UiO : Det juridiske fakultet

Compulsory licenses in EU patent law

Candidate number: 219

Deadline: 1st June 2023

Total words: 38 221

Contents

1 Introduction

1.1 Thesis question and actuality

The topic of this thesis is how compulsory licenses can be used to address a public health concern in the EU. The thesis question is what safeguards EU member states must fulfill when they grant a compulsory license in order to increase access to medicines.

The COVID-19 pandemic highlighted some of the shortcomings of the patent system, as there was a lack of vaccines to cover global needs.[1] The pandemic triggered a discussion about compulsory licenses internationally: a mechanism where national authorities can authorize third parties to use a patented invention without the patent owner's consent. The discussion concerned the TRIPS agreement (Trade-related Aspects Intellectual Property Rights), which provides for minimum harmonization of substantive patent law in the legal systems of the WTO members – and thereby EU member states.

The law on patents and compulsory licenses is interesting from an EU-perspective, since the international agreement TRIPS is an integral part of the EU legal order. The thesis question raises two main categories of sub-questions: constitutional questions concerning the status of TRIPS as an EU legal act and questions concerning the material rules about compulsory licenses in EU patent law. The first category prompts a discussion on how the status of TRIPS as an EU legal act affects the member states' obligations under the agreement, and what the consequences for breaching TRIPS are. The thesis will also examine whether TRIPS confers rights upon individuals, so that patent owners can invoke their rights before the courts. The first category will set the framework for the material rules about compulsory licenses.

The second category of questions constitute the main analysis of the thesis, and discusses what safeguards member states must fulfill when they grant a compulsory license in order to increase access to medicines. This question concerns how TRIPS article 31 interacts with primary law, and whether the right to intellectual property in the Charter of Fundamental Rights of the European Union affects the level of protection provided to the patent owner.

Additionally, patent rights being *national rights* will be examined in the context of the internal market. Since patents amplify the existence of national borders, they constitute a barrier to the free movement of goods. The thesis will discuss how the territorial character of patent rights affects third parties with cross-border supply chains who wish to produce and sell patented medicines to EU member states.

[1] See for instance Foss-Solbrekk (2021).

Although the thesis concerns access to medicines, the analysis of TRIPS is of general character – and therefore relevant for other grounds for issuing a compulsory license.

1.2 Scope and clarifications

The thesis topic concerns national compulsory licenses to increase access to medicines, either to address a public health concern in one member state, or in several member states at once. The thesis will only concern itself with TRIPS as EU law and not the international agreement. This means TRIPS as an annex to Decision 94/800/EC which concluded the WTO-agreements on behalf of the Union.[2] Thus, the reference to "member states" in this thesis exclusively means EU member states. When I discuss third countries, this will be specified.

Firstly, compulsory licenses are only relevant if there is a shortage of medicines, and the patent owner is not able to cover the needs of member state. Otherwise, the free movement of goods will ensure that member states can procure medicines from where they are available. This thesis presupposes that there is an insufficient supply of medicines on the internal market. The topic of free movement of goods will not be actively discussed, but remains as a prerequisite for the discussion in the thesis.

When discussing access to medicines, the term "access" must be determined. The word itself can mean the "right or opportunity to use or look at something".[3] "Access" is not a legal term, but can be understood from a practical standpoint from the experience after the COVID-19 pandemic. Access to medicines can be understood as covering national needs during a public health concern, which also relies on factors such as timely access and low prices.[4] The term "medicines" will be used widely, where the purpose of the medicines must be to somehow address the public health concern in question. This includes vaccines and pharmaceutical products. All three terms will be used interchangeably.

On that note, a public health concern can either be local for a member state, or affect several member states at once. Furthermore, the notion of public health concerns can be interpreted widely or narrowly. The wide definition involves any health problems that the authorities and society label as a concern, including mental health problems and increased obesity among the population. This thesis will use a narrow definition, which only concerns somatic health conditions due to a bacteria or a virus. The concern must be of a certain degree of severity – either in

[2] Decision 94/800/EC: Council Decision of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994).

[3] Cambridge Dictionary (2023).

