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STOCKHOLM INTELLECTUAL PROPERTY LAW REVIEW

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Content

Student Editorial

The second half of 2023 was marked by a string of landmark events for – not only – the IP world. With the Age of Artificial Intelligence (AI) in full bloom, several endeavours in the legal world have sought to illuminate the legal issues that have arisen in its wake.

In April 2021, the European Commission introduced a regulatory framework for AI – the AI Act. Subsequently, following the proposal and the EU Council's adoption of proposals in December 2022, the European Parliament released its adopted negotiating position and amendments in June 2023. After a 'marathon' of negotiations, a provisional agreement on the AI Act was forged on December 9th 2023. With the AI Act Europe establishes the groundwork for what was to become the first international agreement on the regulation of AI.

Albeit IP does not lie at its very core, the AI Act has nonetheless highlighted Europe's stance on the role of copyright for next generation technologies. That is to say that the AI Act aspires to deal with a situation brought by AI that rightsholders have been preoccupied with – i.e. use of their works for AI training purposes. Increased transparency has understandably been a devout desire of rightsholders, which the AI Act seems willing to fulfil. The Act proposes transparency requirements for general-purpose AI systems, including technical documentation, compliance with EU copyright law, and disclosure of summaries of the data used for training models. While this requirement aims to reduce unauthorized use of copyrighted material, concerns still linger regarding its effectiveness in preventing infringement, especially since AI developers are not required to provide exhaustive lists of the training data they have used. Furthermore, AI developers argue that implementing these requirements will be complex and could hinder Europe's AI-driven growth, thereby possibly affecting its competitiveness in the 'tech' field.

Moving to another important AI-related development in the IP field, on the 20th of December 2023 the UK Supreme Court ruled in the *Thaler v. Comptroller* case ([2023] UKSC 49). Dr. Stephen Thaler had filed two patent applications for the Comptroller designating the AI system DABUS as inventor. The UK Supreme Court ruled that the current UK patent legislation did not allow the designation of AI as the inventor, emphasising that the 1977 Patents Act stipulates that only a 'natural person' is eligible to be recognized as an inventor. Furthermore, the Court held that Dr. Thaler was not entitled to obtain a patent for any invention developed by DABUS based on his ownership of the AI system. The outcome of the case is hardly surprising and echoes the outcome of similar unsuccessful attempts by Dr. Thaler to have DABUS recognized as an inventor, also before the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO). While AI raises many interesting questions within the field of patent law, the UK Supreme Court ruling confirms that AI inventorship is still largely non-negotiable in most jurisdictions.

Despite the AI-intense developments the last months of 2023 were preoccupied with, this issue is not limited to that. You may find yourself intrigued by articles from different areas of IP – spanning copyright, trade mark law, patent law, as well as relevant matters such as data exclusivity. Rinder Pietjouw explores the relationship between EU trade mark law and sustainability with a focus on the potential trade mark law holds for the achievement of the EU sustainability goals, as a result of trade marks' capacity to communicate and thus achieve transparency. Emmanouela Roussakis' article deals with EU pharmaceutical legislation or, more concretely, regulatory data exclusivity and the definition of commercially confidential information, considering the balance between commercial interests and transparency in the context of clinical trial data. Dr. Fatih Buğra Erdem's article addresses evergreening practices in patent law and their consequences, including their impact on competition. Last but not least, the article by the founder and content editor of the Stockholm IP Law Review, Professor Frantzeska Papadopoulou, deals with the concept of authorship both in the film industry and in copyright law with a focus on female authors, showing how women have been visible during the debates on authorship and copyright law in the Swedish film industry from early on.

This issue marks the inaugural occasion for the student editors of the Stockholm Intellectual Property Law Review to introduce a SIPLR issue by a student editorial, an endeavor we undertake with great enthusiasm. We take this moment to reflect on the privilege of serving as

editors in a student-led journal. Through the plethora of enlightening contributions, we have the opportunity to delve into the forefront of debates within the IP field and actively participate in their dissemination. This invaluable experience not only enriches our understanding of IP but also serves as a wellspring of inspiration for our academic pursuits. We extend our heartfelt gratitude to all contributors and express a special appreciation to Professor Frantzeska Papadopoulou, Founder of the Stockholm IP Law Review for allowing us to partake in this exciting project and guiding us throughout this journey.

We hope you enjoy reading the latest issue of the Stockholm IP Law Review.

Student editor-in-chief and the editorial team

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The Sustainability of EU Trade mark law

Rinder Pietjouw

ABSTRACT

The EU Sustainable Development Goals have long been a resemblance of the urgent call for climate action and sustainable development. With trade marks being a valuable source of information for consumers, capable of communicating a green reputation, there is a significant risk of consumer deception through greenwashing. Additionally, trade mark law is also used as a means of fostering sustainable development through a guarantee of quality that a trade mark represents. Consequently, trade mark law is concerned with sustainability. This begs the question to what degree EU trade mark law is tailored to achieve the EU Sustainable Development Goals. To answer this question, a thorough assessment is made of the current legal framework of EU trade mark law. The assessment comprises of a look into the influence on sustainable development, together with the discerning of shortcomings in the way the respective aspects of EU trade mark law can add to the achievability of the EU Sustainable Development Goals. It is concluded that EU trade mark law is to a great extent tailored to achieve the EU Sustainable Development Goals, but that with the help of the suggested remedies, EU trade mark law can become a true catalyst of sustainable development.

1. INTRODUCTION

A clean, healthy and sustainable environment is to be recognised as a human right. This is what many UN states have called for in last year's UN General Assembly resolution.[1] A reiteration of what was called for ten years prior and together with this, states were called upon to adopt and implement strong laws that ensure access to information in environmental matters, amongst others.[2] Additionally, the UN resolution reaffirms the commitments made in the UN Sustainable Development Goals (SDGs) and the Paris Agreement.[3] The SDGs reflect a wide array of areas in which sustainable development is necessary in order to negate many of the negative consequences following from everyday behaviour of humans.[4] Recognising a sustainable environment as a human right underlines the gravity of the worldwide crisis of global warming. Next to that, this also reiterates the call for action that has been demanded from states over the last years. This is evidenced by old and new lawsuits against states ensuring the obligations following the Paris Agreement are met.[5]

As a consequence of the awareness of climate change and the increasing dangers it creates, consumers change their purchase preferences to goods and services that are more environmentally sound.[6] On the outset, this is a positive development considering the availability of sustainable goods and services limits damage to the planet, whilst also raising awareness for the need of sustainable development. However, this also invites companies to abuse this desire for sustainability by portraying themselves as sustainable without this being based on facts. This negative development is called 'greenwashing'.

With the increase of attention for one's own ecological footprint, consumers increase the demand for sustainable goods and services. This results in an increase in sustainability related or green EU trade marks (EUTMs), meaning trade mark law has become part of this trend of sustainable goods and services and is used as a tool to meet consumer demand.[7] The increase in green EUTMs as a result of a growing interest in sustainability indicates that EU trade mark law is used as a tool in the shift towards a more sustainable society. Additionally, trade marks have become a way of informing consumers what a brand

1 UN Resolution A/RES/76/300, 'The human right to a clean, healthy and sustainable environment', adopted by the general assembly on 28 July 2022.

2 UN Resolution A/RES/66/288, 'The future we want', adopted by the general assembly on 27 July 2012, p. 4.

3 UN Resolution A/RES/66/288, p. 1 and 5.

4 All of the goals can be accessed via https://sdgs.un.org/goals#goals.

5 Judgment of 20 December 2019, *Urgenda v. The Netherlands*, Case no. 19/00135, NL:HR:2019:2006; *Carême v. France* App no 7189/21 (ECtHR 29 March 2023); *Verein Klimaseniorinnen Schweiz and Others v. Switzerland* App no 53600/20 (ECtHR 17 March 2021); *Duarte Agostinho and Others v. Portugal and 32 Other States* App no 39371/20 (ECtHR 13 November 2020).

6 Sara Cavagnero, 'Governing the fashion industry (through) intellectual property assets: systematic assessment of individual trade marks embedding sustainable claims' [2021] Journal of Intellectual Property Law & Practise 850, 850.

7 EUIPO, Green EU trade marks – 2022 update, p. 7.

stands for or what impact a company has on for instance society and the environment. This should not come as a surprise given the fact that trade marks are given protection due to the ability of providing consumers with information and assisting purchasing decisions.[8] Other than having the function of providing information, the core function of a trade mark is to guarantee the origin of the product by enabling the consumer to distinguish this product from products with another origin.[9] Through this, companies can portray themselves with trade marks which have a sustainable origin, which resonates with the personal interests of consumers who value environmentally sound products and might even be willing to pay more for them. Looking at the functions of a trade mark of providing information and indicating the origin of goods and services, trade marks are more than capable of being used in the context of conveying a sustainable image to consumers. However, with the aforementioned call for strict laws on providing information on environmental matters, it is important that trade marks are used as transparent means of informing consumers on the sustainability of the good or service. The question that remains, however, is to what degree this is, and more specifically, whether this can assist in the achievement of the SDGs. This article aims at finding an answer to this question.

This article will cover multiple aspects of EU trade mark law. Before discussing EU trade mark law in depth, chapter two focusses on the topic of sustainability and the SDGs. The importance of the central topic of sustainability is highlighted and a working definition of the term 'sustainability' is given (paragraph 2.1). Additionally, the fair balance approach with regards to sustainable development is introduced (paragraph 2.2). The following aspects of EU trade mark law will be discussed: descriptive marks (paragraph 3.1), deceptive marks (paragraph 3.2). In addition to these aspects, greenwashing is discussed at length (paragraph 3.3). Through the new directive on green claims, trade marks are also concerned with this important topic. Before coming to the conclusion, the previously discussed solutions on the identified shortcomings of the EU trade mark legal system are revisited in chapter four, thereby providing concrete suggestions for future developments that can further tailor EU trade mark law to achieve the SDGs.

2. SUSTAINABILITY AND THE SDGS

Sustainability is the key topic in this article. Its growing importance is something that has not gone unnoticed by anyone. Naturally, sustainability is at the core of the UN SDGs. Before assessing the achievability of these goals through EU trade mark law, there must first be a clear overview of why it is of such great importance and how it can be defined.

2.1 The importance of sustainability

With the 2015 Paris Agreement and the European Green Deal that followed in 2020, large steps were taken in combatting climate change. Consequently, the improvement of sustainable development had become an issue of great significance.[10] The European Green Deal expanded on this by aiming to put sustainability at the centre of economic policy and the SDGs at the heart of the EU's new policy and legislative measures.[11] Due to the extensive scope of the parties involved, sustainable development and sustainability had become one of the main priorities of states. The importance of sustainability was underlined in a UN Resolution that gave rise to the foundation of the SDGs.[12] In specific, the General Assembly renewed its commitment to sustainable development and ensured the promotion of an economically, socially and environmentally sustainable future for our planet and for present and future generations.[13] With this commitment, the General Assembly confirms the importance of not just sustainability, but also the pillars that shape sustainability. As a result, sustainability is introduced into the day-to-day discussions on international and national policies.[14] The UN has even deemed the roadmap towards sustainability in the shape of the 17 SDGs to be vital to the survival of humanity.[15] The gravity of this cannot go unnoticed. Consequently, one might suggest a larger role for trade mark law on this crucial journey of sustainable development.

On the outset, it is clear that trade mark law was established first and foremost to enable a right holder to protect signs that function as an indicator of origin.[16] Specifically, the proprietor of an EUTM can prevent third-party use of signs that infringe his trade mark.[17] The protection of intellectual property is codified within the CFREU.[18] This means the protection of one's own intellectual creation is deemed to be a fundamental right. Where should this fundamental right be positioned in the paradigm of something that is a threat to humanity? The alarming message of the UN would suggest it is time for a radical change in favour of sustainable development. However,

8 Giovanni B Ramello, 'What's in a sign? Trademark law and economic theory' [2006] Journal of Economic Surveys vol. 20 547, 549.

9 Judgment of 23 May 1978, *Hoffmann-La Roche v Centrafarm*, C-102/77, EU:C:1978:108, paragraph 7.

10 See the Paris Agreement, articles 2(1), 4(1), 6, 7(1), 8(1) and 10(5).

11 European Commission, 'The European Green Deal', paragraph 1.

12 UN Resolution A/RES/66/288, 'The future we want', adopted by the general assembly on 27 July 2012.

13 UN Resolution A/RES/66/288, paragraph 1.

14 Ben Purvis, Yong Mao & Darren Robinson, 'Three pillars of sustainability: in search of conceptual origins' [2019] Sustainability Science 681, 682.

15 UN, The Sustainable Development Goals Report [2022], p. 3.

16 Justine Pila & Paul Torremans, *European Intellectual Property Law* (2nd edition Oxford University Press 2019) 344.

17 EUTMR, art 9(2).

18 CFREU, art 17(2).

it would seem illogical to put aside fundamental rights all together in an effort of maximising sustainability. This does not mean there cannot be a place for sustainable development within trade mark law. By analogy, trade mark law can contribute to sustainable development. The question that remains is how this would be possible. Naturally, not all elements of trade mark law are suitable for including sustainable development, as this was not considered when introducing this legal system. Therefore, there should be a detailed look at the individual elements of the system of trade mark law, thereby identifying how sustainable development can be awarded a role, without devaluating the fundamental rights of the right holder. The most suitable way to explore this is by maintaining a fair balance between trade mark law and sustainable development.

The working definition of 'sustainability' that is supported throughout this contribution, is based on the point of view that sustainability is a system, given by Ben-Eli: "*A dynamic equilibrium in the process of interaction between a population and the carrying capacity of its environment such that the population develops to express its full potential without producing irreversible adverse effects on the carrying capacity of the environment upon which it depends*."[19] This definition makes specific mention of an equilibrium. The approach of sustainability through an equilibrium supports positive development, but to the point that adverse effects become present. This paves the road for a fair balance approach, in specific between the achievement of sustainable development via the SDGs and the protection of the rights of a trade mark proprietor.

2.2 Sustainability and a fair balance approach

The fair balance doctrine is not special to IPR or trade mark law, as it can also be found in EU copyright law.[20] More specifically, it can be found in the InfoSoc Directive.[21] The doctrine entails an interpretation of the rights at hand while establishing a fair balance between the rights of a proprietor, fundamental rights and the public interest.[22] Specifically, the EU Charter of Fundamental Rights mandates a fair balance approach.[23] The CJEU further developed the fair balance doctrine in a series of rulings on the freedom of expression by the users of copyright protected works versus the fundamental right of an author to prevent the use of his work.[24] This resulted in the need to ensure a fair balance between the rights of right holders and users.[25] The CJEU stated that the approach of the fair balance can be taken as a result of the limitations and exceptions to the exclusive rights of the author.[26] However, the CJEU has also ruled that in creating a fair balance, the author's rights should not be limited beyond the limitations and exceptions codified by the lawmaker.[27] As a result, a fair balance must be within the limits of EU law.

Looking at the trade mark law perspective that is taken in this contribution, it should be noted that the dichotomy at hand is between sustainability and the fundamental right of protection of intellectual property pursuant Art. 17 CFREU, creating the legal basis for the rights of the trade mark proprietor in the EUTMR. This would mean the fair balance as found in copyright law cannot be applied in an identical sense as this would presuppose that sustainability is a fundamental right. While it carries great importance, as has been pointed out, sustainability has not been recognised as such. On the other hand, sustainability can undoubtedly be seen as part of the public interest. Moreover, as has been pointed out in the introduction, the right to a sustainable environment is now considered to be a human right by many UN member states. Additionally, the system of EU trade mark law also consists of limitations and exceptions to the rights of a trade mark right holder.[28] By analogy, this also opens up the possibility of a fair balance approach within EU trade mark law. For these reasons, the possibility of a fair balance approach shall be a recurring topic within this article.

3. EU TRADE MARK LAW AND RELATED ASPECTS INTERLINKED WITH SUSTAINABILITY

The previous chapter has laid the groundwork for this article by introducing the concept of sustainability and a suitable definition, as well as presenting the fair balance approach as a way of weighing sustainability against the rights of the trade mark proprietor. With this basis, an in-depth assessment can be made of the different aspects of trade mark law.

19 Michael U Ben-Eli, 'Sustainability: definition and five core principles, a systems perspective' [2018] Sustainability Science 1337, 1340.

20 Thom Snijders & Stijn van Deursen, 'The Road Not Taken – the CJEU Sheds Light on the Role of Fundamental Rights in the European Copyright Framework – a Case Note on the Pelham, Spiegel Online and Funke Medien Decisions' [2019] International Review of Intellectual Property and Competition Law 1176, 1178.

21 Recital 31 Directive 2001/29/EC.

22 Judgment of 8 September 2016, *GS Media*, C-160/15, EU:C:2016:644, paragraph 45.

23 Judgment of 9 July 2020, *Constantin Film*, C-264/19, EU:C:2020:542, paragraphs 35–37; Judgment of 6 December 2017, *Coty*, C-580/13, EU:C:2015:485, paragraphs 34–35.

24 Judgment of 29 July 2019, *Funke Medien*, C-469/17, EU:C:2019:623; Judgment of 29 July 2019, *Pelham*, C-476/17, EU:C:2019:624; Judgment of 29 July 2019, *Spiegel Online*, C-516/17, EU:C:2019:625.

25 Judgment of 29 July 2019, *Funke Medien*, C-469/17, EU:C:2019:623, paragraph 70; Judgment of 29 July 2019, *Spiegel Online*, C-516/17, EU:C:2019:625, paragraph 54.

26 Judgment of 29 July 2019, *Pelham*, C-476/17, EU:C:2019:624, paragraph 60.

27 Judgment of 29 July 2019, *Funke Medien*, C-469/17, EU:C:2019:623, paragraph 60; Judgment of 29 July 2019, *Spiegel Online*, C-516/17, EU:C:2019:625, paragraph 45; Judgment of 29 July 2019, *Pelham*, C-476/17, EU:C:2019:624, paragraph 62.

28 EUTMR, art 14.

3.1 Descriptiveness

3.1.1 The current legal framework

One of the many facets of EU trade mark law that concerns itself with sustainability is the absolute ground for refusal of descriptiveness.[29] In short, this absolute ground for refusal prescribes that trade marks that are perceived as providing information about the goods or services applied for, cannot be registered as such.[30] Particularly, the EUTMR makes mention of the following characteristics: "*the kind, quality, quantity, intended purpose, value, geographical origin or the time of production of the goods or of rendering of the service*". The CJEU has ruled that these characteristics must be objective and inherent to the nature of the product or service.[31] Additionally, the characteristic must be intrinsic and permanent with regards to the product or service.[32] The characteristics mentioned in Art. 7(1)(c) EUTMR tie in with sustainability as this is evidence of how EU trade mark law and sustainability go hand in hand and here is why. When it comes to quality, a sign can be used to indicate that a product is recyclable. With regards to purpose, a good or service might be introduced to save rainforests or to reduce the amount of required packaging materials. The type of production might indicate that an ingredient is sustainably farmed. This way, trade mark law is connected to sustainability in two ways. The one that is most obvious is the way in which sustainable attributes can be communicated to consumers on packaging or via advertisements. The other connection between trade mark law and sustainability follows from the first one, as it is the way in which companies portray themselves as sustainable or environmentally friendly. This is not completely identical to the use of descriptive signs that relate to sustainability, but this also encompasses, potentially purposely, deceiving consumers with the use of green marks that are not descriptive, but are also not based on fact and therefore constitute greenwashing. This topic shall be elaborated on later in this chapter. The connection with sustainability is also supported by the rationale of Art. 7(1)(c) EUTMR. The rationale is that there should not be exclusive rights for descriptive terms, as this would hinder others from using these words as well.[33] Considering the overall importance and popularity of introducing new sustainable products and services with the help of generic green terms, it would be counterintuitive to allow a proprietor to have exclusive rights over something that is, to some degree, beneficial to whole mankind.

3.1.2 Descriptiveness in practice

When it comes to descriptive marks in relation to sustainability, one could argue there is a certain dichotomy. On the one hand, one might argue marks related to sustainability or 'green marks' should be regarded as descriptive on the outset as a result of these marks merely adding a new characteristic and therefore describing goods and services. On the other hand, denying protection for 'green marks' would, to some degree, deny companies the opportunity to market sustainable goods and services. Companies might be hesitant to advertise or promote their sustainable goods and services if the accompanied intellectual property is not protected, due to competitors being able to take advantage of this lack of IP protection. Again, this asks for a fair balance approach between different parties' interests.

The 'green marks' that have previously been referred to have also caught the attention of the EUIPO. In a recent study, the EUIPO reports an all-time high in green EUTM filings in 2021 as a result of growing interest in sustainability.[34] The main finding of the study is a direct correlation between the interest in sustainability and an increase in trade mark filings with terms related to environmental protection and sustainability.[35] This underlines the influence of sustainability on trade marks and why trade mark law should concern itself with this topic.

Green EUTMs usually consist of words, graphic elements or a combination thereof.[36] It must be noted that a word is descriptive if it has a descriptive meaning, signifying it describes a quality or characteristic, for the general public or for a specialised public.[37] Additionally, there can be objections against terms that describe desirable characteristics of the goods and services.[38] This category is highly relevant with regards to green trade marks as sustainability is desired by consumers. However, it must be noted that in case of a composite wordmark, the examination shall focus on the meaning of the sign as a whole, and not that of the individual elements.[39]

As mentioned before, if a term describes "*an intrinsic characteristic that is inherent to the nature of the goods concerned*" it is deemed to be descriptive.[40] This also applies to the use of names of colours as a sign. Particularly relevant in this case would be the use of the name of the colour 'green'. The application for such a trade mark would be refused as it describes a form of environmen-

29 EUTMR, art 7(1)(c).

30 EUIPO, Trade Mark Guidelines, Edition 2023, part B, section 4, chapter 4, paragraph 1.1.

31 Judgment of 6 September 2018, *NEUSCHWANSTEIN*, C-488/16 P, EU:C:2018:673, paragraph 44.

32 Judgment of 7 May 2019, *vita*, T-423/18, EU:T:2019:29, paragraph 44.

33 EUIPO, Trade Mark Guidelines, Edition 2023, part B, section 4, chapter 4, paragraph 1.1.

34 EUIPO, Green EU trade marks – 2022 update, p. 7; The full study report is available at https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/2023_Green_EUTM_report_update_2022/2023_Green_EUTM_report_2022_update_FullR_en.pdf.

