the Digital Economy Fare under the USMCA?*, CIGI (Oct. 8, 2018), www.cigionline.org/articles/how-will-digital-economy-fare-under-usmca.

- Establish a proper definition and scope of protection.
- Grant protection that can expire after fifteen years and the work will be available to the public.
- Economic rights derived from the AI protection should be conferred to the employer, investor or other person for whom the work was prepared or by whom the arrangements necessary for the creation are undertaken.
- Recover investment and maintain the incentive for AI technology development, while recognizing AI as the author.

IV. Final remarks & policy recommendations

As reviewed, the development of AI challenges not only the current regulatory frameworks, but also the basic concepts of copyright, such as the concept of authorship and its relationship with the human being. Literature debates regarding the possibility of giving authorship to AI, but we can see that as AI develops, the arguments against its recognition are blurred. Both the regulatory frameworks and the grounds that support them are not immutable, on the contrary, they should be able to adapt to new scenarios. In this sense, while during the 20th century, technology was treated as something inert (a functional tool for human creation), due to its development, the human concept of author and the subsequent copyrights concession seem to have reached a turning point. The discussion should not be limited to whether current copyright regulations or conventions include the possibility of protecting non-human creations, but as technology has proven, it should move on to the incorporation of this new reality into our legal systems.

In this context, this article proposes the recognition of a new conceptual category for this type of creations: AIGW. This concept distinguished from other computer-related works, as it is based on the autonomy that AI has in the creative process. This autonomy refers to AI as the entity that makes the decisions in the creative process, not due to randomness or pre-established algorithms, but due to the learning process and its capacity to generate and express new ideas.

Once established the need to recognize AI authorship and copyright, the question turns to how to grant AI protection. Evidence has been given that the current intellectual property regime faces many limitations when referring to AI protection. As AI cannot be protected by the current copyright system, it is necessary to establish a special form of protection regime outside the present framework, a sui generis right. This system will be capable of recognizing the contribution of the AI as author, as well as granting ownership to the employer, investor or other person for whom the work was prepared, or the person by whom the arrangements necessary for the creation are undertaken. This system comprises protection that will expire after fifteen years, allowing to recover investment and maintain the incentive for AI technology, while recognizing AI as the author.

The establishment of this sui generis regulation is not a simple process and an international consensus towards this approach would be needed. The inexistence of an international consensus over the forms to regulate AI outcomes has led to tackle these issues through domestic regulations, particularly in developed economies. Different

approaches have been drawn, but a general gap, on the definition of "author" and whether IP may be granted to the owners of machines may be identified.

The recognition of AI as author may open the space for harmonization of domestic regulations, as there is a need to homogenize the definitions related to AI, particularly authorship, and if this could be embraced by a machine, or given to its owner.[15] In this context, international forums have paved the way to establish common definitions, for which discussion in OECD and APEC may be functional towards debating and achieving consensus. Besides, trade agreements, such as CPTPP or UMSCA, have started to define some related issues. While concepts like authorship are not being part of these agreements, chapters on digital trade are ruling on data flows, which are vital for AI growth. Due to the economic impact that technological changes could embrace, it would not be surprising that countries may begin to undertake this discussion through trade agreements.

[15] Swapnil Tripathi, & Chandni Ghatak, *Artificial Intelligence and Intellectual Property Law*, 7(1) CHRIST UNIVERSITY LAW JOURNAL 83, 83-97 (2018).

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