[4] Different reports highlight different definitions to access of medicines, see for instance WTO, WIPO and WHO (2021) p. 194–198. See also Hilty et al. (2021), Mermelstein and Stevens (2021), and Sariola (2021).

the gravity of the disease or be wide-spread. Furthermore, the thesis will also discuss the prevention of a disease before an anticipated outbreak.

The international debate about access to medicines during the COVID-19 pandemic concerned the ability of low- middle-income countries to procure vaccines. There are numerous articles and works on how medicines can reach developing countries. Thus, I find it more sensible to discuss how national compulsory licenses interact with the internal market of the EU, in a purely EU-context. That does not mean that a national compulsory license in the EU only has local benefits. A license will increase the overall production capacity – thereby indirectly facilitating for increased global access to the specific type of medicines.

The Commission has proposed a regulation which allows it to grant an EU-wide compulsory license during a Union emergency.[5] The proposal came less than a month before the deadline of this thesis. I have therefore not been able to adjust the thesis to thoroughly discuss the proposal, but have shortly commented on it where relevant. In addition, I have included a concluding chapter where I shortly discuss the proposal. Regardless of the proposal, the main analysis in this thesis is about TRIPS article 31, which has an independent value. This is because the Commission Proposal also must comply with TRIPS and the right to property.

1.3 Methodology

The thesis will analyze the rules on Union competence in the Treaties, Charter of Fundamental Rights (CFR), and comment on Regulation (EC) No 816/2006 about export of medicines. Thus, I will be applying dogmatic EU law methodology. The methodology for interpreting TRIPS will be commented in chapter 3.4.2. For a general overview of methodology in EU law, please find other literature.[6] This chapter will present the legal sources and challenges relevant for this thesis, whilst the importance of a legal source will also be commented during the substantive interpretation of the law.

The CJEU is the authoritative interpreter of EU law,[7] and EU provisions must be interpreted uniformly and independently from national law.[8] The CJEU has consistently held that:

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[5] COM(2023) 224 final.

[6] Arnesen et al. (2022); Fredriksen and Mathisen (2022).

[7] C-741/19 para. 45–46. See TFEU Article 267 about preliminary ruling from the CJEU. The provision states that the Court "shall have jurisdiction to give preliminary rulings concerning" the interpretation of the Treaties and the acts of the institutions of the Union. The provision makes it clear that if a case is pending before a court with no judicial remedy, the national court *must* request a preliminary ruling by the CJEU, see Article 267 (3). The obligation for last instance courts to request a preliminary ruling highlights that the CJEU has the last word in interpreting and clarifying EU law. See also Hanson (2016) p. 321.

[8] C-34/10 para. 24. This rule applies when a provision does not refer to the law of member states.

> "As regards the interpretation of a provision of EU law, it is necessary to consider, in accordance with the settled case-law of the Court, not only its *wording* but also its *context* and the *objectives of the legislation* of which it forms part, while the origins of the provision may also provide information relevant to its interpretation".[9] (My emphasis.)

Chapter 3 will provide an analysis of the notion of competence, and the constitutional status of TRIPS in the EU. The notion of competence is provided for in TFEU and TEU,[10] and therefore requires Treaty interpretation. The Treaty provisions will be interpreted in line with the general methodology as cited above. In terms of the context, the entire provision read together provides context to a condition, as well as other relevant provisions. Since the rules on competence codify and originate from case law, the CJEU has relied on this case law to interpret the relevant Treaty provisions.[11] I will therefore refer to the historic case law concerning EU competence. The historical development of certain provisions will also be relied on as a supporting argument.[12]

The opinion of the General Advocate will also be referred to in the chapter about competence. The opinion is not formally a part of the judgement but provides a thorough understanding of the case. The opinion can help in understanding the complexity and nuances of the judgement, and will be used a supporting argument to the overall interpretation.[13] Where the Court has decided the case contrary the opinion, it can nevertheless help in understanding how the judgement ought not to be understood.[14]

Chapter 4 concerns the interpretation of CFR, which is also primary law.[15] Article 52 in the CFR lays down the specific rules for interpreting the human rights provisions. According to CFR Article 52 (3), provisions that correspond to rights under the European Convention on Human Rights (ECHR), shall have the same meaning and scope as those rights. Secondly, the explanations to the Charter ("Explanations") must also be given due regard when interpreting the CFR.[16]

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[9] C-3/21 para. 24 with the cited case law.