35 EUIPO, Green EU trade marks – 2022 update, p. 7.

36 EUIPO, Green EU trade marks – 2022 update, p. 34.

37 EUIPO, Trade Mark Guidelines, Edition 2023, part B, section 4, chapter 4, paragraph 2.1.

38 EUIPO, Trade Mark Guidelines, Edition 2023, part B, section 4, chapter 4, paragraph 2.1.

39 Judgment of 8 June 2005, *Rockbass*, T-315/03, EU:T:2005:211, paragraph 56.

40 Judgment of 9 December 2008, *Visible White*, T-136/07, EU:T:2008:553, paragraphs 42–43.

tally friendly services.[41] Another point of relevance in this regard pertains to adding a single colour to a descriptive word element, either to the letters themselves or as a background.[42] Should one, for instance, add the colour green to a descriptive wordmark, this mark will remain descriptive. As a result, raising a green image by attempting to get the attention of consumers via green coloured marks is not possible, unless the included wordmark is distinctive.

Another way in which the criterion for distinctiveness plays a role in the use of green trade marks is related to the use of a figurative element that has a direct link with the characteristics of the goods and services. Even in case the figurative element does not represent the goods and services, it will not contribute to a distinctive sign.[43] An example of this could be the use of the universal sign for recycling or a different variety on the Möbius loop, as can be seen in this advertisement of Coca-Cola. The use of the sign of recycling has a direct link to the recyclable soft drink bottles. Should Coca-Cola try to register the word element of "recycle & re-enjoy it" in combination with the figurative recycling mark, this would most likely not result in a distinctive mark.[44] This could also follow from the fact that commonly used figurative elements in relation to goods and services, like the universal sign for recycling for recyclable goods, do not add distinctive character to the mark as a whole.[45] To get a better understanding of which green signs are considered descriptive, it is useful to take a look at case law.

EcoPerfect

By decision of the BoA of OHIM, the wordmark was deemed descriptive as it would be understood to mean "*environmentally friendly goods or goods produced from environmentally friendly materials or through an environmentally friendly manufacturing process*", therefore describing a characteristic of the goods.[46] The CJEU shows its willingness to make use of the room for interpretation left by the legislator with regards to the non-exhaustive list of characteristics. The Court recognises that a word sign must be excluded in case any of its possible meanings can indicate a characteristic of the goods and services.[47] In this case, the CJEU points out that the phrase 'ecologically perfect', which follows from the wordmark, can indicate an environmentally friendly origin of the goods and services.[48] Thus, the wordmark describes a characteristic of the goods in question and is deemed to be descriptive.[49] The case at hand is of great value, given the fact that the CJEU does not merely come to the conclusion that the mark is descriptive, but it also points towards the value of environmental compatibility to producers and consumers. In specific, the Court aims to protect the designation of environmental friendliness of goods. As a result of other producers wanting to use this type of indication and consumers paying special attention to it, the Court ensures that it can be used freely by all economic operators.[50] Insofar, one could argue the CJEU blocks the road for the registration of green wordmarks, as granting protection to them would hinder competitors. This could be seen as a positive development, looking at how this can support the increasing attention for sustainability and the ways in which consumers can come into contact with it. On the other hand, when one cannot get trade mark protection for a green wordmark, abundant usage of these types of marks shall follow. As a consequence, manufacturers are at liberty to use green marks freely, as there is no risk of infringing third party trade marks, possibly resulting in deceitful use of said green marks. Strangely enough, the approach of keeping designators of environmental friendliness clear of protection was not retained in the upcoming rulings of the CJEU.

CARBON GREEN

In the case at hand, this word sign was filed for reclaimed rubber, namely recycled carbonaceous materials.[51] The BoA of OHIM stated that the sign as a whole is descriptive of the goods, as they are goods manufactured from carbon obtained in an environmentally friendly manner.[52] The CJEU approves of this interpretation based on how the separate words in the sign would be interpreted by consumers. The registered goods are composed of carbon, meaning the word 'carbon' would be perceived as providing information on

41 EUIPO, Trade Mark Guidelines, Edition 2023, part B, section 4, chapter 4, paragraph 2.9.

42 EUTMDN, Common Communication on the Common Practice of Distinctiveness — Figurative Marks containing descriptive/non-distinctive words [2015], p. 3; full text available at: https://www.tmdn.org/network/documents/10181/278891cf-6e4a–41ad-b8d8-1e0795c47cb1.

43 EUTMDN, Common Communication on the Common Practice of Distinctiveness — Figurative Marks containing descriptive/non-distinctive words [2015], p. 5.

44 Following the EUIPO database, Coca-Cola has not registered a trade mark that is visible in this advertisement. The picture therefore merely serves as an example.

45 EUTMDN, Common Communication on the Common Practice of Distinctiveness — Figurative Marks containing descriptive/non-distinctive words [2015], p. 5.

46 Judgment of 24 April 2012, *EcoPerfect*, T-328/11, EU:T:2012:197, paragraph 8.

47 Judgment of 24 April 2012, *EcoPerfect*, T-328/11, EU:T:2012:197, paragraph 42.

48 Judgment of 24 April 2012, *EcoPerfect*, T-328/11, EU:T:2012:197, paragraphs 42–45.

49 Judgment of 24 April 2012, *EcoPerfect*, T-328/11, EU:T:2012:197, paragraph 47.

50 Judgment of 24 April 2012, *EcoPerfect*, T-328/11, EU:T:2012:197, paragraphs 47–48.

51 Judgment of 11 April 2013, *CARBON GREEN*, T-294/10, EU:T:2013:165, paragraph 2.

52 Judgment of 11 April 2013, *CARBON GREEN*, T-294/10, EU:T:2013:165, paragraph 7.

the composition of the goods.[53] Moreover, the description of the goods shows that they contribute to maintaining ecological balance, meaning there is a specific relationship with the word 'green' and the goods.[54] As a result, the combination of both words would be perceived as an indication of the characteristics of the good, meaning the sign is descriptive pursuant Art. 7(1)(c) EUTMR.[55] This case shows how the CJEU stays close to the meaning of the words of the respective wordmark and what these words indicate regarding the goods and services. However, there does not seem to be any considerations pertaining to the need to ensure terms such as 'green' can be used freely by third parties. With 'green' being one of the most generic terms in reference to environmental friendliness, the CJEU could have underlined the danger of awarding protection to such words.

During court proceedings regarding the application for this figurative mark, the BoA had found that the expression 'we care' would be considered as a promotional slogan for the way in which the goods were manufactured.[56] Additionally, the BoA had stated that the use of the colour green would point towards environmental concerns of the applicant. The CJEU agreed with this approach and stated that the slogan solely had a promotional function.[57] In addition, the CJEU referred to a previous ruling in which it had stated that the colour green is customarily used to designate ecological or environmentally friendly products.[58] As a result, this figurative mark was found to lack distinctiveness.[59] The CJEU did not, however, conclude that this sign was descriptive following Art. 7(1)(c) EUTMR. This can be seen as a result of the examiner not raising this ground for refusal in the first examination of the application. Nevertheless, this case shows the CJEU's attitude towards green marks and how these are not distinctive enough to be awarded trade mark protection. Given the fact that this figurative mark solely consists of the colour green, it is of great importance that the CJEU underlines the inadmissibility of such marks. This is due to the increase in brands using the colour green in trade marks and advertisements or on websites and social media.

53 Judgment of 11 April 2013, *CARBON GREEN*, T-294/10, EU:T:2013:165, paragraph 23.

54 Judgment of 11 April 2013, *CARBON GREEN*, T-294/10, EU:T:2013:165, paragraph 25.

55 Judgment of 11 April 2013, *CARBON GREEN*, T-294/10, EU:T:2013:165, paragraph 32.

56 Judgment of 7 June 2016, *WE CARE*, T-220/15, EU:T:2016:346, paragraph 7.

57 Judgment of 7 June 2016, *WE CARE*, T-220/15, EU:T:2016:346, paragraph 38.

58 Judgment of 27 February 2015, *Greenworld*, T-106/14, EU:T:2015:123, paragraph 24.

59 Judgment of 7 June 2016, *WE CARE*, T-220/15, EU:T:2016:346, paragraph 51.

3.1.3 Shortcomings?

Coming back to achievability of the SDGs, it is important to dissect exactly where the shortcomings are in the current legal framework of the absolute ground for refusal of descriptiveness. As has been pointed out previously, the main overlap between trade mark law and the SDGs follows from the promotion of innovation, safeguarding the use of natural resources and increasing awareness of sustainability. The research into the topic of descriptiveness has shown a clear connection with sustainability, but the connection with the SDGs as such, might not be equally present. Descriptive marks are not granted protection due to the importance of third parties being able to use generic terms. This rationale behind the absolute ground for refusal was confirmed in earlier CJEU case law, but seems to have been put aside as a reason for refusal of descriptive marks. The focus has shifted to what can be deemed a characteristic of a good or service and how a description thereof can point towards a mere description of an essential characteristic. A shortcoming that can be identified as a result, is the lack in clarity in relation to when a sustainability related mark can actually attract trade mark protection. In essence, this requires the fair balance to be restored in such a way that proprietors of distinctive sustainability trade marks can exclude others from using them. Goods or services can be deemed environmentally friendly due to a change in many components of the good or service. It would be fitting to not deem wordmarks related to those environmentally friendly aspects to be characteristics in the sense of Art. 7(1)(c) EUTMR, avoiding the denial of trade mark protection of any mark that uses sustainability related vocabulary. However, this could also result in vague green wordmarks, which would increase the risk of false claims. In order to accomplish transparent promotion of innovation through awarding protection to sustainability related trade marks, trade mark offices could offer clear guidelines on where the line is drawn between distinctive signs and green wordmarks that every party should be allowed to use. This way, the rationale of the absolute ground for refusal of descriptiveness would be respected while still incentivising third parties to innovate sustainable goods and services by granting protection for important aspects of those innovations, such as the signs.

On the other hand, by regarding generic vocabulary related to sustainability as commonplace, the CJEU opens up to the possibility of regarding sustainability commonplace or even as a human right. At the least, by not granting exclusive rights to green mark proprietors, the CJEU ensures that any party that wishes to can promote sustainable goods and services via generic terms and phrases. This is in line with multiple SDGs that seek promotion of sustainability. However, the use of generic terms to inform consumers on sustainability might result in deceptive behaviour in the form of for instance greenwashing.

3.2 Deceptiveness

3.2.1 The current legal framework

Deceptive trade marks are of great influence on the attainability of the SDGs as these are marks that can deceive the public regarding for instance environmental efforts by a manufacturer or a sustainable image of a company. In particular, this relates to false or vague sustainability, also known as as greenwashing.[60] However, it is important to take a close look at the general legal framework of deceptive marks before this crucial topic can be discussed in the next paragraph.

Deceptive marks are not eligible for registration as per the absolute ground for refusal in Art. 7(1)(g) EUTMR. Deceptive trade marks are defined as "*trade marks which are of such a nature as to deceive the public, for instance as to the nature, quality or geographical origin of the goods or service*".[61] The use of the wording 'for instance' indicates that the list of characteristics through which the public can be deceived is non-exhaustive. Moreover, the absolute ground for refusal presupposes existence of actual deceit or a sufficiently serious risk that the consumer will be deceived.[62] In practice, the EUIPO finds that the ground should only be applied in case the list of goods and services is worded in such a way that a non-deceptive use of the trade mark is not guaranteed and there is a sufficiently serious risk that the consumer will be deceived.[63] The rationale behind this interpretation is the perception of the average consumer. Assuming a trade mark would be filed with the intention of deceiving consumers contradicts the level of knowledge of the average consumer, as this person is reasonably attentive and not particularly vulnerable to deception.[64] One could argue this contrasts the absolute character of the ground for refusal due to this reasonably high threshold of deceptiveness. On paper, trade mark proprietors would never knowingly file a trade mark application in order to deceive consumers, knowing this could lead to refusal. However, this intent is hard to prove and therefore allows for the filing of trade marks that have a high likelihood of deceiving consumers, but can also be used in a non-deceptive way.

Another element that is crucial to the examination of a deceptive mark is the relation to the characteristics of the goods and services for which the mark was filed.[65] In principle, this relates to the goods and services that are reflected in a mark. A mark cannot be used as an indication for goods and services that it was not registered for.[66] As a result, deceptiveness is assessed based on how the relevant consumer would perceive the sign in relation to the goods and services for which protection is sought.[67] Naturally, as in almost all trade mark cases, this is dependent on the circumstances. The following example will create more clarity with regards to how trade marks related to sustainability can be deemed deceptive following Art. 7(1)(g) EUTMR. This example pertains to a refusal by the EUIPO of an EUTM application for a green trade mark.

Registration of the following mark was sought for Nice class 22.[68] The sign was used in connection with ramie fibre, raw linen, cotton taw, wadding for padding and stuffing upholstery.[69] Firstly, the EUIPO argued that the average consumer would perceive the mark as providing information that the goods contain silk that is produced in an environmentally sound way. The EUIPO also established that these goods would in reality not be produced with this biological silk. As a result, the mark would deceive consumers with regards to the goods that the mark was filed for.[70]

While consumer deception through green claims has been given more attention over the years, this spike of attention does not seem to have included deceptive trade marks as of yet. This does not necessarily mean that greenwashing through trade marks is not combatted, it merely shows that green trade marks, although potentially deceptive, are not categorised as such.[71] One could identify this as a shortcoming in current EU trade mark law with regards to the achievability of the SDGs.

3.2.2 Shortcomings?

Based on the detailed look into the absolute grounds for refusal of descriptiveness and deceptiveness, it seems that the ground for refusal of green marks mostly lies in the descriptiveness of a mark, rather than the deceptiveness of a mark. A possible cause of this is the earlier discussed presupposition of actual deceit or the serious risk of consumer deception. Should this threshold be less high, more cases of sustainability-oriented marks would fall into the scope of Art. 7(1)(g) EUTMR. In order to protect the consumer, one could deem a threshold of a '*risk of deception of the public*' more fitting. This would put more pressure on trade mark applicants to choose unambiguous wording and provide scientific proof for their need to profile themselves with environmentally sound marks. Moreover, actual deceit as a result of the use of

60 Mohamed Arouri, Sadok El Ghoul & Mathieu Gomes, 'Greenwashing and product market competition' [2021] Finance Research Letters 42 1, 1.

61 EUTMR, art 7(1)(g).

62 Judgment of 30 March 2006, *Elizabeth Emanuel*, C-259/04, EU:C:2006:215, paragraph 47.

63 EUIPO, Trade Mark Guidelines, Edition 2023, part B, section 4, chapter 8, paragraph 1.

64 EUIPO, Trade Mark Guidelines, Edition 2023, part B, section 4, chapter 8, paragraph 1.

65 Magdalena Rutkowska-Sowa & Paweł Poznański, 'Legal aspects of green-branding' [2022] Eastern European Journal of Transnational Relations 57, 62.

66 Rutkowska-Sowa & Poznański [2022] 57, 62.

67 EUIPO, Application no. 018128686 '*Ecofloor4ever*' [2020], p. 1.

68 Nice class 22 comprises the following: "*Ropes and string; Nets; Tents and tarpaulins; Awnings of textile or synthetic materials; Sails; Sacks for the transport and storage of materials in bulk; Padding, cushioning and stuffing materials, except of paper, cardboard, rubber or plastics; Raw fibrous textile materials and substitutes therefor*".

69 EUIPO, Application no. 1570508 '*BIOSILK*' [2021], p. 1.

70 EUIPO, Application no. 1570508 '*BIOSILK*' [2021], p. 1.

71 Cavagnero [2021] 850, 865.

green terminology would be possible to point out, would there actually be consolidated or legally binding definitions of the words used that fall under the scope of green terminology.[72] Many self-regulating organs or advertising regulatory bodies provide lists with definitions of sustainability related vocabulary.[73] Once trade mark offices draw inspiration from this and provide a clear line between allowable green terminology in trade mark applications, deception through trade marks is less likely to happen.

Further, one could argue that Art. 7(1)(g) EUTMR can be of essential value in the context of the SDGs. The provision, as has been pointed out, provides a non-exhaustive list of characteristics that can point towards a deceptive nature of a sign. The SDGs promote the spread of accurate information regarding sustainability, to avoid confusion and misleading. Consequently, deceptiveness is the designated ground for refusal to avoid this confusion and misleading regarding sustainability through trade marks. To highlight the importance of this ground for refusal and to induce objections based on this ground by trade mark offices, a notable suggestion would be to codify 'sustainability' as one of the characteristics that can spark a deceptive nature of a sign.

3.3 Greenwashing

A topic that has been mentioned multiple times and that is of great value to this contribution is greenwashing. The importance of this topic follows from its clear interlinkage between sustainability and trade marks. Examples of green trade marks or environmentally sound trade marks have been discussed. The problem these trade marks pose lies in greenwashing, or "*activities by a company or an organization that are intended to make people think that it is concerned about the environment, even if its real business actually harms the environment*", to put it in simple words.[74] One of the ways through which companies can do this is via the previously discussed trade marks that concern themselves with sustainability. Another point that has been previously discussed is how the legal framework of descriptive and deceptive trade marks contains a shortcoming in the shape of a lack of concrete objections towards trade marks that are used to misinform consumers or unjustly create a sustainable image. It is worth discussing whether the regulation of greenwashing can help amend this shortcoming or how this can be utilised as inspiration for how EU trade mark law could be bettered to improve the achievability of the SDGs.

3.3.1 The proposed directive on green claims

In order to provide an accurate look into how greenwashing is regulated through EU legislation, it is prudent to look into the most recent legislation on this topic, being the proposal for an EU directive on substantiation and communication of explicit environmental claims (Green Claims Directive).[75] It must be noted that this directive is not specifically aimed at the field of trade mark law. However, as will be shown, trade marks do fall within the scope of the proposed directive, meaning it is still relevant in the scope of greenwashing. The rationale behind this proposal is the call for more transparency with regards to sustainability and the environmental footprint of products.[76] Additionally, the proposed legislative changes are meant to support achieving SDG 12.6, which aims at encouraging companies to adopt sustainable practices and to integrate sustainability information into their reporting cycle.[77] This is not the only reference to the SDGs in the proposal, as there is also a clear indication of what this proposed directive aims to achieve in terms of progress towards the SDGs. The proposal is expected to lead to consumers purchasing an increasing number of products which do not deceive consumers regarding their environmental impact, thereby ensuring sustainable consumption and production patterns, as prescribed by SDG 12.[78]

Posing as a bridge between trade mark law and the SDGs, greenwashing and its new regulatory framework confirm why trade mark law should be concerned with sustainability. Firstly, one of the key objectives of the proposed directive is increasing the level of environmental protection and contributing to the overall green transition within the EU.[79] Without specifying a direct link to the SDGs, it is clear that for instance SDG 13, which promotes taking action to combat climate change, is contributed to through the objective of the proposed directive. In addition, it has been confirmed by the EC that sustainable consumption relies on transparent communication. In specific, the proposed directive aims at combatting greenwashing by ensuring that consumers receive reliable, comparable and verifiable information that allows them to make sustainable decisions.[80] Information is also communicated towards consumers via trade marks. Therefore, characterising trade marks as green claims when green terminology is used in the mark, would add to the already expected progress towards sustainable consumption, thus achieving goal 12 of the SDGs. The legislator has left room for this possibility considering an environmental claim is defined as follows: "*as **any message or representation**, which is not mandatory under Union law or national law, including text, pictorial, graphic or symbolic representation, in any form, including labels,*

72 Cavagnero [2021] 850, 865.

73 An example of this is the ICC framework for responsible environmental marketing communications, see: https://icc.se/wp-content/uploads/2021/11/20211123-Marketing-Environmental-framework_2021.pdf.

74 Definition of the term 'greenwashing' provided by the Oxford Dictionary, see https://www.oxfordlearnersdictionaries.com/definition/english/greenwash?q=greenwashing.

75 Proposal for Directive 2023/0085 COM(2023) 166 final.

76 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 2.

77 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 2.

78 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 17.

79 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 7.

80 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 1.

brand names, company names *or product names, in the context of a commercial communication, which states or implies that a product or trader has a positive or no impact on the environment or is less damaging to the environment than other products or traders, respectively, or has improved their impact over time*".[81] When looking at the wording of this definition it is clear that also registered trade marks fall under the scope of an environmental claim as these can be a message or representation that can imply, in short, environmental friendliness. In addition, brand names and company names have even been highlighted as an example of what falls under the scope of an environmental claim. Consequently, trade marks fall under the scope of the proposed directive.

The proposal can be seen as a huge improvement on the current EU legal framework on greenwashing in the shape of the directive on unfair commercial practices.[82] This directive does not discourage the use of green claims, nor does it provide any guidelines or provisions tailored to sustainability related claims or trade marks.[83] However, the proposed directive does not replace the directive on unfair commercial practices, it complements it.[84] The improvement of the legal framework on greenwashing follows from the following changes: firstly, the list of product characteristics regarding which a trader should not deceive a consumer in Art. 6(1) of the directive on unfair commercial practices is amended to include *'environmental or social impact, 'durability' and 'reparability'*.[85] Next, the list of actions which are to be considered misleading in Art. 6(2) of the directive on unfair commercial practices now includes '*making an environmental claim related to future environmental performance without clear, objective and verifiable commitments and targets and an independent monitoring system*'.[86] Further, the list of commercial practices considered as unfair now includes greenwashing related practices, such as making a generic environmental claim without being able to demonstrate the appropriate environmental performance.[87]

3.3.2 Shortcomings?

When examining the proposed directive closely, it is clear that the EC aimed at tackling the problem of greenwashing with the fair balance approach. A fair balance had to be found between the interests of companies, the protection of consumers and the welfare of the internal market.[88] The search for a fair balance becomes more apparent when one considers that consumer protection and environmental protection are recognised as fundamental rights.[89] This opens up to an interesting question pertaining to whether sustainability can be framed within the fundamental rights discourse. It has been previously discussed that following the recent resolution many UN member states consider sustainable development to be a human right.[90] Similarly, the CFREU also prescribes that "*A high level of environmental protection and the improvement of the quality of the environment must be integrated into the policies of the Union and ensured in accordance with the principle of sustainable development*."[91] In a way, sustainability has already been recognised as a fundamental right based on the evident reference to the principle of sustainable development. A new perspective is provided on the fair balance approach when sustainability is granted a place in the framework of fundamental rights. Consequently, the right to intellectual property following Art. 17(2) CFREU can be directly weighed against the right to sustainability following Art. 37 CFREU.

When looking at the interests at hand, a significant decision in favour of the interest of companies is that the proposed directive does not specify how companies should substantiate the environmental claims they make.[92] Worth noting is that the EC is well aware of the grave impact this can have on the internal market. Not providing a uniform approach for the substantiation of environmental claims could lead to fragmentation of the internal market as a result of the different approaches and different requirements that companies must adhere to throughout the EU. Consequently, this will result in legal uncertainty and increase compliance costs and unfair competition within the EU.[93] Further harmonisation on the topic of substantiation of environmental claims can therefore be of crucial value in future. In this regard, the Product Environmental Footprint (PEF) could have posed as a solution. With this method, companies measure and communicate about the environmental performance of goods and services and organisations across the whole lifecycle, whilst relying on scientifically accurate methods.[94] There even was an extensive pilot period from 2013–2018. Surprisingly, the EC did not implement this method in the proposed directive.

Another pressing matter that arguably was not dealt with in the appropriate fashion is the lack of a complete ban on generic climate claims, specifically pertaining to the scope in which trade marks are included. In the preamble of the proposed directive the EC recognises that climate related claims are particularly prone to ambiguity and deception.[95] Given examples of such claims are 'cli-

81 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 2–3.

82 Directive 2005/29/EC.

83 Cavagnero [2021] 850, 866.

84 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 1.

85 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 5.

86 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 5.

87 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 5.

88 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 8–9.

89 CFREU, arts 37–38.

90 UN Resolution A/RES/66/288.

91 CFREU, art 37.

92 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 8.

93 Proposal for Directive 2023/0085 COM(2023) 166 final, p. 8.

94 European Commission, 'Environmental Footprint Pilot Guidance document, – Guidance for the implementation of the EU Product Environmental Footprint (PEF) during the Environmental Footprint (EF) pilot phase' [2016], vol. 5.2, p. 10.

95 Proposal for Directive 2023/0085 COM(2023) 166 final, preamble (21).

mate neutral', 'carbon neutral' and 'net-zero'. Claims like these beg the question which part of the value chain they pertain to, when climate neutrality will be reached and how this will actually be realised. A full prohibition on climate-related environmental claims does pose as a solution, as has been shown by the French legislator through its amendments of the national Environment Code.[96] The 2022 amendment of the Environment Code contains a prohibition on the use of the terms "carbon neutral", "zero carbon", "with a zero carbon footprint", "climate neutral", "fully offset", "100% Compensated" or any wording of equivalent meaning within advertisements.[97] Moreover, the earlier proposed directive 2022/0092 on unfair practises includes a prohibition of generic environmental claims as well, accompanied by a long list of examples.[98] In case the proposed directive on green claims would have included a comparable prohibition, companies would have more guidance on how to use a climate-related environmental claim and, most importantly, consumers would no longer be exposed to ambiguous and misleading generic claims.

4. WHAT IS NEEDED?

4.1 General remarks

Throughout the previous chapters, multiple challenges and shortcomings have been pointed out with regards to the discussed aspects of the EU trade mark regulatory system. These shortcomings relate to the overall topic of this article, being the achievability of the SDGs. It has been argued that EU trade mark law is concerned with sustainability due to the ever-growing number of companies using trade marks to promote sustainability and to portray themselves as sustainable. Consequently, the EU trade mark system would benefit from a more thorough incorporation of sustainability in the regulatory system. The identified shortcomings point towards different solutions for the different aspects of the EU trade mark law system. However, some aspects can benefit from the same solutions. Therefore, it is the aim to further elaborate on fitting solutions that can further introduce sustainability into EU trade mark law with the objective of achieving the SDGs. In light of current legislation and the previously discussed legislative proposals, unnecessary regulatory overhauls are not the goal, but rather a last resort. A key element in identifying possible solutions to the highlighted shortcomings is maintaining a fair balance approach. One might be eager to afford protection to consumers, but this could negatively impact the freedom to conduct business and interfere with the internal market.[99] Therefore, all relevant interests must be weighed against each other.

4.2 Possible improvements

When it comes to the topic of descriptiveness, the main shortcoming lies in the application of the rationale behind this ground for refusal, being that third parties should be able to use generic terms. Based on CJEU case law, it has been pointed out that the CJEU has been more attentive to what classifies as a characteristic of a good. In order for the rationale to regain priority, potential registrars would benefit from clarity as to what classifies as a generic term and what the characteristics of goods are pursuant Art. 7(1)(c) EUTMR. By opting for a non-exhaustive list of characteristics, the EU legislator clearly chose to leave the CJEU a margin of interpretation, but on the topic of sustainability it would be valuable if relevant characteristics were outlined, together with examples of what generic environmental terms should be avoided. Inspiration can be drawn from already existing guidance documents[100] on the use of green terminology and the 2022 proposed directive on unfair commercial practises. While most of these guidelines pertain to the use of green terminology in advertising, the examples given do still indicate the importance of not using such terms based on their ambiguous nature. As a result, it would be of value to provide guidelines that prescribe usage of the aforementioned terms that should be avoided in trade marks. Naturally, a non-exhaustive list would be more fitting, due to the large extent of green terminology, but looking at the aforementioned guidance documents, the following terms should definitely be avoided in trade marks: 'eco', 'eco-friendly', 'green', 'environmentally friendly', 'ecologically safe', 'good for the environment', 'sustainable' and 'carbon friendly'.

Looking at the given examples of guidelines, a role can be played by trade mark offices, based on the fact that they can introduce guidelines on this topic. Guidance documents, issued by either trade mark offices or governmental regulatory bodies, can prove to be pivotal as they do not require a regulatory overhaul but can provide the clarity that lacks from regulatory provisions or case law. This is supported when looking into the shortcomings of the other ground for refusal, deceptiveness.

By providing guidelines illustrating which green terminology would be considered misleading, potential registrars are assisted in avoiding consumer deception. This is not only useful for companies and consumers, but this also assists trade mark offices in efficiently assessing registrations containing green terminology. Consequently, all parties' interests are considered and a fair balance can

96 Code de l'environnement, LOI n° 2021-1104 du 22 août 2021 portant lutte contre le dérèglement climatique et renforcement de la résilience face à ses effets. Available at https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043956924.

97 Décret n° 2022-539 du 13 avril 2022 relatif à la compensation carbone et aux allégations de neutralité carbone dans la publicité, art 1. Available at https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000045570611; translated via www.deepl.com.

98 Proposal for Directive 2022/0092 COM(2022) 143 final, preamble (9).

99 CFREU, art 16.

100 UN, Guidelines for Providing Product Sustainability Information [2017], p. 26; ICC, ICC Framework for Responsible Marketing Communications [2021], p. 8.

be struck. A different approach would be a small regulatory change with regards to the threshold of the risk of consumer deception following Art. 7(1)(g) EUTMR. In case this threshold is lowered, registrability of signs is reduced, which would be at the cost of signs not related to sustainability. The suggested amendment would be '*risk of deception of the public*' instead of actual deception of the public. This would be in line with the proposed directive on green claims which aims at mitigating the risk of greenwashing and the risk of misleading consumers.[101] However, it must be noted that this regulatory change would apply to all EUTM applications, meaning the lower threshold of consumer deception would also apply to marks that are not concerned with sustainability or do not contain green terminology. A fitting alternative would be the CJEU recognising 'sustainability' as a characteristic that can be misled through. Knowing the list of characteristics in Art. 7(1)(g) EUTMR is non-exhaustive, this provides the CJEU the opportunity to highlight the risk of deception of the public with regards to sustainability-oriented signs. Additionally, this would prevent a regulatory change while it simultaneously underlines the role sustainability plays in EU trade mark law.

One of the discussed topics that recently received a regulatory change is greenwashing. The proposed directive on green claims has been thoroughly discussed and one is inclined to regard the introduced regulatory changes as positive. Most importantly, parties sporting environmental claims now have codified obligations to substantiate these claims. A fitting addition to this regulatory change would be a uniform approach to the substantiation of environmental claims. This could be achieved through guidelines or by reinstating the PEF system. The use of the PEF system would be in line with the recommendation of the EC that promotes usage of this method in "*relevant policies and schemes related to the measurement and/or communication of the life cycle environmental performance of all kinds of products, including both goods and services, and of organisations*".[102] In this regard, green trade marks could fall under the scope of a communication of the environmental performance of goods and services, making the PEF system a suitable way of substantiating green claims and green trade marks. Consequently, this increases sustainability reporting and consumers are more aware of sustainably produced goods due to the increased availability of sustainability related information. Lastly, with regards to green claims, a complete ban on generic green claims would further eliminate the risk of greenwashing.

5. FINAL REMARKS

Coming back to the question of to what degree EU trade mark law is tailored to achieve the EU Sustainable Development Goals, on the first hand it can be pointed out that EU trade mark law does indeed concern itself with sustainability, perhaps more than one would expect at a first glance. Most importantly in this regard is the fact that trade marks are used as a way of communicating sustainability to consumers while also granting a sustainable image to those using sustainability related trade marks.

By refusing registration for generic environmental claims, the absolute ground for refusal of descriptiveness ensures the possibility of third-party use of terms that can promote sustainability, thereby spreading awareness of the importance of sustainability, while at the same time incentivising innovation. Through the absolute ground of deceptiveness, EU trade mark law ensures that awareness is spread in a transparent way. By providing accurate information, consumers' purchasing decisions will result in sustainable consumption as a result of the environmentally sound products and services they opt to purchase. The need for relevant information and spreading awareness on sustainability is also supported via the proposed directive on green claims. This new product of legislation has the potential to resolve ambiguity created by green trade marks, considering trade marks fall under the scope of this proposed directive. Additionally, claim substantiation and sustainability reporting have now been codified, increasing overall transparency with regards to sustainability related trade marks.

It follows from this that trade mark law is evidently capable of promoting sustainability and is therefore, to a great extent, tailored to achieve the SDGs. The extent to which EU trade mark law can add to the achievability of the SDGs can, however, be improved as evidenced by the identified shortcomings in each of the discussed aspects of EU trade mark law. Without immediately reaching for legislative amendments, this contribution has provided multiple solutions that can further improve the contri-

101 Proposal for Directive 2023/0083 COM(2023) 155 final, preamble (27) and (15).

102 EC, Commission Recommendation on the use of the Environmental Footprint methods to measure and communicate the life cycle environmental performance of products and organisations, C(2021) 9332 final, p. 3.

bution of EU trade mark law to the SDGs. By providing a guideline including a non-exhaustive list of terms that should be avoided when registering a trade mark, trade mark registrars can obtain a sustainable image based on transparency. This transparency serves consumers as they are enabled to consume sustainably as a result of factual information supporting their purchasing decisions. The CJEU can also play an important role by recognising sustainability as a characteristic through which the public can be deceived. With the help of these solutions, EU trade mark law will not merely be tailored to achieve the SDGs, it can become a true catalyst of sustainable development.

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Evergreening Patents and Discontinuous Innovations

Dr. Fatih Buğra Erdem

ABSTRACT

This article approaches the evergreening patent issue in the context of blocking innovation by seeking to extend exclusivity on patent rights since intellectual property law can provide immunity from competition law enforcements up to some extent. In consequence of evergreening patent practices, patentees extend and, consequently, cement their privileged positions pursuant to their patent rights (in an anti-competitive way). Patenting a follow-on innovation limits generic competition on the old one and therefore, any inconveniences in the patent system would likely distort competition since other manufacturers with the intention to penetrate the same market are restricted from the competition. Yet, innovation remains a crucial factor as technology companies cannot be expected to act responsibly regarding the use of their market powers unless the legal framework for promoting innovation is defined. They might, for instance, formulate a strategy that suppresses their innovations for the same reasons, such as evergreening patents offering new features for their latest products rather than providing compatible updates. In this regard, this study argues whether and to what extent gaps in the current patent system could be filled by the complementary nature of competition law provisions, in particular Article 102 TFEU.

Keywords: Evergreening patents, Innovation, EU Competition Law, Article 102 TFEU

A. INTRODUCTION

Innovations in proprietary technologies have become one of the most important economic constituents. Businesses are encouraged by being furnished with tools for recouping investment in the form of substantial intellectual property (IP) rights including patent protection to produce and implement their innovations.

Once patent protection expires, others can copy and sell the product, competing with the original version of the product. It should be noted that a patent expiration, does not necessarily mean that the product can be copied because product could be protected by other non-expired patents, meaning the invention in the patent can then be copied. As from the expiration of the original product's patent protection, it is expected that the replacement product in the market will be enlarged with generic versions of the product. This would likely decrease the price and increase the competition between generic manufacturers.[1] Therefore, regulations should support boosting generic competition by facilitating access to the market. The evergreening of patents may lead to abuse and misuse of the patent system to fend off competition law.[2] Such conduct will likely pave the way for taking benefit from monopoly rights given by law.[3]

B. THE LEGAL CONTEXT OF THE EVERGREENING ISSUE

Evergreening refers to patentees' conduct to extend their exclusive rights granted by patent protection. This is also known as strategic patent planning where originator manufacturers take precautions against generic manufacturers in advance to get a competitive edge. The evergreening patent indicates the exploitation of patent protection in which patent holders draw advantages from sore points of patent regulations and related regulatory processes just before the end of this protection. This strategy is gener-

1 One may argue that not always does the patent expiry lead to an immediate price decrease – e.g. the former patent product may still enjoy a dominant position, or competitors may lack the know how to compete with the patented product.

2 L Lukose, 'Patent ever greening: Law and Ethics' in M Bottis and E Alexandropoulou-Egyptiadou (eds), *Broadening the Horizons of Information Law and Ethics – A Time for Inclusion* (University of Macedonia Press 2017) 351.

3 A Kumar and A Nanda, 'Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries' (2017) 6(1) Pharmaceuticals Regulatory Affairs 4; M Törnvall, 'The Use and Abuse of Patents – Evergreening in the Pharmaceutical Sector' (Graduate Thesis, Lund University 2013) 26–51.

ally used by innovators having a large volume of research investment costs through making slight modifications to extend the period of exclusive rights.[4] The European Commission (EC) did not explicitly use the term 'evergreening' to justify its decisions. Instead, this situation has been mentioned as a tool for preventing or delaying generic products' entries.[5] Some of the evergreening practices specified in the EC's Pharma Report include but are not limited to patent filing strategies,[6] patent-related litigation,[7] patent settlements,[8] life cycle strategy[9] but not limited to.

As patent evergreening is a broad concept, this section limits itself to the introduction of second-generation products by obtaining new patent protections through showing only incremental innovations. The introduction of second-generation products is one of the most frequently used strategies to keep rivals away from generic competition. Despite the expiration of patent protection, generic product manufacturers will always have market entry barriers as consumers are directed towards improved second-generation products.[10] Patent holders generally introduce second-generation products; in other words, follow-on products, into the market to return more profits by using their original products' fundamental structure via incremental innovations. Although this innovation contributes to the existing technology leastwise, second-generation products will also benefit from patent protection if they meet patentability conditions.

There are strident criticisms in the literature against evergreening patenting strategies not only in pharmaceuticals but also other technology-intensive industries as they suppress the benefits of introducing generic substitution.[11] Since generics are copies of the product that is already on the market, one prima facie sees no suppression but there are two issues, which can cause suppression here. First, the product or service may be bound or tied such that the consumers are likely to purchase a latter-generation product. For instance, in the context of the software market, consumers will not be keen on changing their software, which they have already become accustomed to using. Moreover, the plug-ins in the software may not be compatible with generic substitutions. Furthermore, consumers may be under obligation to pay during the contract term, and they may get a better deal before the expiration of the contract in return for a renewal of the contract with the new product. These are just a few examples of how generic manufacturers can be excluded from the competition, and therefore, doctrinal discussions concerning tying and bundling concepts are open to change in terms of Article 102 TFEU.[12] Second, the innovator may misinform the patent office and apply for a patent, which shows just an improvement (not novelty) of the patented product or has already been obtained by itself or third parties. However, Becker highlighted that the evergreening patents problem does not exist since it is not possible to re-file the same invention for an extension.[13] Every patent office elaborates on both breakthrough and incremental innovation applications whether there are usefulness, novelty, and non-obviousness to issue patent protection. Therefore, the problem ensues from the patent system, and the likely solution is to raise the bar for patenting by asking for better quality patents.

Patentees will obtain a monopoly position with the help of their exclusive right since they are the sole sellers or manufacturers of certain products. From this perspective, patents block competition. More specifically, they block price competition because others cannot copy the patent-protected product. This will likely constitute a contradiction with the purposes of EU competition law. However, IP rights stimulate dynamic (innovative) competition by motivating competitors to innovate and introduce competing products.[14]

The issue concerning evergreening patents will appear when patent holders restrict (delay) generic competition by abusing IP systems' regulatory laxness through obtaining follow-on patents.[15] There will accordingly be two main headings in light of evaluating Article 102 TFEU: (i) whether and to what extent an extension of exclusivity may be considered as anti-competitive conduct, (ii) and whether and to what extent businesses making incremental innovations deserve monopoly rights.

In the grand scheme of things, the innovativeness of countries indicates the level of their social welfare.[16] As

4 Kumar and Nanda (n 4) 1–6.

5 European Commission, Pharmaceutical Sector Inquiry (Preliminary Report, 2008) para 466 <https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf> accessed 3 November 2020.

6 Ibid, paras 467–546.

7 Ibid, paras 547–644.

8 Ibid, paras 202–855.

9 Ibid, paras 987–1049.

10 Such products are nearly the same with primary products but having innovative contents.

11 G Dwivedi, S Hallihosur and L Rangan, 'Evergreening: A deceptive device in patent rights' (2010) 32(4) Technology in Society 324–330; S Midha, 'Strategies for drug patent ever-greening in the pharmaceutical industry' (2015) 3(3) International Journal of Pharmaceutical Sciences and Business Management 11–24.

12 S Holzweber, 'Tying and Bundling in the digital era' (2018) 14(2-3) European Competition Journal 342–66; Communication from the Commission 2009/C 45/02 of 24 February 2009 Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings [2009] OJ C 45/7 (Guidance of enforcement priorities in applying Article 82 of the EC).

13 K Becker, 'Pharma patents in Europe: where are we going?' (2009) 1(2) Future Medicinal Chemistry 227–228.

14 See for a general reading, S Anderman, *The Interface Between Intellectual Property Rights and Competition Policy* (Cambridge University Press 2007); S Anderman and H Schmidt, *EU Competition Law and Intellectual Property Rights: The Regulation of Innovation* (OUP 2011); C Villarejo and T Kramler, 'Intellectual Property Rights and Competition Rules, a Complex but Indispensable Coexistence' in S Anderman and A Ezrachi (eds), *Intellectual Property and Competition Law: New Frontiers* (OUP 2011) 61–73.

15 The patentee relies on the rules of the patent system to obtain follow-on patents, and if the invention meets the patentability requirements, the patent will be granted. However, the patentee may misinform the patent Office or take advantage of weak patent systems.

16 OECD, 'The Knowledge-based economy' [1996] OCDE/GD(96)102, 3; OECD, *'A new economy? The Changing Role of Innovation and Information Technology in Growth* (OECD Publishing 2000) 27–81.

such, the effectiveness of patent protection systems matters to encourage businesses to be more innovative. An effective patent system can promote technological innovation by presenting judicious compromises. At the same time, such a system also gains favour to the frequency of innovations by providing an appropriate environment for new inventions.[17] However, on the other hand, any deficiency in the patent system may lead to evergreening applications, which eradicate all the benefits of IP protection.

I. Theoretical Examination of Evergreening Patents

The term 'evergreening', as explained above, refers to several behaviours towards further exploiting granted patent protection via legal and illegal strategies. These strategies are generally lawful, but it does not mean that they are exempted from the application of Article 102 TFEU. Whish and Bailey, accordingly, stress the importance of applying this article in case of exercising patent rights in an abusive way.[18] In regard to the theoretical background of evergreening practices, patent law aims to contribute to industrial progress by inspiring scientific works and newer technologies.[19] With this regard, it can be claimed that patents as temporary monopoly rights are necessary for the prevention of likely market failures because innovators will be discouraged in the absence of patents where newcomers can freely make copy-paste and penetrate the market without any research costs.

The theoretical base of evergreening can be explained from Lockean and Schumpeterian perspectives. From the labour theory of Locke, as a moral principle, the state ought to grant a right to an innovator, who puts a mental effort into an invention.[20] As this (tangible or intangible) invention contributes to the public, it deserves protection. However, arguably, this theory does not support evergreening patents when it is considered that there is a lack of creative efforts on evergreening patents,[21] which are not availed to the public. According to Posner, if IP rights encourage businesses to innovate, the pitfalls of granting such exclusivity could be tolerated.[22] Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) similarly stated that granting IP rights contributes to the development of technology through increasing technological knowledge, the effective spread of innovation, and socioeconomic welfare by holding the balance between holders' rights and obligations. If granting a patent is accepted as a social contract between innovators and society, innovators will have monopoly rights where the society tolerates for a length of time to gain favour from innovators' creations. This theory is vital for the emergence of innovations, which lay foundation for patent systems.[23] Nevertheless, breach of covenant will likely come in sight when it comes to patent evergreening in which innovators abuse this contract by extending their monopoly rights by showing minor alterations. In other words, in the case of evergreening patent issues, the supposed contract becomes unjust and theoretically deficient.