[10] The Treaties are primary law.

[11] For instance Opinion 3/15. See also Craig and de Búrca (2020) p. 109–110.

[12] See for instance C- 614/20 para. 57–67.

[13] Fredriksen and Mathisen (2022) p. 355.

[14] Arnesen et al. (2022) p. 58.

[15] TEU article 6 (1).

[16] Article 52 (7). The explanations are meant as a guidance for interpreting each provision of CFR.

ECHR will be interpreted and relied on in the thesis, either by itself or in conjunction with CFR. The interpretation of ECHR is mainly done in line with VCLT Articles 31 and 32.[17] According to VCLT Article 31 (1), "[a] treaty shall be interpreted in good faith in accordance with the *ordinary meaning to be given to the terms* of the treaty in their *context* and in the light of its *object and purpose*" (my emphasis). I will use case law by the European Court of Human Rights (ECtHR), since it is an important and decisive source for interpretation.[18]

The thesis generally requires an extensive analysis of case-law from the CJEU and sometimes the General Court. The case law of the Court is an important, sometimes decisive, factor during the interpretative phase. Although the CJEU is not formally a court of precedent, both the CJEU and the General Court frequently refer to case law.[19] Some of the rules that will be discussed are developed in case law, and cannot be found in the Treaties. This is the case of the rule on primacy of EU law over national law, and direct effect. In such cases, the case law is the main source of the law. The working language of the Court is French, whilst the language of the referring court in preliminary proceeding is considered to be the authentic version.[20] This thesis will mainly use the English translation of the judgements.

The thesis will also interpret secondary legislation such as the Exports Regulation and legal acts concerning the Unitary Patent system. The interpretation will be supplied with the preambles of the legal acts, in order to highlight the objectives. Although they are not formally a part of the legal act, and therefore not binding, they have nevertheless been extensively relied on by the CJEU.[21] Furthermore, primary law also constitutes the context of the legal acts in a broad sense. Secondary law cannot conflict with primary law, due to the hierarchy of norms.[22] The Court has specifically held that when the wording of a provision in secondary law "is open to more than one interpretation, preference should be given *as far as possible* to the interpretation which renders the provision consistent with the Treaty" (my emphasis).[23] However, the interpretation cannot be contrary to the meaning of a provision. Furthermore, secondary law must

[17] The Vienna Convention on the Law of Treaties of 23rd of May 1969 (VCLT) is the main framework for concluding and interpreting treaties. Although it is not signed by all countries globally, the contents are considered as international customary law; Hollis (2020) p. 459. Elgesem (2021) p. 449.

[18] Elgesem (2021) p. 474.

[19] Finn Arnesen et al (2022) p. 55.

[20] Rules of procedure of the Court of Justice art. 41.

[21] C-554/13 para. 42 and Arnesen et al. (2022) p. 53.

[22] TFEU Articles 263, 267 and 288–290. See Arnesen et al. (2022) p. 51 and Craig and de Búrca (2020) p. 141–152.

[23] C-61/94 para. 52. Although the passage refers to the Treaties, the judgement can be understood as a reference to primary law in general.

also be interpreted harmoniously with international agreements of the Union.[24] I will refer to both CFR and TRIPS when interpreting secondary legislation.

Legal literature will be relied on and frequently referred to in the thesis. Legal literature is not a relevant factor when interpreting EU law, unlike in the Norwegian legal tradition. However, legal literature can provide useful information on the understanding of the law. Legal discussions and varying opinions about a provision, and the interpretation of it, can highlight the interpretative difficulties – which can fuel a discussion *de lege lata* and *de lege ferenda.*

1.4 Structure of the thesis paper

Chapter 2 will provide a general overview of substantive patent law, and explain the fragmented legal landscape in the EU. This chapter is meant as a short introduction to the patent system and explain the pursued aims. The rationale behind the patent system will also be used as an argument for understanding the objectives of TRIPS, which will be essential throughout the analysis of TRIPS article 31.