From the Schumpeterian perspective, innovators should always be promoted via exclusive rights as those innovations will eventually be beneficial to society. Otherwise, investments in research and development will decrease because of free-riding strategies, and consequently, technological progression will decelerate.[24] However, on the other hand, evergreening patents require relatively fewer investment costs and efforts. Therefore, one can claim that evergreening practices are not deserving of patent protection[25] even though they are commonly examined under monopoly-profit incentive theory, which supports rewarding monopolies in exchange for their innovations.[26] It would be highly controversial to grant patent protection (as a property or a privilege) for evergreening practices where the risks are very low due to the inessentiality of time and cost for introducing a new product. One may accordingly claim to shorten/weaken patent protections for evergreening patents. However, it would not be appropriate because technology is developed cumulatively by depending on previous technologies. Hence, any restrictions on IP laws would likely result in suppressing technologies.

In conclusion, providing a reasonable economic incentive for an innovator seems instrumental to leverage consumer welfare and, more generally, public benefit from different theoretical perspectives. By courtesy of exclusive rights stemming from patent protection, the innovator will be able to estimate its potential profit before introducing the innovation.[27] However, the vagueness of determining novelty and non-obviousness of inventions is the essence and the abstract of the matter where patent holders push the limits of the patent system, and arguably

17 W Cornish, D Llewelyn and T Aplin, *Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights* (Sweet and Maxwell 2003) 114.

18 R Whish and D Bailey, *Competition Law* (OUP 2018) 814–827.

19 P Groves, *Source Book on Intellectual Property Law* (Cavendish 1997) 48.

20 J Locke and R Filmer, *Two Treaties on Civil Government* (Routledge 2018); E Maughan, 'Protecting the rights of inventors: how natural rights theory should influence the injunction analysis in patent infringement cases' (2012) 10 Georgetown Journal of Law and Public Policy 233–234.

21 J Mueller and D Chisum, 'Enabling Patent Law's Inherent Anticipation Doctrine' (2008) 45 Houston Law Review 1101.

22 R Posner, *Economic Analysis of Law* (Aspen 1998) 43.

23 W Landes and R Posner, *The Economic Structure of Intellectual Property Law* (Harvard University Press 2009) 294–295.

24 B Ilic and B Pretnar, 'The Economic notion of the incentive to invent in the legal perspective of patent protection' (2004) 6 Economic and business review for Central and South-Eastern Europe 286.

25 M Abbas, 'Evergreening of Pharmaceutical Patents: A Blithe Disregard for the Rationale of the Patent System' (2019) 15(2) Journal of Generic Medicines: The Business Journal for the Generic Medicine Sector 56.

26 For counter argument concerning broader incentives for innovators, see E Kitch, 'The Nature and Function of the Patent System' (1977) 20 Journal of Law and Economics 265.

27 J Kesan, 'Economic rationales for the patent system in current context' (2014) 22 George Mason Law Review 897; M Lemley, 'Ex ante versus ex post justifications for intellectual property' (2004) 71 University of Chicago Law Review 129.

abuse it, via slight modifications, which are the Achilles' heel of the system.

II. An application of TFEU Provisions in Evergreening Issues

Manufacturers, who have patent protection, can benefit from monopoly rights and derive a profit without competitive pressure in each period. They generally resort to evergreening patent rights for extending this privilege through patenting follow-up inventions as long as these inventions only make a minor addition to first-generation products.[28] This intellectual monopoly privilege is at the centre of both international trade and intellectual property laws, particularly for the pharmaceutical industry. However, it also has a clear link with Article 102(b) TFEU in terms of limiting technical development to the prejudice of consumers because the expiration of a patent prevents patent holders from retaining more royalties, which are provided by the monopoly market. Such patenting strategies lead to market entry barriers, which restrict fair competition.[29] Therefore, the evergreening problem needs further examination from a competition law paradigm.

Evergreening patents are considered lawful under patent law as well as currently under EU competition law.[30] What is certain is that the lawfulness of evergreening patents prima facie seems to be governed by patent law rather than competition law and as per Article 345 TFEU, the Union law is not entitled to examine patent rights whether they are obtained lawfully or not because they are granted as national rights. However, it is evident that IP rights do not provide effective immunity if they are against EU competition law.[31] Competition law only controls the exercise of IP rights by preventing all potential monopolistic abuses arising out of misusing IP rights.[32] Hence, conducting a detailed investigation is a must to evaluate whether evergreening patenting practices are competition on merits or breach of Article 102 TFEU since patenting of second-generation products by originator manufacturers likely restricts the market access of generic manufacturers.

Even though it is hard to establish a link between evergreening practices and special conditions of Article 102 TFEU, those practices can still be prevented under this article. When determining fresh types of abuses in the context of Article 102 TFEU, an intention to eliminate competition is considered by the Commission. Hence, the link can be established by assessing the competitiveness of evergreening practices and their impact on competitive markets. However, the claim of eliminating competition intention shall be supported with objective and economic data. In these premises, Article 102 TFEU would be enforceable when considering anti-competitive results and detrimental effects on consumer welfare.

EU patent law has arguably a weak legal infrastructure to cope with evergreening practices. Hence, as concerns evergreening practices, Article 102 TFEU will always come up even though it constitutes a contradiction with member countries' national patent laws. In terms of EU law, the *AstraZeneca* decision provided useful principles that may be relevant to evergreening.[33] Hence, the trace of evergreening can be found in the *AstraZeneca*[34] case in the context of Article 102 TFEU.[35] However, there was no such a similar decision in regard to the strategic use of patents before this case where *AstraZeneca* delayed and even prevented the introduction of its generic products by abusing its dominant position through bending the rules of the patent system. The concerned case redressed the frame of Article 102 TFEU enforcement, and the current frame indicates that every conduct, which seems completely lawful and has a likely anti-competitive effect, may be subjected to an abuse of dominance investigation. Therefore, bending the patent protection issue (evergreening) requires further explanation to make out the degree to which it contrasts with the aims of competition law.

III. Case Law regarding Evergreening Issues

Evergreening patenting issues have so far been mostly encountered in pharmaceutical companies' cases[36] such

28 European Commission, Pharmaceutical Sector Inquiry (Preliminary Report, 2008) para 480, 994 <https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/pre-liminary_report.pdf> accessed 3 March 2022.

29 The BEUC accordingly made the following opinion: "patent strategies can constitute barriers to the entry of new generic medicines into the market. We are very much concerned by the phenomenon of so-called "evergreening", which describes a specific tactic used by originators to extend patents by seeking to obtain as many patents as possible during the development of the product and the marketing phase, and to obtain a patent extension for new manufacturing processes, new coating and new uses of established products. Originators can also slightly change an active ingredient and present an old medicine as a new product and register a new patent. We consider that these practices are anti-competitive and prevent generics' entry into the market. They also incur higher health care expenditures and/or higher prices for consumers." See, European Commission, 'Pharmaceutical Sector Inquiry – Final Report' (2009) SEC(2009)952, COM(2009)351 final, para 1107.

30 H Gubby, 'Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective' (2020) 11(1) Global Policy 46–55; M Törnvall, 'The Use and Abuse of Patents – Evergreening in the Pharmaceutical Sector' (Graduate Thesis, Lund University 2013) 26–51.

31 See argument to the contrary, L Kjølbye, 'Article 82 EC as Remedy to Patent System Imperfections: Fighting Fire with Fire?' (2009) 32(2) World Competition 163–188.

32 R Boscheck, 'Intellectual Property Rights and the evergreening of pharmaceuticals' (2015) 50(4) Intereconomics 221–226.

33 It should be noted that Astra Zeneca case was about the misuse of the patent procedures, i.e. the company provided incorrect information to the patent offices. So, there was some unlawful behaviour on the side of the patentee. See, J Drexl, 'AstraZeneca and the EU Sector Inquiry: When do patent fillings violate competition law?' in J Drexl and N Lee (eds), *Pharmaceutical Innovation, Competition and Patent Law* (Edward Elgar 2013) 290–322.

34 Case C-457/10P, *AstraZeneca AB and AstraZeneca plc v European Commission* [2013] ECLI:EU:C:2012:770.

35 This cannot be simply classified as an evergreening practice since there was an unlawful behaviour by misusing the patent procedures where *AstraZeneca* provided incorrect information to patent offices.

36 Recent trend is referring evergreening patent, particularly in the pharmaceutical market with trivial amendments and tweaking existing formulas to demonstrate originality. See, Lukose (n 2) 1.

as the *AstraZeneca* and *Lundbeck* cases,[37] where patent holders had strived to extend the duration of their granted exclusive rights.[38] However, exploiting IP rights to the core is significant for all other high technology-intensive markets, such as electronics and software markets. Such strategies cement patentees' negotiating and competing positions, which established an anti-competitive environment for generic product markets.[39]

The European Court of Justice particularly emphasised in detail in the *Lundbeck* that follow-on patent claiming (on escitalopram) did not prevent rival producers from introducing generic versions of original products after the patent protection expires.[40] Most importantly, in terms of the use of patents, more specifically evergreening patent issue, has been thoroughly discussed in the *AstraZeneca* renounced its marketing authorisation for Losec -in Denmark, Norway and Sweden- to have an advantage over its competitors when it introduced its second-generation product, namely *Losec* MUPS. This complicated producing generic versions of *Losec* as there was no announced formula, and consequently, competitors encountered market entry barriers because producing an equivalent product would likely be costly and time-consuming.[41] Even though *AstraZeneca's* conduct of withdrawing its marketing authorisation of *Losec* seemed prima facie lawful, other parties claimed that such a conduct eliminates effective competition for rival businesses.[42]

The court carried out an investigation against *AstraZeneca* because of two main conducts. First, the claim that *AstraZeneca* extended its original patent protection for its medicine named *Losec* by providing patent offices and courts with deceptive statements. *AstraZeneca*, in its defence, stated that the General Court misinterpreted the notion of competition on merits and it made a mistake by applying Article 102 TFEU without showing intentional fraud or deceit. Second, it has also been claimed that *AstraZeneca* has rightly but differently interpreted 'the Supplementary Product Certificate Regulation' in good faith by adding that patent applications would likely be decreased, and this consequently distorts competition in the absence of this alternative interpretation.[43] However, it would also be irrelevant to argue good faith for the application of Article 102 TFEU, which is generally based on objective justifications.

Courts can consider the alternative interpretation as a misinterpretation of law even if likely anti-competitive effects are seen.[44] By looking at *a contrario*, courts are also able to find the conduct lawful even if it has a restrictive effect on generic competition as long as objective justifications are seen. However, Article 102 TFEU will become an issue in any circumstance if businesses wander from the competition on merit.[45] The CJEU revealed that relevant conduct prevents generic competition, and therefore, it should not be evaluated in the context of competition on merit.[46] As a result, the CJEU dismissed the appeal from the EC decision of *AstraZeneca* of abusing its dominance by the deregulation of *Losec* (in other words, withdrawing marketing authorisation). Therefore, the anti-competitive effects of this deregistration process were found enough to apply Article 102 TFEU even though *AstraZeneca* claimed lawfulness of withdrawing on the strength of its intellectual property right.

IV. Evergreening in the context of Article 102 TFEU

To establish a relationship between EU competition law and evergreening patents, it is necessary to refer to the Commission's Guidance on Article 102 Enforcement Priorities, which ensures market integration.[47] All concerning provisions are significant to stabilise the functioning of the market by levelling the playing field for all undertakings.[48] Hence, the CJEU lays a burden on dominant undertakings to not anyhow distort competition in the internal market by mentioning their special responsibilities.[49] The standard of undistorted competition indicates that business decisions shall not fit the purpose of eliminating competitors without any economic justification. The lawfulness of business conduct under their special responsibilities is taken into consideration with the concept of 'competition on merits'[50] which also has an amphibology. The use of intellectual property rights may cause trouble at this juncture even though having an exclusive right will not per se present an infringement if it is not being abused.[51] Therefore, it is required to specify

37 Case C-457/10P, *AstraZeneca AB and AstraZeneca plc v European Commission* [2013] ECLI:EU:C:2012:770; Case C-591/16P H. *Lundbeck A/S and Lundbeck Ltd v European Commission* [2021] ECLI:EU:C:2021:243.

38 Evergreening patent issue is a highly controversial topic concerning to both patent law and competition law. This issue is not bounded with pharmaceutical industries, it is also seen in technology-intensive industries.

39 World Intellectual Property Organization, The Changing Face of Innovation (Report, 2016) <https://www.wipo.int/publications/en/details.jsp?id=227> accessed 1 November 2021.

40 Case AT.39226 *Lundbeck* [2013] C(2013) 3803 final.

41 Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012] ECLI:EU:C:2012:770, para 130.

42 Ibid, paras 125–127.

43 Ibid, para 69.

44 Ibid, paras 94, 99, 112; C-209/10 *Post Danmark A/S v Konkurrencerådet* [2012] ECLI:EU:C:2012:172, para 64.

45 *AstraZeneca* (n 42 para 129.

46 Ibid, para 131.

47 Guidance of enforcement priorities in applying Article 82 of the EC (n 13) para 1.

48 V Korah, *An Introductory Guide to EC Competition Law and Practice* (Hart Publishing 2007) 13.

49 Case 322/81 *Nederlandsche Banden-Industrie-Michelin v Commission* [1983] ECR 3461, para 57; *AstraZeneca* (n 42) para 134; Case T-83/91 *Tetra Pak International SA v Commission of the European Communities* [1994] ECLI:EU:T:1994:246, para 114; Case T-203/01 *Manufacture française des pneumatiques Michelin v Commission of the European Communities* [2003] ECLI:EU:T:2003:250, para 97; Case C-497/99 P *Irish Sugar plc v Commission of the European Communities* [2001] ECR 2001 I-05333, para 112.

50 Case 62/86 *Akzo Chemie BV v Commission of the European Communities* [1991] ECLI:EU:C:1991:286, para 70.

51 Case C-53/87 *Consorzio Italiano della Componentistica di Ricambio per Autoveilici (CI- CRA) and Maxicar SPA v Regie Nationale des Usines Renault* [1988] ECR 6089, para 18.

an objective justification in terms of the enforcement of Article 102 TFEU and this justification is formed by case law to offer a remedy. In accordance with the above, courts should bring in a verdict by evaluating economic justifications after they determine actual or likely conduct, causing the elimination of competitors.[52] Hence, the EC must put forward an objective justification, which would reverse the burden of proof to the detriment of the EC. However, the CJEU frequently refused economic efficiency defences as they only rest upon commercial interest, which does not overlap with consumer interests.[53]

One can claim that the EC now considers a more economic efficiency-based approach in Article 102 TFEU examinations,[54] but this approach cannot be applied to all concerning issues. For example, the EC concludes an infringement decision when it comes to royalty discounts without examining any actual or likely anti-competitive effect as it was the case with the *Michelin II*.[55] However, it seems that undertakings are frequently able to put forward their efficiency defences in case they are on trial even if it is debatable how much the Commission leaves the door open for such defences.[56] Nevertheless, it is certain that the concept of special responsibility has been expanded considerably by way of case law.[57] In *Michelin I*, the CJEU determined that dominant undertakings have special responsibilities not to distort competition in the internal market via exclusionary abuses. Besides, the *AstraZeneca* case consolidated the enlargement of the special responsibility concept, which has already been enlarged with the *Michelin I*.[58] As stated by Friedman, businesses have special responsibilities to raise their profits.[59] However, they shall also behave accordingly not to harm competition. Businesses, as a matter of fact, keep their profitableness on the forefront, they are disposed to suppress innovations by retarding, non-introducing or in other similar ways. Therefore, they generally have tendencies to explore all avenues for exploiting the patent system as much as they can. However, since no patent system allows double patenting (unless the patent applicant shows novelty and non-obviousness),[60] the exploitation of the relevant patent most of the time appears completely lawful. However, it does not mean that undertakings fulfil their special responsibilities under competition law, and therefore, it ought to be required to imply competition law provisions. To summarise, concerning the affiliation between patent protection and the progression of innovation, there is a need for an absolute statement of 'special responsibility' concept because businesses may likely suppress innovations and make their strategic decisions counterproductive. Therefore, broad-in-scope concepts like undistorted competition and competition on merits should be supported by more accurate statements in case law.[61]

C. CONCLUSION

Evergreening strategies have negative impacts in terms of continuity of innovation and access to innovation. Especially in cases related to such innovation, suppression practices become more complex. For this reason, the evergreening patent, eliminating generic competition and its price-reducing effect, has often been a more frequently discussed subject in the pharmaceutical sector. Some of the specific evergreening practices may be listed as patenting existing medicines with new formulations or compositions, patenting new combinations of drugs, patenting an in-use drug for a new use, or patenting a known drug with a new dosage.[62] These products, generally called next or second generation, have insignificant and minor changes and do not put the product in an entirely new form. However, this does not mean that the evergreening issue only occurs in the pharmaceutical sector; patent holders from different sectors also have effective strategies with regard to patents' lifecycle management.

The advancement of technology depends on providing patent protection for both incremental and breakthrough innovations. Therefore, it is necessary to provide substantial incentives to actualise and ensure follow-on innovations.[63] Patent granting authorities control all applications firmly, but some applications are approved even if they do not deserve any protection. This issue is due to the weakness of the patent authority or patent system itself. More particularly, evergreening issues are stemming from -including but not limited to- strategic patenting, lax rules, and the malfunction of patent examination

52 Case C-202/07 P *France Télécom* v *Commission* [2009] ECR I-2369.

53 *Irish Sugar* (n 50) para 189; Case T-201/04 *Microsoft Corp v Commission* General Court [2007] ECLI:EU:T:2007:289; Commission Decision of 27.6.2017 relating to proceedings under Article 102 of the Treaty on the Functioning of the European Union and Article 54 of the Agreement on the European Economic Area, para 711.

54 Case T-286/09 RENV, Intel Corporation v Commission; General Court of the European Union, 'The General Court annuls in the part the Commission decision imposing a fine of EUR 1.06 billion on Intel' (Press Release No 16/22, 26 january 2022).

55 Case T-203/01 *Manufacture française des pneumatiques Michelin* (n 50).

56 It would not be wrong to say that most of the time, the Commission leans towards approving efficiency claims as seen in: *Microsoft Corp* (n 52); Case AT.39740 – Google Search (Shopping) [2017] C(2017) 4444 final.

57 F Murphy, 'Abuse of Regulatory Procedures-the AstraZeneca Case: Part 3' (2009) 30(7) European Competition Law Review 314.

58 *Nederlandsche Banden-Industrie-Michelin* (n 50) para 57.

59 M Friedman, 'The Social Responsibility of Business is to Increase its profits' in W Zimmerli, K Richter and M Holzinger, *Corporate Ethics and Corporate Governance* (Springer 2007) 173–178.

60 An invention regardless of it is a product or process should have novelty and non-obviousness to get a protection according to article 27 of the TRIPS agreement. It also needs to be available for an industrial application. See, Abbas (n 26) 53–60.

61 The CJEU gave the first signs of this new move in *AstraZeneca* with regard to flexibly apply Article 102 TFEU.

62 Abbas (n 26) 54; G Gonen, 'Innovation in known drugs – the European Angle' (2017) 12(3) Washington Journal of Law, Technology and Arts 278.

63 C Holman, T Minssen and E Solovy, 'Patentability Standards for Follow-on pharmaceutical innovation' (2018) 37(3) Biotechnology Law Report 136; R Merges, 'Uncertainty and the Standard of Patentability' (1992) 7(1) Berkeley Technology Law Journal 33.

mechanisms through filing several patent applications to prevent third parties' research initiatives.[64]

The most likely solution of evergreening is to apply patentability requirements as strictly as possible by delving into the existence of an inventive step This would be one of the best possible ways to nail down the continuity of introducing technological advancements by calculating the innovator's actual contribution to innovative progress. Therefore, it seems that realising inconveniences in the patent system will likely answer the evergreening problem[65] such that the determination of the extent to which new patent applications contribute to innovation is under the patent office's responsibility.

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64 S Parker and K Mooney, 'Is 'evergreening' a cause for concern? A legal perspective' (2007) 13(4) Journal of Commercial Biotechnology 235–241.

65 Holman, Minssen and Solovy (n 62) 160.

Pharmaceutical Data Exclusivity in the Light of Access to Clinical Data: Is the EMA oversharing?

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ABSTRACT

In the ever-evolving landscape of EU pharmaceutical regulation, this article unravels the complexities of regulatory data exclusivity and commercially confidential information (CCI). Examining EU legislation, CJEU jurisprudence, and EMA policies, it navigates the delicate balance between proprietary rights, transparency, and fundamental freedoms in the pharmaceutical industry. Central to the discussion is the conflict between safeguarding commercial interests and the public interest in clinical trials data disclosure. By offering nuanced perspectives, the article contributes to the ongoing dialogue, providing legal practitioners and pharmaceutical stakeholders with a concise understanding of the evolving regulatory landscape.

1. INTRODUCTION

In the ever-evolving landscape of pharmaceutical regulation within the European Union (EU), the intersection of proprietary rights, transparency imperatives, and fundamental freedoms has become a focal point of legal discourse. This article delves into the intricate web of regulatory data exclusivity for pharmaceutical products, unravelling its nuances and examining the definition of commercially confidential information (CCI) as illuminated by EU legislation and the jurisprudence of the Court of Justice of the European Union (CJEU), in reference to policies of the European Medicines Agency.

As the pharmaceutical industry remains at the forefront of innovation and research, the delicate balance between safeguarding commercial interests and promoting transparency has prompted a series of complex legal considerations. A cornerstone of this discussion revolves around fundamental rights enshrined in the Charter of Rights of the EU and the compelling public interest in the disclosure of clinical trial data. This discourse takes centre stage in conflict with the rights of pharmaceutical companies to conduct their business securely while pursuing economic incentives vital for sustained innovation.[1]

This exploration encompasses a presentation of pivotal EU legislation and European Medicines Agency policies and guidance, including the delineation of regulatory data exclusivity and the evolving definition of CCI. Drawing insights from case law, particularly decisions handed down by the CJEU, we navigate the legal intricacies that shape the boundaries of information deemed commercially confidential.

This article aims to contribute with nuanced perspectives to the ongoing dialogue surrounding the delicate equilibrium between the public's right to information and the imperative for pharmaceutical companies to protect their confidential data. By exploring the multifaceted dimensions of regulatory data exclusivity and CCI, the author seeks to provide legal practitioners and stakeholders within the pharmaceutical sector with a comprehensive understanding of the evolving regulatory landscape.

Regulatory Exclusivities

The idea of marketing government-authorized drugs in a competitive market without intellectual property (IP) protection is often considered as an insufficient motivator for drug development. This is due to the risk of competitors copying the innovator's product and selling it at a lower cost, having incurred fewer development expenses. The rationale behind data exclusivity is rooted in the significant investments required for producing clinical test data, such as conducting clinical trials. Protecting this test data from use by generic and biosimilar companies[2]

1 Daminova Nasiya 'The European Medicines Agency 'Transparency' Policies, the CJEU and COVID-19: Do the CFREU Provisions Retain Any Relevance?', MTA Law Working Papers 2021/1, ISSN 2064-4515.

2 Liddicoat Jonathan, Liddell Katherin, Aboy Mateo et al. 'Has the EU Incentive for Drug Repositioning Been Effective? An Empirical Analysis of the "+1"' Regulatory Exclusivity. IIC 52, 825–851 (2021) <https://doi.org/10.1007/s 40319-021-01088-0> accessed 17 November 2023.

is seen as a strategy for the promotion of medical research and development (R&D). The rationale behind data exclusivity aligns with the principles behind patents and other pharmaceutical market exclusivities, assuming that safeguarding the investments made in R&D by granting exclusive rights is necessary and effective in stimulating innovation.[3]

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) includes an obligation for WTO members to protect certain types of test data against unfair commercial use but does not mandate data exclusivity. TRIPS data protection is required only for data related to a new chemical entity, previously undisclosed, and requiring significant effort to generate. TRIPS does not specify a time period for this protection and allows the use of test data for regulatory approval of competing products.[4]

European governments utilize their regulatory frameworks for drug approval to offer non-patent-based incentives, aiming to encourage the discovery of new medicines and shield sponsors of new drugs from competitive pressures. The prevalent incentive takes the form of regulatory data protection for drugs with new active ingredients, often termed as new chemical entity (NCE) exclusivity for small molecule drugs. In this arrangement, regulatory authorities confer exclusive rights to the drug sponsor over the preclinical and clinical data utilized to secure regulatory approval, for specified periods. This type of regulatory exclusivity proves advantageous as it hinders generic competition. Generic companies, lacking access to these data, are unable to leverage the streamlined drug approval processes provided by regulatory agencies. The benefit stems from the fact that generic companies, without access to the initial clinical trial data, are unable to take advantage of the efficient drug approval procedures that depend on existing data. In the absence of access to this information, generic competitors must conduct their own clinical trials and submit separate data, resulting in a more time-consuming and expensive approval process. This regulatory challenge serves as a barrier to generic competition throughout the exclusivity period, giving the original pharmaceutical company an opportunity for market exclusivity to recoup expenses and create earnings. New chemical entity exclusivity is commonly implemented in significant drug markets, including the US, EU, Switzerland, Canada, Israel, Japan, South Korea, Singapore, and Taiwan, even if the sponsor's data are publicly accessible.[5]

Data exclusivity is granted automatically and controlled through a regulatory system. Holders of these rights, predominantly drug companies, are not required to apply or provide evidence of eligibility. Regulatory exclusivity offers commercial advantages, being costless to obtain, automatically enforced, and generally not subject to challenge.[6] These exclusivity periods commence upon marketing authorization, providing sponsors with certainty over the duration of market protection. The introduction of orphan drug exclusivity in the EU in 1999 led to increased development efforts and product registrations for rare diseases, showcasing how exclusivities incentivize the industry, extend research interest, and contribute to public health progress and improved living quality. The global importance of regulatory exclusivities is evident in the concerted efforts of industry and trade representatives in the US and EU to negotiate expanded pharmaceutical data protections worldwide.[7]

2. EMA'S INITIAL TRANSPARENCY POLICY

Before Regulation 726/2004 of the EU came into effect, the legal framework for the authorization, supervision, and pharmacovigilance of medicinal products for human use was primarily governed by Directive 2001/83/EC. This directive, adopted in 2001, established the regulatory framework for the licensing of medicinal products within the European Union. It outlined the requirements for obtaining marketing authorization, the obligations of pharmaceutical companies, and the procedures for monitoring and ensuring the safety of medicinal products on the market. Directive 2001/83/EC provided the basis for the harmonization of pharmaceutical regulations across EU member states, aiming to create a single market for medicinal products while ensuring a high level of public health protection. However, recognizing the need for further consolidation and centralization of regulatory procedures, Regulation 726/2004 was later introduced to enhance and streamline the authorization process, centralize certain aspects of supervision, and strengthen pharmacovigilance activities at the EU level.

Regulation 726/2004, which initiated the current legal framework, brought about several modifications. Initially, Article 14(11) substituted the 10-year data protection period with eight years of data exclusivity, running concurrently with 10 years of market exclusivity. Data exclusivity denotes a timeframe during which competitors are barred from seeking authorizations for generic versions. In contrast, market protection, often termed as market exclusivity, signifies a period when competitors can secure authorizations for generics, but these generics cannot be introduced to the market until the conclusion of the mar-

3 Beverley-Smith Hue, "Rights in Data and Information" in Rochelle Dreyfuss, Justine Pila (eds) The Oxford Handbook of Intellectual Property (first edition published 2018, Oxford University Publishing) 17.

4 Correa Carlos, Reto M Hilty 'Access to Medicines and Vaccines Implementing Flexibilities Under Intellectual Property Law' (published 2022, Springer Nature Switzerland AG) 1-6.

5 Morgan Robert Maxwell, Gwilym Roberts Owen, Edwards Aled Morgan 'Ideation and implementation of an open science drug discovery business model – M4K Pharma' [version 1; peer review: 2 approved, 1 approved with reservations]. Open Res 2018, 3:154 <https://doi.org/10.12688/wellcomeopenres.14947.1> accessed 17 November 2023.

6 ibid 4.

7 ibid 5; Armouti Wael, Nsour Mohammad 'Data Exclusivity for Pharmaceuticals in Free Trade Agreements: Models in Selected United States Free Trade Agreements.' Houst J Int Law. 2017; 40(1): 105–138.

ket protection period. Three options are also available for securing an additional year of exclusivity.[8] For example, an extra year of marketing exclusivity can be granted for new therapeutic indications demonstrating significant clinical benefits compared to existing therapies (Article 10(1), para. 4). Additionally, one year of data protection is available for new indications of well-established substances (Article 10(5)), and one year of protection is provided for data supporting a change in classification, such as from a prescription drug to an over-the-counter medication (Article 74a).[9] These supplementary exclusivity terms are not cumulative, ensuring that the overall protection does not surpass eleven years. Therefore, Europe presently employs an "automatic" protection approach under the 8+2+1 principle for both small molecule drugs and biologics like vaccines.[10]

The EMA holds the responsibility of approving safe and effective medicinal products through Market Authorizations and indirectly standardizing research procedures in the EU. This involves collecting clinical trials data (referred to as CTD) submitted as part of the Market Authorization application dossier. According to Article 8 of Directive 83/2001 on medicinal products for human use, an application must be made to the competent authority of the Member State for authorization to market a medicinal product. Furthermore, Article 8 elaborates on the documents that must accompany the application, specifying in subparagraph (i) that results of clinical trials must be submitted as well.[11]

Since its inception, the EMA has prioritized operational transparency, a principle reaffirmed in Article 73 of Regulation 726/2004. This regulation, which established the Agency, asserts the applicability of Regulation 1049/2001 regarding public access to EU documents. It grants public access to content related to the institution's responsibilities, with exceptions limited to circumstances involving public interest, privacy, individual integrity, protection of commercial interest, and the effectiveness of EU decision-making.[12] It is also noteworthy that, in the event of an exception claim that is based on commercial interest of the enterprise, an additional stage of proportionality assessment is added. The EMA is also mandated to develop a registry and a database on medicinal products to make documents accessible.

The Treaty of Lisbon further supported openness, transparency, and the right to access documents in EU Law. For instance, Art. 15 TFEU obliged the EU's legislature to act publicly and established that citizens shall have the right to access documents held by all Union institutions, bodies, and agencies. Moreover, the right of access to documents, and its nature as a fundamental right, is further emphasised by Art. 42 of the Charter of Fundamental Rights of the European Union (CFREU), which is now of 'the same legal value as the Treaties'. [13]

The EMA's approach to transparency in documents submitted by pharmaceutical enterprises has evolved, influenced notably by the European Ombudsman. In 2010, the Ombudsman criticized the EMA's limited public access to documents. In particular, she mentioned the limited access of the EU public to the Agency documents which did not seem to be consistent with the overriding interest in providing sufficient information to the healthcare professionals and patients, leading to the adoption of Policy 0043.[14]

This policy aimed to regulate retroactive access to information, allowing for the redaction of commercially confidential information without providing a precise definition of the term. This unwillingness to directly address the matter of confidential information is consistent with the EMA's previous actions. In 2007 the Agency published the 'Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents', and had carefully avoided a precise definition of this term, proclaiming that the 'commercially confidential information' shall be generally considered to fall broadly into two categories: (a) confidential intellectual property, 'know-how' and trade secrets (including e.g. formulas, programs, process or information contained or embodied in a product, unpublished aspects of trade marks, patents etc.) and (b) commercial confidences (e.g. structures and development plans of a company).[15]

Before December 1, 2010, the EMA treated documents submitted for Market Authorization as presumptively confidential. Policy 0043 introduced a detailed procedure for public access to clinical trial data, conditional upon a request that discloses the identity of the applicant permitting the redaction of personal data and commercially confidential information, though the latter term remained undefined.

8 ibid 5.

9 ibid 2.

10 Ballardini Rosa Maria, Mimler Marc, Minssen Timo, Salmi Mika 'Addressing Exclusivity Issues During the COVID-19 Pandemic and Beyond, 3D Printing, Intellectual Property Rights and Medical Emergencies: In Search of New Flexibilities' IIC – International Review of Intellectual Property and Competition Law, volume 53, issue 8 accessed 17 November 2023.

11 Directive (EC) 2001/83 Of The European Parliament And Of The Council [2001] on the Community code relating to medicinal products for human use.

12 Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents [2001] OJ L 145.

13 ibid 1.

14 Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency (The European Ombudsman Official Website, 2010). Available at <https://www.ombudsman.europa.eu/en/decision/en/5459> 10 June 2019 accessed 17 November 2023.

15 Principles To Be Applied For The Deletion Of Commercially Confidential Information For The Disclosure Of EMEA Documents, EMEA/45422/2006, 15 April 2007.

3. CHANGES IN THE SCENERY

Policy 0070

The Policy, effective from January 1, 2015, aimed to enhance transparency by making clinical data, crucial for regulatory decisions, available for public scrutiny and future research in the interest of public health. This was achieved through the EMA's proactive publication of clinical reports submitted for regulatory approval on its Clinical Data portal. In December 2018, the Policy was suspended due to the EMA's relocation from London to Amsterdam following the UK's departure from the EU. During the pandemic, the Policy was reinstated exclusively for COVID-19 treatments and vaccines. Most recently, in December 2022, the EMA Management Board agreed to gradually reinstate the Policy and held a Webinar in May 2023 to initiate the procedures and inform interested parties. The EMA advised applicants to prepare their Redaction Proposal Document Packages early, to make use of the pre-submission meetings offered by the EMA, and to contact the EMA proactively for any specific product issues. When redacting CCI, applicants should cite detailed and precise justification, explaining exactly how its publication would undermine its economic interests. Applicants should also ensure consistency of redactions of CCI across clinical data submitted to both CTIS and which is subject to publication under the Policy. As a first step, the Policy was relaunched in September 2023[16] for medicinal products with NAS status. In response to a letter of the European Ombudsman concerning "[t]he proactive transparency of clinical trial data", the EMA pointed out that the reinstation of the Policy only for certain medicinal products is in accordance with the public and stakeholders' interests. The gradual reinstation ensures that the Policy will be implemented properly and achieve optimal results while the Clinical Data Policy Service works on the improvement of the technical tools before moving to the next step, which is the expansion of the Policy beyond NAS-containing medicinal products.[17]

Whilst the substance of the Policy has not changed, certain procedural aspects have been amended. In the previous iteration of the Policy, the EMA was obliged to publish the redacted/anonymised clinical reports within 60 days of the issuance of the Commission Decision. Under the reinstated Policy, the EMA will be required to publish the redacted/anonymised clinical reports within 120 days of the adoption of the CHMP opinion. The aim of the policy is to cover the disclosure of clinical data, namely, clinical reports and, on a second level, Individual Personal Data (IPD), submitted under the centralised marketing authorisation procedure. This data is submitted as part of a Marketing Authorisation Application (MAA), a post-authorisation procedure for an existing centrally authorised medical product, procedure under Article 58 of Regulation 726/2004. The data may also be submitted by a third party in the context of a MAA or post-authorisation procedure or requested by the Agency as additional clinical data in the context of the scientific assessment process for the aforementioned situations. The types of data that are not covered by the Policy are also clarified in the text.

In order to enable public scrutiny and to encourage the application of new knowledge in future research the Terms of Use (ToU) for the access to clinical are set out in the document. General access to clinical reports is allowed for any registered user that has agreed to the terms, for general and non-commercial use but only in "view-on-screen" format. A slightly more demanding registration process is required in order to download, save and print the content, solely for academic and non-commercial research purposes, as the user must also disclose information concerning their identity (i.e. name, date of birth, passport or ID card number, expiry date of the document; for juridical persons, the affiliation and position within the organisation of the user should also be provided). Both sets of ToU have the following elements in common: a) No attempt shall be made to re-identify the trial subjects or other individuals from the information b) The clinical reports may not be used to support a MAA/ extensions or variations to a MA nor to make any unfair commercial use of the clinical reports c) A watermark is applied to the published information to emphasise the prohibition of its use for commercial purposes d) The Agency accepts no responsibility for the user's compliance with the ToU.[18]

A pressing matter that aims to be regulated in the Policy is the management of Confidential Commercial Information (CCI) in clinical reports. The method that has been pursued by the EMA is the redaction of said information upon justified proposal of the Market Authorisation Holder and after scrutiny by the EMA. An important contribution of the Policy is the establishment of redaction principles which should be followed by the applicants. Namely, information that is in the public domain or publicly available will not be redacted. Furthermore, justification may be founded on the deterioration of the applicant's position due to the nature of the concerned product or based on the competitive situation of the therapeutic market, or due to the approval status in another jurisdiction, the novelty of the clinical development or a new development by the same company. In short, for the information to be redacted as commercially confidential a detailed justification that illustrates how their disclosure would undermine the economic interest of the undertaking is necessary. [19]

16 Tsang Lincoln, Peterson Hannah 'Relaunch of the EMA's policy on the proactive publication of clinical data' <Relaunch of the EMA's policy on the proactive publication of clinical data – Lexology> accessed 17 November 2023.

17 Reply of the European Medicines Agency in response to the letter of the European Ombudsman concerning "[t]he proactive transparency of clinical trial data" (Case SI/3/2023/MIK) EMA/88457/2023 29 September 2023.

18 European Medicines Agency policy on publication of clinical data for medicinal products for human use EMA/144064/2019.

19 ibid 18.

Regulation 536/2014

Regulation 536/2014, also known as the EU Regulation on clinical trials, introduced a comprehensive framework for the approval and oversight of medicinal product trials within the EU. One of its prominent features is the establishment of a centralized procedure, streamlining the authorization process by enabling sponsors to submit a single application for approval across the entire EU. This not only reduces redundancy, but also expedites the approval timeline. Although the Regulation entered into force on 16 June 2014 the timing of its application depended on the development of a fully functional EU clinical trials portal and database.[20] In terms of transparency, the regulation mandates the disclosure of crucial trial information, ensuring accessibility to details regarding authorization, conduct, and outcomes. In other words, the Regulation places a significant emphasis on transparency and information sharing in the context of clinical trials, marking a departure from the previous EU framework. The establishment of a centralized EU portal and database, providing a single-entry point for the submission and assessment of clinical trial data streamlines the process, enhances accessibility, and ensures consistent information sharing across all member states. Sponsors are required to provide detailed summaries of their clinical trial protocols, results, and layperson summaries, which will be made publicly available, fostering transparency. As a result, the transition to electronic submission via the EU portal enhances efficiency in document handling. Moreover, the regulation incorporates robust pharmacovigilance requirements, guaranteeing continual safety monitoring and prompt reporting of any adverse events.

In comparison to the previous Clinical Trials Directive 2001/20/EC, the new regulation introduces more rigorous transparency measures. The EU portal and database enable the public, including patients, researchers, and healthcare professionals, to access comprehensive information about ongoing and completed clinical trials. This move toward greater transparency aligns with broader trends in healthcare and medical research, emphasizing the importance of open access to information. By facilitating the sharing of trial data, Regulation 536/2014 aims to encourage collaboration, prevent duplication of efforts, and contribute to the overall advancement of medical knowledge. It is worth noting that, the EMA's publication policy and the EU database initiative are distinct measures. While the former provides for the publication of data submitted to the EMA for marketing authorisation through the centralised procedure after 1 January 2015, the latter applies to clinical trials data which are a result of trials approved under the new regulation.[21] EMA Management Board confirmed to the European Commission on 21 April 2021 that the EU Portal and Database were fully functional. The publication of the subsequent Commission notice on 31 July 2021 fixed the date of applicability of the Clinical Trials Regulation on 31 January 2022.[22] On 31 January 2023, the CTIS became the sole repository for submission of data and information relating to clinical trials as per regulatory requirements.

4. COMMERCIALLY CONFIDENTIAL INFORMATION

The concept of CCI must be understood in the context of Article 15(3) TFEU, extending public access rights to documents of all EU institutions, bodies, offices, and agencies.[23] While this provision enhances democratic legitimacy, its application is inherently challenging. The EMA must balance factors like the public's need for information, effective public health protection, and fostering innovation in European medical research, against the business interests of pharmaceutical enterprises. This challenge arises due to the absence of general regulation, the classification of 'sensitive' documents in the EU, and the lack of a comprehensive transparency mechanism in this domain.

As previously mentioned, the fundamental Regulation No 1049/2001 regarding public access to European Parliament, Council and Commission documents, is applicable for the Agency's activities. In the same manner, limitations to access are also applicable, allowing refusal of access in the event that the information pertains to: public interest (Art. 4(1)a), privacy and the integrity of the individual (4(1)b), protection of commercial interests of the individuals and/or the enterprises (Art. 4(2)), or/and the effectiveness of the EU institution's decision-making process (Art. 4(3)). Institution-specific rules for public access procedures and detailed exceptions to exclude information from access are required, especially considering the Art. 4(2) clause of Regulation No. 1049/2001 concerning "commercial interests of a natural or legal person, including intellectual property rights".

Subsequently, Policy 0070 and Regulation 536/2014 were introduced, allowing proactive publication of clinical trials data. Notably, as previously mentioned, the Policy introduced a publication process on the EMA website, providing on-screen access for general users and downloadable access for registered identified users, primarily for academic and non-commercial research. The Policy defined 'commercially confidential information' as any

20 Clinical trials – Regulation EU No 536/2014 <https://health.ec.europa.eu/medicinal-products/clinical-trials/clinical-trials-regulation-eu-no-5362014_en> accessed 6 December 2023.

21 European Commission, 'Impact Assessment Report on the Revision of the "Clinical Trials Directive" 2001/20/EC Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/ EC' SWD (2012) 200 final accessed 3 December 2023.

22 Commission Decision (EU) 2021/1240 of 13 July 2021 on the compliance of the EU portal and the EU database for clinical trials of medicinal products for human use with the requirements referred to in Article 82(2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council < https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2021:275:TOC> accessed 3 December 2023.

23 ibid 1.

non-public information in clinical reports submitted to the Agency, where disclosure may undermine the legitimate economic interest of the applicant or authorisation holder.

Both Regulation (EC) 726/2004 and Regulation (EU) 536/2014 include an exception from disclosure for commercially confidential information. However, the lack of a legal definition led the EMA to consider CCI as any non-public information where disclosure could undermine economic interests or competitive positions. The policy clarified that clinical data, including clinical reports and IPD, are generally not considered CCI except in limited circumstances. The policy annex outlined elements of clinical reports potentially considered as CCI, such as product development rationale, biopharmaceutics, clinical pharmacology, benefits and risks, conclusions, and summaries of studies. These sections could be redacted upon the EMA's review of the submitted justification.

The Clinical Trials Regulation modernized rules on public access to clinical trials data, mandating the submission of clinical study reports within specific timelines. The EU Clinical Trial Portal and Database further facilitated public access to clinical trial information. Article 81(4) of the Clinical Trials Regulation indirectly addressed commercially confidential information, allowing exclusion from public access based on justified confidentiality, considering the marketing authorization status and an overriding public interest.

Facing resistance from the pharmaceutical industry, the EMA released external guidance on implementing Policy 0070, providing specific guidelines for redaction and data anonymization. The 2016 guidance outlined categories of information not considered CCI, namely, information that is already in the public domain, information that does not bear any innovative features (common knowledge), additional information the disclosure of which would be in the public interest, and information lacking sufficient or relevant justification. The guidance, also, requires detailed specifications from applicants on how disclosure would affect their commercial interests, with the final decision resting with the EMA. The guidance established a high threshold for disclosure due to broad interpretations allowed by vague definitions.[24]

Despite stringent policies, Art. 4(2) of Regulation No 1049/2001 poses an additional challenge to pharmaceutical companies. Even if an applicant satisfies all requirements, CCI could still be disclosed in the event of an 'overriding public interest,' such as access to EMA documents and protection of public health in the EU.

5. INTERPRETATION OF THE DEFINITION IN CJEU CASE LAW

In recent years, a dynamic interaction has evolved between the CJEU and the EMA data disclosure policies, highlighting a delicate balance between the imperative for complete clinical study report disclosure and the pharmaceutical companies' assertions regarding the safeguarding of their commercial interests and innovation incentives through data confidentiality. CJEU reviews EMA decisions under Article 263(1) of the TFEU and any arbitration clause in the Agency's contracts, showcasing the complex landscape in which EMA operates.[25] This legal precedent illustrates the dilemma faced by the EMA, caught between the pressure for complete disclosure of clinical study reports and the demands of research-oriented pharmaceutical companies seeking to safeguard their commercial interests on the one hand, and innovation incentives through data confidentiality on the other.

The genesis of this interplay can be traced back to the AbbVie case in 2013, where a university science student sought access to clinical study reports from AbbVie for academic purposes. Despite AbbVie's claim that these reports fell under the exception of CCI as per Article 4(2) of Regulation No 1049/2001, the EMA, relying on Policy 0043, decided to grant access. AbbVie, contesting this decision, raised concerns about the potential violation of its rights, including the right to an effective remedy under Article 47 of the EU Charter. The General Court acknowledged the urgency of AbbVie's request, emphasizing the risk of irreparable harm to its business secrets and right to a private life under Articles 7 and 47 of the Charter. However, the case was settled out of court with AbbVie and the EMA reaching an agreement on the redacted versions of clinical reports, leaving issues concerning the scope of CCI protection under Policy 0043 and CFREU provisions unresolved.[26]

Following this decision, a similar case was brought to the attention of the Court. EMA v. InterMune UK and Others was slightly different as in this case, a "rival" pharmaceutical company demanded access to clinical reports.

24 External Guidance On The Implementation Of The European Medicines Agency Policy On The Publication Of Clinical Data For Medicinal Products For Human Use, EMA/90915/20167.

25 ibid 1.

26 Case T-44/13 R, AbbVie, Inc. and AbbVie Ltd v. European Medicines Agency (EMA) [2013] Order of the President of the General Court, 25 April 2013, ECLI:EU:T:2013:221 43.

Once again, interim measures were granted, based on a similar reasoning on the foundation of Articles 7 and 47 of the Charter, until a final decision on the appeal was made and the case was referred back to the General Court to assess the possibility of partial disclosure of information. Nevertheless, the Court, adopting a more proactive stance, emphasized that mere claims of fundamental rights violation were insufficient, insisting on considering the commercial value of the information. This led to a clearer definition of CCI, emphasizing the professional and commercial importance evaluated by the undertaking. The case was again settled out of court through an agreement.[27]

Several subsequent cases, such as PariPharma v. EMA, PTC Therapeutics International Ltd v. EMA, and MSD Animal Health Innovation GmbH and Intervet international BV v. EMA, show pharmaceutical companies striving to protect their data from EMA's transparency policy. The claimants argued that clinical and non-clinical study reports should be regarded as trade secrets, emphasizing the commercial importance of the information. In order to support the argument, the claimants used both the Charter, namely Articles 7 and 42 (access to EU documents), and Art. 4(2)a of Regulation No 1049/2001 and Art. 339 TFEU to demonstrate the absence of an emerging "overriding public interest" that would justify the disclosure. A part of their argumentation that can be considered crucial for the subsequent decisions, is that the claimants asserted not only that the especially sensitive parts of the reports should be covered by confidentiality protection, but rather, that this protection must extend to the reports as such, because the sensitive parts are embedded in a series of arguments.[28]

In the process of examining these requests, the intervener on the PariPharma case attempted to demonstrate that Article 47 of the Charter must be interpreted as supportive to the access as a tool for competing business interest. However, the General Court dismissed a general presumption of confidentiality, asserting that a significant part of the information in these reports is public domain and cannot be considered within the scope of commercial interest under Article 4(2) of Regulation No 1049/2001.[29] The Court clarified that the economic value of the dossier is a factor but not sufficient to classify information as commercially confidential alone. It emphasized that EMA should individually examine each document to determine whether the data falls under the exception for trade secrets outlined in Article 2(4)(a) of Regulation 1049/2001. In contrast, the EMA's 2016 Guidance suggested that the resources invested in clinical trials are irrelevant to justifying redaction, and applicants must demonstrate specifically how the release would undermine commercial interests.[30]

The provisions of Article 39(2) and (3) of the Agreement on TRIPS do not create a general presumption of confidentiality for information contained in a market authorisation application, as they do not give absolute precedence to the protection of intellectual property rights over the principle of transparency. There is no general presumption of confidentiality protecting sensitive clinical and non-clinical documents.[31] As a consequence, the fundamental rights that were mentioned are not relevant ground for the refusal of disclosure of data.

6. A DELICATE BALANCE

In 2019, following appeals by PTC Therapeutics and Intervet regarding CJEU decisions, the Advocate General expressed an opinion favouring a general presumption of confidentiality due to perceived deficiencies in EU legislation safeguards. These appeals marked the first instance of EU's document access regime issues within the pharmaceutical and veterinary sectors being brought before the Court.

AG Hogan contended that the General Court had incorrectly applied the test for recognizing a general presumption of confidentiality.[32] In fact, between the General Court decisions and the appeal, the CJEU delivered a judgment in ClientEarth v. Commission (Case C-57/16 P), setting the test for the recognition of a general presumption in respect of a new category of documents. According to this decision, showing that "it is reasonably foreseeable that disclosure of the type of document falling within that category would be liable actually to undermine the interest protected by the exception in question", is sufficient to secure protection, regardless of whether the information is new.[33] AG Hogan argued that these specific documents met this test, given the expensive and time-consuming nature of the information and the high-level summary available publicly. The potential for a competitor to gain key know-how without significant investment justified recognizing a general presumption of confidentiality for these documents.

Moreover, the AG disagreed with the General Court, asserting that TRIPS provisions meant the CCI exception should align with safeguarding data against unfair com-

27 Case C-390/13 P(R), European Medicines Agency (EMA) v. InterMune UK Ltd and Others[2013] Order of the Vice-president of the General Court from 28 November 2013, ECLI:EU:C:2013:795. 55.

28 Case T-235/15, Pari Pharma GmbH v. European Medicines Agency (EMA) [2018] ECLI:EU:T:2018:65. 65 and Case T-718/15, PTC Therapeutics International Ltd v. European Medicines Agency (EMA) [2018] ECLI:EU:T:2018:66. 66 and Case T-729/15, MSD Animal Health Innovation GmbH and Intervet international BV v. European Medicines Agency (EMA) [2018] ECLI:EU:T:2018:67.

29 Case T-235/15, Pari Pharma GmbH v. European Medicines Agency (EMA) [2018] ECLI:EU:T:2018:65. 65 49.

30 External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use, EMA/90915/2016.

31 Case C-175/18 P PTC Therapeutics International Ltd v. European Medicines Agency (EMA) and European Confederation of Pharmaceutical Entrepreneurs (Eucope) [2018] ECLI:EU:C:2020:23 112.

32 Case C-175/18 P PTC Therapeutics International Ltd v European Medicines Agency (EMA) Opinion of the Advocate General Hogan delivered on 11 September 2019 ECLI:EU:C:2019:709 98, 166.

33 Case C-57/16 ClientEarth v. European Commission [2018] ECLI:EU:C:2018:660.

mercial use. If effective steps were not taken to ensure such protection, disclosure could compromise the applicant company's data protection, especially when global protection is unattainable outside the EEA. Despite this argument, the CJEU did not adopt AG Hogan's suggestion, stating insufficient evidence from claimants regarding the potential harm to their business interests. The CJEU emphasized that a mere "risk" of a competitor using data for economic purposes was not adequate grounds for a general presumption of confidentiality. However, the Court contributed methodologically, emphasizing that pharmaceutical companies seeking to prevent third-party access must explicitly demonstrate how information disclosure would foreseeably undermine a protected interest.[34]

In reference to the fundamental rights of the Charter as a tool against the disclosure of CCI, the CJEU had already "closed this door" in Amicus Therapeutics UK and Amicus Therapeutics v. EMA, when the Court prominently disregarded the notion that Articles 7 and 17 of the Charter constituted an automatic exception to the principle of disclosure for documents related to private entities' commercial activity referring to the Deza v. ECHA case outcome. Despite the inapplicability of Regulation 536/2014 to the case, the Court interpreted its provisions as reinforcing the EU legislature's emphasis on maximum transparency of EMA documents.[35]

Cases after the 2019 AG opinion indicate the Court's continued reluctance to grant data the status of CCI, particularly based on alleged fundamental rights infringement. Regulation 536/2014 and new Policy 0070 may further strengthen this stance. This raises concerns about potential rights violations for pharmaceutical companies (for instance, Arts. 16, 17 and 47 CFREU), emphasizing the need for intensified dialogue with the EMA during the redaction process.[36]An illustrative example of absence of fundamental rights in the dialogue with pharmaceutical companies has been the Covid-19 emergency which led to several conditional licenses from the EMA. None of the companies attempted to invoke the Charter provisions (Arts. 7, 16, 17, 47 and 42 for instance) as a ground to block access of the third persons to the application kit submitted to the EMA while submitting the application kits for the COVID-19 medicines and vaccines.[37] This could suggest a potential reluctance of companies to utilize the Charter as an effective tool to protect their commercial interests, given the evolving body of the CJEU's case law that evidently reflects a decline in the relevance of CFREU guarantees in the Court's rationale.

The balance between commercial interests of pharmaceutical companies and general public's right to access EU documents is a key consideration. For the exception to apply, the risk of hindering commercial interests must be reasonably foreseeable, not purely hypothetical. However, when clinical data is requested, evaluating the prospective effects of disclosure may be challenging, as at the point when access to clinical data is petitioned for, the prospective effects of disclosure may not be adequately foreseeable. The impact on the commercial interests of original drug sponsors, particularly in terms of facilitating the entry of a competing drug, must be considered. The EMA's goal of establishing a level playing field through disclosure seems contradictory, potentially accelerating the development of competing drugs and undermining the economic interests of information owners.

While the EMA's objectives of fostering innovation and transparency are commendable, their relevance to the public interest assessment under Article 4(2) of Regulation (EC) 1049/2001 is questioned. Economic efficiency-oriented policy goals may require a more in-depth economic analysis and specialized regulatory treatment. The right of access to documents might be too narrow to fully support economically oriented objectives. In the pharmaceutical industry, the reservation for "non-commercial research" purposes may not adequately protect the commercial interests of trial sponsors, as any information from marketing authorization dossiers reused by other developers could facilitate the launch of a new, potentially competitive drug.[38]

7. IS EUROPE OUT OF THE RACE?

Sharing clinical trial data is crucial for enhancing transparency, ensuring scientific progress, minimizing research inefficiency, and maintaining trust in the pharmaceutical industry.[39] In 2013, a significant portion of the industry, represented by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), committed to various initiatives, including sharing participant-level data, study-level data, and protocols from clinical trials of US and EU registered medicines with qualified researchers. They also pledged to provide public access to clinical study reports, share summary result reports with trial participants, establish public web pages displaying data sharing policies, and publish results from trials with medical importance.[40]

34 Manley Maria Isabel, Chatzidimitriadou Zina 'Crucial Development on the Presumption of Confidentiality in the Access to Document Saga (PTC Therapeutics v EMA and MSD Animal Health Innovation, Intervet v EMA),' <Crucial Development on the Presumption of Confidentiality in the Access to Document Saga (PTC Therapeutics v EMA and MSD Animal Health Innovation, Intervet v EMA) – Lexology> accessed November 17 2023.

35 ibid 5.

36 Daria Kim 'Transparency Policies of the European Medicines Agency: Has the Paradigm Shifted?' [2017] 25(3) Oxford Medical Law Review 456.

37 ibid 23.

38 ibid 34.

39 ibid 33.

40 The FDA defines Commercially Confidential Information (CCI) as valuable data or information held in strict confidence within one's business, but the FDA may use discretion to release it if there is a compelling public interest; Modi Natansh, Kichenadasse Ganessan, Hofmann Tammy, Hasel Mark, Logan Jessica, Veroniki Areti, Venchia-

Despite these commitments, the pharmaceutical industry operates in a highly competitive environment. In Europe, the pharmaceutical sector is a key contributor to the economy, generating over €200 billion in Gross Value Added (GVA), providing 2.5 million jobs, and leading in R&D intensity. Over the years, however, Europe's share in global pharmaceutical innovation has declined, with the United States outpacing it. The region's policies have often prioritized affordable medicines over industrial competitiveness, contributing to its diminishing influence in global pharmaceutical innovation. It is noteworthy to highlight that in 1960, Europe was the source of nearly two-thirds of all new medicines. By 1990, pharmaceutical companies in Europe accounted for over half of the worldwide R&D spending, but this percentage has consistently decreased over the years, reaching 35 percent in 2020.[41]

In the past years, most policies and strategies in the pharmaceutical space have put affordable medicines front and centre and left goals such as strengthening the EU's placement in the pharmaceutical market as a complimentary purpose. Securing affordable medicines is a perfectly legitimate policy goal, but it is not industrial policy and does not per se complement the competitiveness of the European pharmaceutical sector. An example of Europe's decline is evident in the development of Advanced Therapy Medicinal Products (ATMP), where the Asia-Pacific region has been more competitive in attracting clinical trials. Despite European institutions being prominent in academic research, R&D investments tend to go elsewhere. While Europe may not adopt the pricing freedom of the United States, it is crucial for policymakers to explore alternative strategies to compensate for disadvantages such as persistent cost-containment policies and market fragmentation within the EU.[42]

8. CONCLUSION

Intellectual Property Rights could be the cornerstone of making Europe an increasingly attractive market for pharmaceuticals. Regulations as the GDPR and Regulatory Exclusivities that are more generous than in any other competing market could serve as an assurance for the undertakings' data safety. However, a strict transparency policy negates this increased level of protection. The 2019 AG opinion offers a legal depiction of this issue, illustrating that the balancing that has been conducted in past cases does not consider the importance of knowledge valorisation, and the fact that a company's data is a fundamental factor to its freedom to conduct business and to maintaining competitiveness in the market. The most important aspect of this issue is the globalization of the market and international competition, meaning that if Europe upholds a strict policy in reference to CCI it will possibly become uncompetitive as a result.

With the implementation of the Lisbon Treaty, the EUCFR has officially transformed into a legally binding instrument of primary law. It stands at the heart of the Union's legal structure, serving as a key reference for CJEU judges as they evaluate the alignment of measures taken by the EU or its Member States with fundamental rights. Thus, Article 16, which expressly addresses the freedom to conduct business has gained a primary law status as well. A pivotal ruling shedding light on the extent of this essential right is the Sky Österreich case. Here, AG Bot applied Article 16 of the Charter on his own initiative, and the CJEU, once more, harkened back to its precedents emphasizing the non-absolute nature of the freedom to conduct business.[43] As was mentioned in paragraph 47 that: "[o]n the basis of that case-law and in the light of the wording of Article 16 of the Charter, which differs from the wording of the other fundamental freedoms laid down in Title II thereof, yet is similar to that of certain provisions of Title IV of the Charter, the freedom to conduct a business may be subject to a broad range of interventions on the part of public authorities which may limit the exercise of economic activity in the public interest."[44] It seems that the CJEU has interpreted the phrase "in accordance with Union law and national laws and practices" to reflect a broader limitation to curtail the freedom to engage in

rutti Rebecca, Smit1 Amelia, Tufaha Haitham, Jayasekara Harindra, Manning-Bennet Arkad, Morton Erin, McKinnon Ross, Rowland Andrew, Sorich Michael and Hopkins Ashley 'A 10-year update to the principles for clinical trial data sharing by pharmaceutical companies: perspectives based on a decade of literature and policies.' BMC Med. 2023 Oct 23;21(1):400. doi: 10.1186/s 12916-023-03113-0. PMID: 37872545; PMCID: PMC10594907.

41 Erixon Fredrik, Guinea Oscar 'Strategic Autonomy and the Competitiveness of Europe's Innovative Pharmaceutical Sector: A Wake-up Call' <https://ecipe.org/publications/strategic-autonomy-competitiveness-europes-innovative-pharmaceutical-sector/> accessed 17 November 2023.

42 ibid 39.

43 Groussot Xavier, Petursson Gunnar Thor, Pierce Justin 'Weak Right, Strong Court – The Freedom to Conduct Business and the EU Charter of Fundamental Rights' (April 23, 2014). Lund University Legal Research Paper Series No 01/2014, Available at SSRN: https://ssrn.com/abstract=2428181 or <http://dx.doi.org/10.2139/ssrn.2428181> accessed 6 December 2023.

44 Case C-283/11 Sky Österreich GmbH v. Österreichischer Rundfunk [2013].

business for the greater public good than what would be applicable otherwise. It could as well be argued that the CJEU views the inclusion of this language in Article 16 as a reflection of its own case law, which has consistently shown a degree of ambiguity regarding the freedom to conduct business.[45]

It could be argued that, so far, the CJEU maintains a "weaker" right status for the freedom to conduct business. Based on European legal tradition, this is a sensible more human-centred practice that aligns with the latest policies of the EU.[46] However, it is worth considering that Europe is part of an international market that runs on competitive terms. Undoubtedly, the importance of open science and access to knowledge should not be diminished. Nevertheless, it must be acknowledged that a legal order which does not protect data which is the product of tremendous investments, will not offer an appropriate incentive for R&D. The pandemic has proven that in extreme situations, sharing of research data can be safeguarded based on urgency and threat to public health as was, indeed, the case even though Transparency Policy 0070 was at halt. Moving from a general presumption of confidentiality to a general presumption of openness and demanding pharmaceutical companies to prove an existing harm can arguably be an imbalanced practice. Notably, because the "harm" will only be apparent after the publication of data and at that point the harm to the undertaking will be irreparable and especially considering that CCI is a notion that has been greatly shaped by case law instead of being clearly defined in legislative texts creating legal uncertainty.

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45 Oliver Peter 'What Purpose Does Article 16 of the Charter Serve?' in U. Bernitz et al. (eds.), General Principles of EU La and European Private Law (Kluwer, 2013), 293.

46 Picod Fabrice 'Charte des Droits Fondamentaux de l'Union Européenne. Commentaire Article par Article, Bruylant, 2017.; Plasseraud, Lucie, 'The Relationship Between the Internal Market and Fundamental Rights: Strengthening; Freedom to Conduct a Business in the Service of the European Union Economic Integration' (July 24, 2019). Available at SSRN: https://ssrn.com/abstract=3491655 or <http://dx.doi.org/10.2139/ssrn.3491655> accessed 6 December 2023.

The Sex of the Author: On Authorship, copyright and the individual

Frantzeska Papadopoulou

ABSTRACT

This article explores the meaning of "authorship" and "author" on the basis of female authorship in the early Swedish film history as well as in contemporary film productions. Film, as a new protectable subject-matter raised fundamental questions as to the meaning and origin of authorship as a copyright concept. The need to identify an author was closely related to its recognition as an art form. The role of female authors in film, as well as how these rights were and are claimed and recognized are central questions discussed in the article.

Keywords: authorship, film, Selma Lagerlöf, film production

Authorship and film, or authorship in film, coalesce in exciting if also rather blurry ways. Interestingly enough, both 'authorship' as a concept of legal significance in the copyright environment, and film as a new technological (if not artistic) achievement received their first official international exposure in Paris, the former during the *Congrès Littéraire International* on the 17th of June 1878, and the latter in the public screening of the Lumière brothers' films in Paris on 28 December 1895.[1]

It is not at all difficult to imagine why the application of the term 'authorship' in film production and consumption culture has been anything else frictionless. First, it took several decades for the public opinion and finally for the legal system to recognize as a form of art or in general an intellectual work subject to copyright protection. At the same time, film is as such a complicated subject-matter in terms of its process of production, the importance of the active involvement of several contributors and the difficulty to discern who in fact is the mastermind, the "genius" behind the artistic quality of the end-result.[2] The multi-level and multi-party contribution, necessary for a film production is *de facto* contradictory to the credits to the sole author. These factors also explain why an "authorship" discourse, that of the *auteur theory* emerges as late as in the 1940s in film theory.[3] At the same time the *auteur* becomes central in the film context when the industry reached a certain maturity and there was an importance to claim its "fine art" status.

Authorship as such is a rather contemporary concept used to define the person that bares the sole responsibility and enjoys the benefits for the creation of an original work, initially literary works. Certainly, authorship constitutes evidence of origin, originality, a matter of branding, but also often evidence of the legal control on works. Previously, legal control in printed works was awarded to printers and publishers by means of royal privileges. It is not until the late 1800s that the 'author' appears as a unique individual, a genius that deserves to be compensated for his work. Gradually this "author" becomes an autonomous legal subject and authorship becomes of central importance for the operation of the copyright system as a whole.[4]

In fact in contemporary film studies, authorship has been awarded a number of different functions; that of origin, expression of personality, sociology of production, as a signature or as a reading strategy, as a site of discourses or as a technique of the self.[5] It becomes thus a concept that is filled with content both with regards to the author's internal need for expression, as well as with

1 Rune Waldekranz, *Filmens Historia: De Första Hundra Åren: Del I* (Norstedts 1986). See also SB Dobranski, "The Birth of the Author: The Origins of Early Modern Printed Authority" in Stephen Donovan, Danuta Fjellestad and Rolf Lundén (eds), *Authority Matters: Rethinking the Theory and Practice of Authorship* (Rodopi 2008); Abraham Drassinower, "Copyright, Authorship and the Public Domain: A Reply to Mark Rose and Niva Elkin-Koren" (2018) 9 Jurisprudence 179. NB. I am aware that this fact is contested.

2 Marja Soila-Wadman, *Kapitulationens Estetik: Organisering och Ledarskap i Filmprojekt* (Företagsekonomiska institutionen 2003) 42.

3 For an elaboration on the evolution of the concept of "author", see Peter Jaszi, "Toward Theory of Copyright: The Metamorphoses of "Authorship" (1991) Duke Law Journal 455; Benjamin Kaplan, "An Unhurried View on Copyright" (1967) Columbia University Press 52; Martha Woodmansee, "The Genius and the Copyright: Economic and Legal Conditions of the Emergence of the 'Author'" (1984) 17 Eighteenth-Century Studies 425.

4 John Feather, *Publishing, Piracy and Politics: An Historical Study of Copyright in Britain* (Mansell 1994); Rosemary J Coombes, *The Cultural Life of Intellectual Properties: Authorship, Appropriation, and the Law* (Duke University Press 1998).

5 Janet Staiger, "Authorship Approaches" in David A Gerstner and Janet Staiger (eds), *Authorship and film* (Routledge 2003).

regards to their communication with the public and with other authors.

Authorship constitutes further the theoretical foundation of modern intellectual property rights, the mere existence of copyright presupposes the identification of an author. The concept has however at the same time constituted an expression of a paternalistic and gender-biased discourse where the author, and thus also the owner of intellectual property rights, is in fact a man, a "he".[6] There is very little feminist analysis of copyright law, and thus also of the gender perspective of authorship as such.[7]

One could of course wonder why a discussion on authorship is relevant, and how it actually contributes to address the core concepts of this book, namely the presence and power of women in the Swedish film industry. The reason should however be obvious. Authorship is today used as an all-encompassing term within a widespread area of cultural exchange, it signals property, control but also creativity, personality, the power to include and to exclude, and of course branding. The questions posed by this chapter are thus: 1) how does the presence of an author emerge in the field of film industries in Sweden, in regard to praxis, rights and legislation. 2) What are the specific features of a feasible female author within the film industry? Is authorship equivalent to presence? 3) what are the means that are able to create a "portrait" of an author in the film industry and is it possible for an alleged female author to have control over her own "portrait".

In order to address these questions, this chapter investigates the evolution of the concept of authorship from a specific theoretical point of view of the Auteur-theory developed in the late 1940s by French film critics, its introduction to the world of film and the role it plays to the application of the copyright system. Subsequent to a theoretical and legislative overview of the terms author/auteur this chapter will proceed to look into how authorship has been comprehended and exercised by women who have aspired/aspire to the position of author/auteur in the film industry.

THE GENESIS OF AUTHORSHIP

Although Foucault's thought-provoking text "Qu' est-ce que en auteur?", was published already in 1968 posing central questions on the definition and validity of the concept very little has been written about the origins of the term *auteur*. In his article, Foucault poses a series of interesting questions in relation to the genesis of the concept, namely:

> it would be worth examining how the author became individualized in a culture like ours, what status he has been given, at what moment studies of authenticity and attribution began, in what kind of system of valorization the author was involved, at what point we began to recount the lives of authors rather than of heroes, and how this fundamental category of "the-man-and-his-work criticism" began.[8]

6 The historical presentation of the "author" will refer to the male author, the "he".

7 Andreas Huyssen, *After the Great Divide: Modernism, Mass Culture, Postmodernism* (MacMillan 1988) 192; Seán Burke, *Authorship: From Plato to the Postmodern: A Reader* (Edinburgh University Press 1995) 145; Melissa Homestead, *American Women Authors and Literary Property* (Cambridge University Press 2005); Carys J Craig, "Reconstructing the Author-Self: Some Feminist Lessons for Copyright Law" (2007) 15 Journal of Gender, Social Policy and the Law 207; Ann Bartow, "Fair Use and the Fairer Sex: Gender, Feminism and Copyright Law" (2006) 14 Journal of Gender, Social Policy and the Law 551.

8 Michel Foucault *Diskursernas Kamp* (Symposion 2008), 141. See also Roland Barthes, *Image, Music, Text* (Fontana 1977) 142; Seán Burke, *The Death and Return of the Author: Criticism and Subjectivity in Barthes, Foucault and Derrida* (Edinburgh University Press 1992); Per I Gedin, *Litteraturen i Verkligheten: Om Bokmarknadens Historia och Framtid* (Rabén Prisma 1997); Leif Dahlberg, "Rätt och Litteratur" (2003) TfL 3.

What seems to be rather clear however is the fact that the term (at least in its contemporary use) is a new normative construction, and one promoted by a group of literary authors that wished to find a legal basis that would allow them to actually make a living of their writing. It is in fact their struggle to acquire a legal protection for the products of their labor that constituted the starting point for what came to be *the author* and in extension that of the *auteur*. In the Renaissance and post-Renaissance era of the early 19th century, the 'author' is a craftsman, the "master of an art" who provided form to clay, color and words. These "craftsmen" were expected to contribute with literary and cultural expressions, in order to satisfy their sponsors, mainly the royal court and the social elite. It was also these sponsors that provided for the financial, political and social protection necessary for these authors to live and thrive. The dependence of the authors on their sponsors had most certainly their side-effects, since it also dictated very often also what was produced and how. In this very subjective world of artistic and literary evaluation, certain authors and artists of extraordinary quality were considered to have a divine source of inspiration, the glory of God or a muse. The cultural hegemony of the cultural elite was gradually abandoned due to new political and economic circumstances, and in the late 18th century artistic creations and literature were increasingly accessible to a broader public. Authors and artists abandon their protegés status, and adopt that of public celebrities.

In this attempt to better serve the cause of linking authorship to a livelihood, late 19th century theorists have undermined the role of the craftsman and elevated the role of "genius" that is not of divine origin, and originates from the talents and personality of the "author" himself/herself. The central role the personality, skills and inspiration of the individual "author" leads to the genesis of the "original genius". Undermining the role of the divine has a decisive impact on the internal relationship between the author and the work. Art and literature becomes the outcome of the "author's" genius, a commodity and thus also the author's property. Although the role of royal and nobility patronage is fading, authors find themselves in new dependency relations, this time exploited by printers and publishers who get richer and richer, while they (the authors) received a limited honorarium. Interestingly enough, the privileges of the printers and publishers originate in the royalty, the historical patrons of art and literature.[9]

It is under such circumstances, that the first official international proclamation of the "author", is made. In 1878, the year of the *Exposition Universelle* in Paris and the *Congrès Littéraire International*, initiated by the *Societé des gens de lettres de France*. Victor Hugo holds the inaugural speech and in it is actually he who for the first time constructs the modern international "author".[10] According to Hugo, if you deprive the author of his property then you deprive him of his independence. The "author" is a genius, possessing extraordinary qualities, an intellectual capital that should enjoy the extensive protection of the legislator. It is this speech that lays the theoretical ground for the Berne Convention (1886), the international treaty regulating copyright law and signed and ratified by in principle all countries in the world.[11]

A discourse on the genius in film, author, that strikingly reminds of the origins of the literary author as he was presented in the speech of Hugo, rises some seventy years later in post-war France. It is the *director as auteur, a* term, concept and value that gradually finds its way to film critics and filmmakers in other countries in the late 1950s and 1960s. Two seminal texts contributed to launching the notion of the auteur – embedded, as it was, by a theory called – *le politique des auteurs* – were Alexandre Astruc's *Du Stylo à la caméra et de la caméra au stylo* (1948), and François Truffaut's *Une certaine tendence du cinéma français* (1954).[12]

In fact, some of the earliest attempts to theorize around the film medium approached filmmaking as an art form, and emphasized the filmmaker as an artist comparable to a painter or a novelist.[13] In a similar manner as in the case of literary authors previously, the fact that there was no explicit proclamation of the role of the director as *auteur*, does not *per se* also mean that the director's contribution would have been regarded as insignificant prior to the all-encompassing breakthrough of the concept. Indeed, silent film directors like D.W. Griffiths in the US, Carl Theodor Dreyer in Denmark and Viktor Sjöström in Sweden (to name just three examples) were renowned for their artistry and their individual and specific cinematic style.

In this respect, the *auteur* has been presented as the man who initiates the concept, writes the script, including dialogue of his films, he directs and finances them as well. It is the one that has the sole responsibility for the artistic creation in a cinematographic work and the one to receive the sole credit.[14][15] However, Truffaut, together with other *Cahiers* critics, promoted a rather inclusive approach. In

9 Bo Peterson, *Välja och Sälja: Om Bokförläggarens Nya Roll Under 1800-talet, Då Landet Industrialiserades, Tågen Började Rulla, Elektriciteten Förändrade Läsvanorna, Skolan Byggdes och Bokläsarna Blev Allt Fler* (Norstedts 2003); Nancy Miller, "Changing the Subject: Authorship, Writing and the Reader" in Teresa de Lauretis (ed), *Feminist Studies/Critical Studies* (Palgrave Macmillan 1995); Christopher Buccafusco, "A Theory of Copyright Authorship" 102 (2016) Virginia Law Review 1229.

10 Eva Hemmungs Wirtén, *No Trespassing: Authorship, Intellectual Property Rights, and the Boundaries of Globalization* (University of Toronto Press 2004).

11 DA Brooks, *From Playhouse to Printing House: Drama and Authorship in Early Modern England* (Cambridge University Press 2000); Sam Ricketson and Jane Ginsburg, *International Copyright and Neighbouring Rights: The Berne Convention and Beyond* (2nd ed, Oxford University Press 2006); Gunnar Petri, *Författarrättens Genombrott* (Atlantis 2008) 28; Janet Clare, "Shakespeare and Paradigms of Early Modern Authorship" 1 (2012) Journal of Early Modern Studies 137.

12 Alexandre Astruc, *Du Stylo à la Caméra... et de la Caméra au Stylo. Écrits (1942-1984)* (L'Archipel 1992).

13 See for instance Riccioto Canudo, "Naissance d'un Sixième Art: Essai sur le Cinématographe", translated as "The Birth of the Sixth Art" in Richard Abel (ed), *French Film Theory and Criticism: A History/Anthology (1907-1930)* (Princeton University Press 1988); Menno ter Braak, *De Absolute Film* (WL en J Brusse 1931).

14 Francois Truffaut, "Une Certaine Tendence du Cinéma Français" 6 (1954) Cahiers du Cinéma 15.

15 Our translation from the French original.

order to stress the artistic value of commercial genre productions as well, the French film critics supported their arguments by analyzing the works of Hollywood directors such as Howard Hawks and Alfred Hitchcock. In order to overcome the criteria asking for possession of the means of production and control of all phases in the production chain, the focus was put on the *style* of each director in a film. The style became the expression for the uniqueness and the artistic value of the final artistic product, the film. Thus, the notion of *auteur* came to signify not only filmmakers telling their own stories, but also directors who succeeded in making personal films even when working from other people's screens.[16]

Looking at the Swedish paradigm, the film industries had, during several decades, aspired the status of art (as in opposition to the aura of low-brow amusement) for their products. This was not only because of the importance to label "art as art", but as an effort to appeal to the culturally refined groups in society. Appealing to this stratum, was in its turn expected to contribute to substantial increases in the box-office income. Parallel to this, and towards the end of the 1940s, the government increased "amusement taxes" based on every paid ticket in different kinds of entertainment facilities, including film shows. On the other hand, theatre performances and musical concerts, being considered as cultural forms, were exempted from the amusement tax. The film industry was presented with a pure economic interest that of receiving similar tax reliefs as the stage theatres. In order to achieve that, film had to be considered as an acknowledged fine art, as an expression of high culture. Fine art and high culture presuppose the existence of the alleviated author. Identifying the film director as an *auteur* came well at hand under such conditions.

In the late 1940s, when *auteur theory* emerges, the film industry has received both the self-confidence and the recognition of its artistic value and seeks a way to individualize the director as the "author".[17] It seems only natural that if film is to be recognized as a work of art, there should also be an "author". The ideal of the "author" that creates freely without any constraints from sponsors, corresponds to the ideal of the "author" of the post-Renaissance era. It also makes a perfect match with the concept of the artist at the introduction of Modernism in art and literature at the turn of the 19th century where a piece of art was to be seen as the expression of a unique mind and an individual's view of life and values.[18]

AUTHORSHIP IN FILM: ARE THE IGNITION POINTS TIMELESS?

As previously shown in this chapter, authorship is a term loaded with different values, carrying different meanings and thus giving rise to a variety of legal implications. One important aspect in this discussion at hand is what is meant by "authorship" and how the film industry uses the term. What is it really, we are looking at when identifying authorship in film? Is it the level of creativity? Or is it a matter of ownership claim? Is it control of the creative process of film production, or is it control over the end result? Or is it a matter of being attributed the credits to a film? Is it merely a matter of branding? And can it be so that while using the same term, "authorship in film" we weigh and value completely different aspects/meanings of the term?

In the beginning of the 20th Century, Sweden participated in the intellectual and legislative debates as to whether cinematographic works are dramatic works or photographs and thus whether they would qualify for copyright protection to begin with. The Law on the right to literary and music works of 1919, did not mention film as protectable subject matter. The same year however, the Law on the protection of photographic works (FL) was adopted and was deemed as most appropriate to foster the protection of this new "subject-matter".[19] This law was of course of relevance for the film industry, as cinematographic works were initially considered a series of photographs. During this first period, discussions were concentrated on the status of copyright protected works used for the purposes of a film production (books, music), as well as on whether and under which conditions a film could be subject to copyright protection as such.[20] A review of the literature and the legislative works in this respect shows that film directors were granted a central position in the film protection debate. In the public inquiries both regarding the 1919 legislation and its 1931 revision, the contribution of the film director was expressly considered more important than that of the theatrical director in stage productions.[21] Nevertheless, in neither of these legislative works is the film director expressly awarded copyright protection for the film as such. Knoph excludes in his work any possibility of protecting the film director as an author, yet at the same time he provides that the contribution of the film director is independent enough from the film as such and could thus be a basis for some form of protection. This was contrary to what the court decided with regards to a theatrical director in the Mazurka case.[22]

16 Miranda Banks, "Production Studies" 4 (2018) Feminist Media Histories 157.

17 Rune Waldekranz, *Filmens Historia: De Första Hundra Åren: Del I* (Norstedts 1986); Tytti Soila, "The Phantom Carriage and the Concept of Melodrama" in Helena Försås-Scott, Lisbeth Stenberg and Bjarne Thorup Thomsen (eds), *Re-mapping Lagerlöf* (Nordic Academic Press 2014).

18 Peter Luthersson, *Modernism och Individualitet: En Studie i Den Litterära Modernismens Kvalitativa Egenart* (Symposium 1986).

19 Martin Fredriksson, *Skapandets Rätt* (Daidalos 2010).

20 Gösta Eberstein, *Den Svenska Författarrätten* (Norstedts 1926); Ulf von Konow, *Författares och Tonsättares Rätt Enligt Gällande Lagstiftning: Kommenterande Utredning till Lag om Rätt till Litterära och Konstnärliga Verk den 30 Maj 1919 med Däri Genom Lag den 24 April 1931 Gjorda Ändringar och Tillägg* (Natur och Kultur 1941); Åke Lögdberg, *Auktorrätt och Film* (Gleerup 1957).

21 Elisabeth Liljedahl, *Stumfilmen i Sverige: Kritik och Debatt – Hur Samtiden Värderade den Nya Konstarten* (Svenska Filminstitutet 1975).

22 See the court case of the Supreme Court of Sweden, NJA 1943:101 s. 411. Ragnar Knoph, "Om Ophavsmannens 'Moralske' Rett til Sitt Verk

It is important to note here however, that authorship in film as such was not officially recognized until the 1960 Swedish Copyright Act (URL). In lack of adequate legislative framework, the rights of directors, actors, producers were safeguarded (when that was the case) by means of contractual agreements. What is noteworthy in this respect is the fact that although film productions fell outside the scope of the legislation, these agreements were still very laconic (very short in length and including only general terms). It seems that relations in the Swedish film industry of the time were to a large extent self-regulated, by unwritten codes of conduct, that were easy to follow and enforce considering the limited size of the industry at the time. The "author" in this respect, that was recognized was the author of the original literary work on the basis of which the film was produced.[23]

The 1960 Swedish Copyright Act has entailed a new era for the film industry by including in the copyright legislation a list of *sui generis* rights and so-called neighboring rights, several of which concern film, namely rights for performing artists, producers, and even photographers.[24] Neighboring rights, although placed strategically under the same legislation, enjoy a somewhat different legal status than that of copyright. Protection criteria differ, as does the duration of protection granted. Rights are not exclusively based on the creative expression of the right holder as the financial investment in the film also may determine the grant of the exclusive rights (44-47 §§ URL). In fact, these rights may protect a legal person (a company or organization) and do not require the existence of a human, an author/auteur, as is the case with traditional copyright. Furthermore, they reward economic investment and not creativity or originality. It seems thus, that copyright legislation partly deviated from the need to anchor exclusive rights on the Renaissance 'author'.

According to article 2.1 of the Council Directive 93/98/EEC of the 29th of October 1993 harmonizing the term of protection of copyright and certain related rights, the author of the film as such was the principal director. While some other countries, such as the UK, have opted for a more hands-on clarification of the legal status of "authorship" in film, Sweden has chosen a more neutral position.[25] The copyright is awarded to the person/persons who have contributed with creativity and originality in the final artistic character of the work/the film. This leaves the question of "authorship" rather open and subject to an *in casu* evaluation.[26][27] In the Public Inquiry it is provided that the principal director of a film will also be the author of the film.[28] Following the same line is the law proposal 1994/95:151,[29] confirming the same view but at the same time not considering it necessary to specify this in the legislative text as such.[30]

The fact that copyright is in fact a two-faceted exclusive right containing both an economic right (2 § URL) and a moral right (3 § URL) brings an additional and not unimportant perspective to the discussion. Rights transferred by means of contract or assignment concern only the economic rights of copyright (the right to reproduction, distribution etc)[31]. The moral rights are non-transferrable and remain with the original author of the work. This means that in theory the director, screen-writer or any other joint-author to a film might claim moral rights and object to a certain form of exploitation of a film even after the transfer of their economic rights (See for instance the case *Hajen som visste för mycket* in which the director of the film opposed it being disrupted for advertisements when broadcast by the Swedish television channel TV4, as this was considered to distract the atmosphere and historical character of the film.[32])

It is thus important to clarify that when using the term "authorship" from a legal perspective we refer in fact to a bundle of rights. The contemporary abstruseness of the legislation with regards to the copyright protection of film works is compensated by elaborate contractual agreements, concentrating the economic rights (be it traditional copyright or neighboring rights) in the hands of the producer/distributor. What authorship thus bestows the film author with above the economic rights of copying, distributing and that of public performance, is the right to be named, the right to have the final say, the "final cut" on the artistic approach of the film, and the right to require that the film is distributed in ways that are not defamatory for the author.

IN SEARCH OF THE 'SHE' GENIUS

Considering the above, the conceptual idea of the author/auteur has historically been a man, a "he". Victor Hugo, 75 years old at the time of his seminal speech quoted previously in this chapter, clearly identifies the male author.

Efter den Nye Lov Om Åndsverker" in *Festskrift tillägnad Presidenten Juris doktor Herr Friherre Erik Marks von Würtemberg den 11 maj 1931 av nordiska jurister* (1932) 316. Åke Lögdberg, *Auktorrätt och Film* (Gleerup 1957).

23 Åke Lögdberg, *Auktorrätt och Film* (Gleerup 1957); Stig Strömholm, *Europeisk Upphovsrätt: En Översikt Över Lagstiftningen i Frankrike, Tyskland och England* (Norstedts 1964); Stig Strömholm, *Upphovsrättens Verksbegrepp* (Norstedts 1970); Stig Strömholm, "Upphovsmans Ideella Rätt – Några Huvudlinjer" 88 (1975) TfR 289; Stig Strömholm, "Upphovsrätten Som Nationell Disciplin – Exemplet Droit Moral" 74 (2005) NIR 6.

24 Latin for of its own kind, and used to describe a form of legal protection that exists outside typical legal protections -- that is, something that is unique or different.

25 DA Brooks, *From Playhouse to Printing House: Drama and Authorship in Early Modern England* (Cambridge University Press 2000) 39; Pascal Kamina, *Film Copyright in the European Union* (Cambridge University Press 2016) 47.

26 Jeffrey Knap, "What is a Co-Author?" 89 (2005) Representations 1.

27 A case-to-case evaluation needs to be made in this regard.

28 See Lagförslag av Auktorrättskommittén (SOU 1956:25) 134.

29 Governmental Bill (1994/95:151) 25.

30 Kathy Bowrey, "Who's Writing Copyright History?" 18 (1996) European Intellectual Property Review 322; Stig Strömholm, "Upphovsrätten Som Nationell Disciplin – Exemplet Droit Moral" 74 (2005) NIR 6; Martin Fredriksson, *Skapandets Rätt* (Daidalos 2010) 217-219.

31 Pascal Kamina, *Film Copyright in the European Union* (Cambridge University Press 2016) 89.

32 The director of this film was Claes Eriksson (1989).

He also lived in a period of time when women had no legal rights after marriage, not even the acclaimed authors could in fact represent themselves and decide upon the management of their rights.[33] Looking into central principles and terminology of copyright law leaves no doubt of its gendered origins. The right of the author, according to copyright law, to have his name attached to his work is named "paternity right", as in fact the right of the father to protect the patrilineal line. The parental metaphors do not stop here, the author "creates", "originates" he also acquires the rights to "reproduction" and when the identity of the author is unknown the works are "orphan".[34] Regrettably of course, both authorship as a political and legal term, and the concept of *auteur* in film theory, was developed almost entirely by men who developed the intellectual construction of a male author, the only one who could be a "genius". One female person with an influence in the early discussion on authorship was the American film critic Pauline Kael, discussed below. One could of course attempt to understand (though not justify) why this was the case.

The notion of the auteur-director was created by male film critics, and the filmmakers that they canonized were also men. In 1963, a few years before Barthes and Foucault wrote their pieces on the (missing) author, Pauline Kael criticized "auteur theory" as 'an attempt by adult males to justify staying within the small range of experience of their boyhood and adolescence'.[35] After her, many feminist film theorists have rejected auteurist approaches to film, claiming that a focus on the director is inherently tied to a sexist cult of male personality. Yet, many feminist film scholars have also opted to use the idea of authorship to celebrate the work of women directors.[36]

Despite of the origins of author and auteur and their dependence on the male prototype, the "she" geniuses of the film industry are non-negligible. There is a long list of important contributions of women in the history of film production, be it as authors of literary works adapted to films, screen-writers, set decorators, directors or producers.[37] It becomes also equally important to see how their acclaimed authorship (and the rights this bestowed them with) was acclaimed and defended by them, as well as how this was welcomed by the state, the stakeholders of the film industry and the audience.

On the basis of what was previously concluded as a core of authorship in film, namely the moral rights to the work, it is of interest to investigate how these rights were exercised by "she" geniuses of the film industry historically. An interesting illustration is that of state censorship emerging as a means to control the content and distribution of films in Sweden. The Nobel prize winning author, Selma Lagerlöf was one of the female authors with the most notable resistance to the attempts of the censors to inflict on her authorship. In 1925, the Gustaf Molander film *The Sons of Ingmar* (*Ingmarsarvet),* based on the first part of Lagerlöf's trilogy *Jerusalem*, attracted the interest of state censorship. The distributor (SF) was in fact informed that certain scenes should be removed (in particular a scene with a woman drowning after a fight for a lifebuoy). The distributor replied that Lagerlöf was strongly against such interference in her creative work, since this would severely damage the artistic value of the film. In the letter informing of their final decision, the censors state clearly that they do not share Lagerlöf's opinion, but will however respect her wish.[38]

This decision is noteworthy since it illustrates how censorship and authorship collide in film, but also and above all, because Lagerlöf managed to defend her rights as the "author" and in fact impose her approach on the censors. At a period of time, where there was no established, self-evident author for the film work as such, the author of the literary work -that the film was based on- often became the frontal figure both to defend its intellectual and artistic sanctity as well as a brand name under which the film would be advertised.

In fact, this was not the first time the censors chose to abstain from interfering with Lagerlöf's authorship. Already in 1917, there were serious concerns for the film *The Woman He Chose* (*Tösen från Stormyrtorpet)* based on Lagerlöf's book with the same name, and whether it should be classified as white (prohibited for both adults

33 See Martha Woodmansee, "The Genius and the Copyright: Economic and Legal Conditions of the Emergence of the 'Author'" (1984) 17 Eighteenth-Century Studies 425; Eva Heggestad, *Fången och Fri:1880-talets Svenska Kvinnliga Författare och Hemmet, Yrkeslivet och Konstnärskapet* (Uppsala Universitet 1991).

34 Rose Mark, "Mothers and Authors: Johnson v Calvert and the New Children of Our Imaginations" 22 (1996) Critical Inquiry 613.

35 Pauline Kael, "Circles and Squares" 16 (1963) Film Quarterly 12.

36 Annette Kuhn, *Queen of the B's: Ida Lupino Behind the Camera* (Greenwood Press 1995); Tytti Soila, *Att Synliggöra det Dolda: Om Fyra Svenska Kvinnors Filmregi* (Brutus Östlings Förlag Symposium 2004); Joan Simon, *Alice Guy Blaché: Cinema Pioneer* (Yale University Press 2009).

37 Carol Rose, "Bargaining and Gender" 18 (1995) Harv JL & Pub Pol'y 547; Carol M Rose, "Women and Property: Gaining and Losing Ground" 78 (1992) 421.

38 Gösta Werner, *Rött, Vitt och Gult: Färgerna i Censurens Banér: Den Svenska Filmcensurens Bedömningar av Victor Sjöströms och Mauritz Stillers Filmer 1912-1936* (Statens Biografbyrå 2002) 95.

and children) since it included the rape of a woman, a child born outside of wedlock and a father who refused to take responsibility for his actions. However, the censors seemed unwilling to interfere with the work of Lagerlöf, recognizing her status and admitting some form of 'sanctity' in her intellectual work.[39]

Fig. 1. Caption: The poster from the film is illustrative of the predominant position Lagerlöf had as an 'author' of the film as such.

Lagerlöf's interface with censorship provides an interesting historical illustration of the power and impact of female authorship in the early film industry. Contemporary stories of authorship expressed in the interviews conducted by Tytti Soila reveal that while the Copyright Act of 1960 provided for a more solid legal basis concerning rights on film works, authorship, as exercised and experienced by women in the film industry has surprisingly been limited. These interviews had as a main focus the role of Mai Zetterling in the history of Swedish film. Zetterling's artistic work was admirable taking into consideration that Swedish film history could enumerate not more than three female film directors previous to her. In her interview, Stina Ekblad compares the creative space offered to Ingmar Bergman and to Mai Zetterling respectively and concludes that when Bergman used erotic scenes it was acceptable, while when a female director would do the same, it became less artistic and much more criticized.[40] According to Ekblad a female director, such as Zetterling, had to be so much more in order to establish a career in the film industry, and at some point, this "much more" became "too much". Gunnel Lindblom discussed the film *Flickorna* (1968), which she considers to this day to be a very important and powerful film raising issues of women empowerment, but that met the criticism of the male audience, as well as of the women's rights organizations, most probably due to its female director.[41]

Director Marianne Ahrne provides that although she thinks that many of the commercially successful films made by male directors could have been made by women, women are in general more interested in preserving the integrity of their authorship. Women have a story they want to tell in their films.[42] This is also, according to Ahrne, the reason why most women make documentary films in Sweden, because in the production of those, the director has much more creative space and a much more active authorship. Equally characteristic is what she says about her films, among which she is able to see a distinction. Some of them, being her "works", "works on life and death", these seem to be the results of difficult and painful process, and as she herself says, "works made after taking a big risk".[43]

In her book *Ravinen,* film director Lisa Ohlin describes in diary form her work with the production of the film *Walk with me*.[44] In the detailed description of the working process with the specific film, Ohlin writes about her process of becoming a director, her love for film, and the difficulties she has encountered in her career due to the fact that she is a woman. Her creative freedom is limited by producers but also by photographers and other members of the production team that would normally be expected to execute her requests. The book describes all the turns that the lengthy production has taken, changes in the budget, changes in the cast as well as in the directions given by producers and distributors that have clear view on what is needed in order for the film to become a success. All these comments and creative "contributions", gradually limit Ohlin's creative activity to the minimum.

The content of the book is not revolutionary as such and the difficulties faced during the production of the specific film are not unique. It is however very interesting because it exposes to the broader public, an industry-internal truth, namely the vital importance of being asked to make films, to become an author, that forces

39 Gösta Werner, *Rött, Vitt och Gult: Färgerna i Censurens Banér: Den Svenska Filmcensurens Bedömningar av Victor Sjöströms och Mauritz Stillers Filmer 1912-1936* (Statens Biografbyrå 2002) 82; Anna Nordlund, "Selma Lagerlöf in the Golden Age of Swedish Silent Cinema" in Helena Försås-Scott, Lisbeth Stenberg and Bjarne Thorup Thomsen (eds), *Re-mapping Lagerlöf* (Nordic Academic Press 2014); Tytti Soila, "The Phantom Carriage and the Concept of Melodrama" in Helena Försås-Scott, Lisbeth Stenberg and Bjarne Thorup Thomsen (eds), *Re-mapping Lagerlöf* (Nordic Academic Press 2014).

40 Tytti Soila and Maaret Koskinen, Interview with Stina Ekblad (25 October 2008).

41 Tytti Soila, Interview with Gunnel Lindblom (26 April 2011).

42 Tytti Soila, *Att Synliggöra det Dolda: Om Fyra Svenska Kvinnors Filmregi* (Brutus Östlings Förlag Symposium 2004) 35-36.

43 Ibid. 36.

44 Lisa Ohlin, *Ravinen* (Type & Tell 2018).

directors to remain silent, to avoid conflicts with someone that potentially can in the present or in the future, influence their chances to future projects. A film director does not want to be considered difficult and picky, and thus accepts comments on the script, the scenery, the lighting even the way the film is to be directed by producers, distributors and other financers such that should not have a decisive impact on the creative work of the film. While the scope of creativity that Ohlin as a director was able to exercise was extremely limited, she was the one held solely accountable for the commercial failure of the film. Thus, authorship that should be twofold, i.e. originating in the expression of the personality of the author, and at the same expressing the origin of the creative work, has in this case constituted solely a grounds for accountability. While Ohlin had to accept and execute the directives of others, the result of the intellectual creation, the film was her responsibility. Ohlin is clear on the difficulties she had had to deal with during her career due to her sex. Everything from comments from male colleagues on her private and professional choices, the unwillingness of photographers to execute her orders, questioning her ability to direct, the sexual violence she was exposed to by a producer, and the defiance she had to deal with from the press when she chose to make a film about men (questioning what made her do a film about men, and whether she thought she was able to). It becomes obvious that the hurdles faced by authors in the film industry due to the particularities of the industry and economic restraints are accentuated when the author is a woman.

Apart from the economic restraints and the way producers restrict creativity and thus also indirectly authorship, there is another perspective of importance, inherent to film productions, that is their collective and collaborative nature. The film as a creative work, cannot potentially be attributed to the contribution of only one author (the director), there are several contributions that could be decisive for the final character of the film as such.

These contemporary voices make it clear, authorship of women in the film industry is framed and constrained. Whether it is budget limitations (women make films with lower budgets in general), or the difficulties in taking the lead of the production team, or finally the constraints posed by distributors, women are not able to create freely. Their authorship is thus consequently limited, and its exercise timid.

DOES AUTHORSHIP MATTER?

In conclusion, the cases presented here show that women's presence within the Swedish film industry has been tangible and even belligerent from very early on. They have been visible through concrete debates on issues of authorship and copyright, making a stand, claiming their rights.

The case of Selma Lagerlöf shows that for a woman, being successful in the debate concerning author/auteurship, a considerable amount of cultural capital has been necessary. Lagerlöf was an internationally acknowledged, Nobel prize winning author and member of the Swedish Academy. However, she clearly was a path breaker, and this study also shows that during the past decades the amount, awareness and self-confidence of women within the (Swedish) film industry has increased exceedingly.

One needs to address one important question in this respect, namely, is the gender of the author important when investigating power, presence and portrayal in film? And if so, why and to what extent? In fact, a decisive issue when discussing power, presence and portrayal, precedes any discussion of authorship, namely the possibility to be given the chance to make a film in whatever position that may be. This possibility of actually being part of the creative process of making a film, is what makes a woman, an author. If you are excluded from film productions, then authorship is a very theoretical exercise. It seems however that even at times when women were still questioned with regards to their intellectual capacity, the exercise of their fundamental rights and their right to a legal personality, a number of "she" geniuses emerged and occupied central positions in the film industry.

Today, authorship is framed by the strict constraints of the reality in which film productions take place, namely the very few opportunities directors have to make a film, the strict budgets, the extensive role and impact of other stakeholders such as producers and distributors. The competition in the creative space of the author is high, the stakes are high, and thus the sanctity of aesthetics, creativity and intellectual investment of the author (whoever that may be, the screen writer, the director, the producer, the author of the original book etc), will if needed be sacrificed to protect the commercial viability of the film or its broader distribution. Such a limited approach to authorship, means also that women directors, produc-

ers, authors in general are deprived of the power to choose what stories to tell, how to tell them, what to portray and for whom. It means in the end that their power to control the result of their work is limited. All the compromises they are willing to make, will without a doubt have an impact on the scope of their authorship. In this respect, it seems that these constraints are general and irrespective of gender.

Hence the sex of the author is vital. It is vital since the film industry is *de facto* an industry where women are still to this day underrepresented, it is vital because according to statistics women get to do films with lower budgets, it is also vital since women, the "she" geniuses, have very often to deal with bigger hurdles in their exercise of authorship, exercising authority in the production team, or negotiating with the production company (reference to relevant part of the book). It is also of central importance, since authorship has formed film politics and in particular gender politics and goals of the Swedish Film Institute. A lack of understanding of what authorship in film entails, what rights it includes, and to what extent these are framed by other objectives, such as budgets, corporate

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Lydia Lundstedt, *Cross-Border Trade Secret Disputes in the European Union: Jurisdiction and Applicable Law*, Elgar Monographs in Private International Law (Edward Elgar Publishing October 2023) ISBN: 978 1 03531 510 9 Extent: 334 pp

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BIOGRAPHY

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In today's knowledge-based and data-driven economy, information is a company's most valuable asset. The most common form of legal protection for information are laws that protect trade secrets. In contrast to patents, copyright, and trademarks, whose importance for protecting intangible assets is well-recognised, trade secret protection has often come in their shadow as the less important form of protection. The importance of legal protection for trade secrets is however gaining acceptance and many Member States of the European Union (EU) have sharpened their laws on trade secret protection. In determining the form and level of trade secret protection, States consider (often constitutional) rules on the freedom of information, the freedom to compete and operate a business, employee mobility, and privacy. Depending on the social, political, and economic environment of the State, the form and level of protection may vary considerably.

To ensure a 'sufficient and consistent level' of protection under the laws of all the Member States, the EU enacted Directive 2016/943 on the Protection of Undisclosed Know-how and Business Information (Trade Secrets) against their Unlawful Acquisition, Use and Disclosure. The Directive is in the form of a minimum directive, so Member States may provide for more far-reaching protection. Complicating matters is the fact that trade secret protection is a bit of a 'strange bird', which is reflected in

the diverging doctrinal bases for trade secret protection. This divergence continues even after the implementation of the Trade Secret Directive, where some Member States continue to provide protection under unfair competition law, others have introduced a sui generis form of protection, and one Member State protects trade secrets as an intellectual property (IP) right. In addition, all Member States continue to protect trade secrets under contract law, and under the legal systems of some Member States, a trade secret holder may raise concurrent claims based on contractual and non-contractual grounds.

Trade secret protection is even more diverse on the international level. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) guarantees only a minimum level of protection for 'undisclosed information' and leaves a wide margin of discretion with respect to how Members can afford protection. The inclusion of trade secret protection in a treaty on intellectual property adds to the confusion about the correct classification of trade secrets.

With the ease of digital communications, employee migration, and international trade, trade secret violations can easily have a cross-border, and even a global dimension. Unlike physical assets, information can move at the speed of light and become ubiquitous instantaneously. In this respect, trade secrets are like (traditional) IP rights in that trade secrets and IP rights consist of commercially valuable information that are often exploited over national borders in order to take full advantage of their economic potential. In another respect, however, trade secrets differ from IP rights, which pursuant to the territoriality principle, may be in the public domain in some States without affecting their protection in others. This is not the case for trade secret protection because if the information becomes freely accessible, it will no longer fulfil the criterium of secrecy that is required for its continued protection.

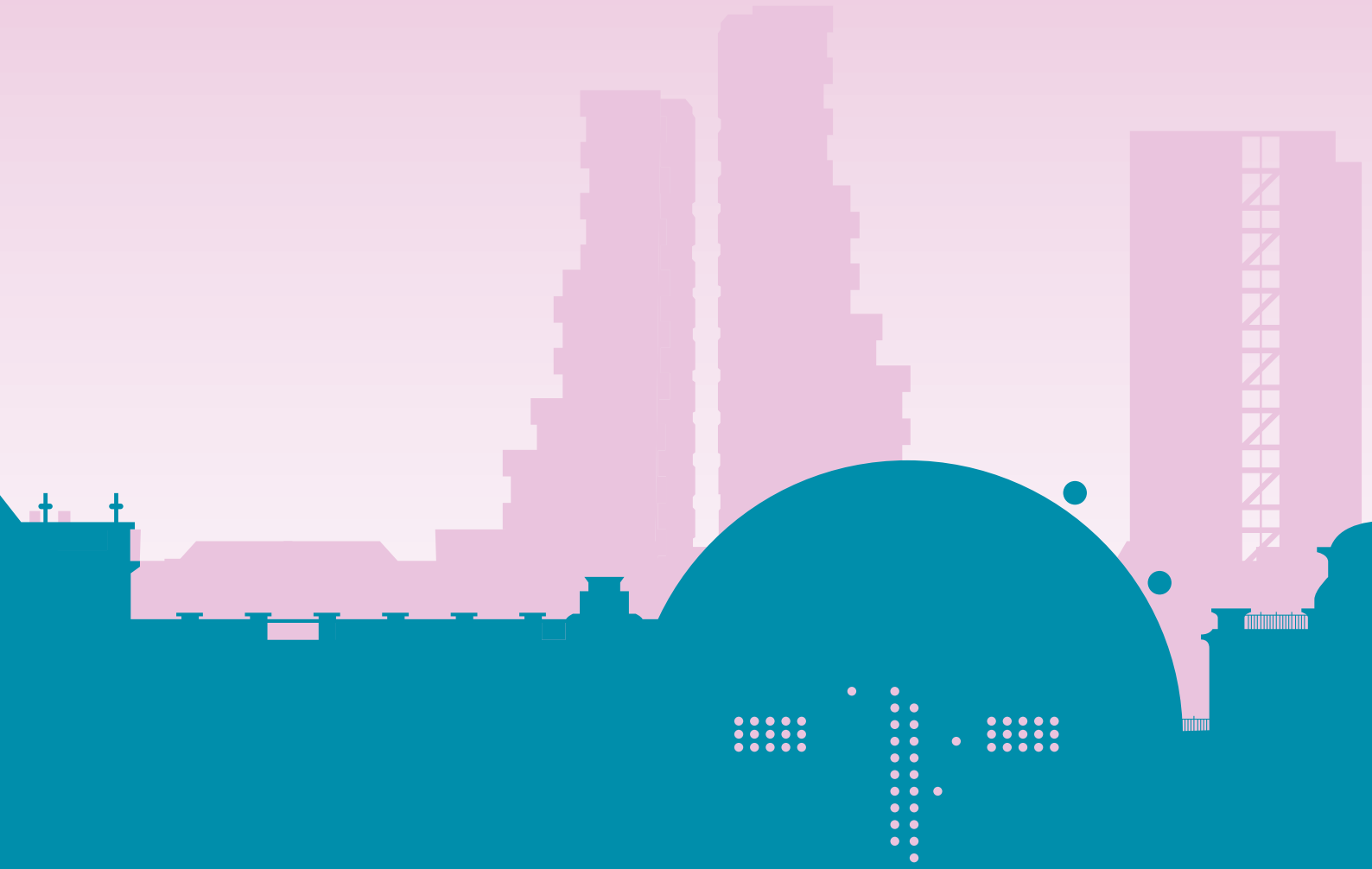
Within the EU, one would expect that the environment would be conducive for the litigation of cross-border trade secret disputes because the rules on private international law are harmonised at the EU level. Despite this, cross-border litigation and enforcement of trade secrets is considered to be extremely difficult and is also rare. This may be due to the varying doctrinal bases for trade secret protection and the fact that trade secret violations can take place in contractual and non-contractual contexts. Moreover, if the trader secret holder brings proceedings against a former employee, weaker party rules will affect the choice of forum and applicable law. Another complicating factor is that in some cases, jurisdiction and the applicable law is based on the location of damage, which is difficult to localise as trade secrets are intangible and can be acquired, disclosed, and used everywhere. What is more, there may be a number of potential defendants located in different countries that allegedly violated the trade secrets, and it may be difficult to join them all in one proceeding and under one law.

The book investigates how the EU private international law rules can be interpreted to facilitate the objectives of the EU Trade Secret Directive when trade secrets are litigated and enforced over national borders. A basic assumption is that effective and consistent protection of trade secrets in cross-border situations is facilitated when the parties can resolve their dispute before one court that has jurisdiction over the entire dispute and under one law, resulting in a judgment capable of being enforced in all Member States. When analysing which Member States have jurisdiction and which law or laws are applicable as well as the scope of the jurisdiction and of the applicable law, the book considers the competing interests of the parties and the EU public interest in general.

The book is divided into two parts. Part I (chapters 1–4) provides the necessary factual, theoretical and substantive law background for the book. Following a brief introduction in chapter 1 which lays out the research questions and method, chapter 2 describes the most common factual scenarios involving civil law trade secret disputes, i.e., disputes with contractual parties, employees, and competitors, and the different justifications and doctrinal bases for trade secret protection. Chapter 3 investigates the public international law framework for the protection of trade secrets. It describes the international minimum standard of protection to which states must adhere and investigates whether this framework contains any guidance on how protection must be afforded in cross-border situations. Chapter 4 describes the substantive law on the protection of trade secrets under EU law. It describes the EU minimum standard of protection and investigates whether the Trade Secret Directive contains any guidance on how protection must be afforded in cross-border situations. It also provides a brief comparative outlook over trade secret protection in two non-EU legal systems.

Part II (chapters 5–10) focuses on the private international law aspects. Chapter 5 provides a theoretical background to the process of characterisation. Chapter 6 briefly describes the (albeit limited) international framework for the protection of trade secrets in private international law. Chapter 7 analyses the application of the EU rules on jurisdiction in relation to the three categories of defendants described in chapter 2. Chapter 8 analyses the application of the EU rules on choice of law in relation to the three categories of defendants. Chapter 9 analyses the application of overriding mandatory rules, public policy and non-excludable rules. Finally, Chapter 10 answers the research questions and provides some final conclusions.

The book fills a lacuna in the existing legal literature, which has mostly focused on the substantive law of trade secrets and ignored their treatment under private international law. The book offers an academic perspective on a complex area of law but takes a practical hands-on approach which makes the book accessible to academics and practitioners alike.



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