Chapter 3 will thoroughly discuss the constitutional status of TRIPS in the EU, and is dedicated considerable space in this thesis. This is because TRIPS in the EU has been a controversial and complicated topic in the legal order of the Union, and raises several questions as to how member states must comply with the agreement. One of these questions is the matter of competence to legislate. The chapter will therefore concern the constitutional aspect of the member states' obligations under TRIPS, and will set the framework for the substantive analysis of TRIPS in chapter 4.

Chapter 4 will concern the interpretation of TRIPS article 31, and therefore the safeguards governing the granting of a compulsory license by national authorities. The territorial aspect of compulsory licenses will be thoroughly discussed. Furthermore, the chapter will highlight the importance of the right to property in CFR, where the interpretation of TRIPS must be supplemented with primary law. Lastly, chapter 5 will provide concluding remarks and comment on the Commission Proposal, and shortly examine whether it can solve the challenges of the compulsory licensing scheme in the EU.

[24] C-61/94 para. 52. This is also due to the hierarchy of norms, where international agreements concluded by the Union prevail over secondary law.

2 Short introduction to the patent system

2.1 The rationale behind the patent system

The thesis question requires an analysis of compulsory licenses to increase access to medicines in EU patent law. Before doing so, a short introduction to the patent system is necessary. This chapter does not aim to thoroughly explain the ins and outs of the patent law, but simply provide a general overview.[25]

Patents rights confer upon its inventor a time-limited exclusive right to use the invention himself. Patents are mainly national rights, since they are mostly granted by the government within its territory.

Patent rights are also termed as an intellectual property right (IPRs, or just IP). IPRs is an umbrella term used for non-material objects which can give rise to an exclusive right for its creator or right holder. Non-material objects include inventions, music, designs and literal works. Amongst the different types of IPRs, the patent system only concerns itself with technical inventions with industrial application. The common feature of non-material objects is that they concern creations resulting from a personal effort. What makes these "objects" non-material is their contents, not their exterior form. For instance, it is not the specific coffee machine in your kitchen, but the technicality and the specific composition that is subject to legal protection. Thus, intellectual property transcends its physical form, where the non-material object remains in every copy of the invention.[26]

The rationale behind the patent system can be explained through several theories, but the most prevalent ones are from a natural law and social economics perspective. The natural law perspective provides that the person who has made an effort in making a new invention, should be rewarded for this effort.[27] In this regard, the philosopher John Locke held that knowledge is property, and must be given the same status as any physical property. Since inventions are a product of knowledge, they must be confer a "property right" to the inventor – albeit the preciseness of placing "knowledge" within the logic of traditional property law can be discussed.

[25] This entire chapter is based on the following works: Stenvik (2021), Schovsbo et al. (2018), Correa (2020), Pila and Torremans (2016), Terrell (2020), and Chisum et al. (1998). Since the aim of this chapter is to provide a general overview of material patent law, I will not refer specifically to these works unless I have used certain phrases or points from any of the books.

[26] Schovsbo et al. (2018) p. 30.

[27] The CJEU has also referred to the exclusive right as a reward for the creative effort of the patent owner, albeit while balancing the exclusive right with the free movement of goods. See C-15/74 para. 9 and C-187/80 para. 10.

The social economics perspective is the most practical and widely accepted theory behind the patent system. Economic theory provides that knowledge is a social good, which should benefit the entire society. From this starting point, all members of society should be able to freely use new knowledge and inventions. However, making new inventions can be incredibly time-consuming and expensive. If everyone could use and copy the invention without rewarding the inventor, then very few would be motivated to invest in new technology. By this, fewer inventions would be introduced to society, causing a stagnation in technological and industrial development. Thus, the patent system attempts to solve this potential problem, by conferring an exclusive right to the inventor – in which the inventor is granted a monopoly status for the exploitation of the invention.

Since knowledge in principle is a social good, the patent system must have a legal basis and be limited in scope. I assume that all EU countries have a legal basis for their patent system.[28] The inventor's exclusive right is time-limited, usually 20 years. The exclusive right makes it possible for the inventor to use and commercialize his invention, and recoup the investments made during the developing stage. Thus, the patent system makes it lucrative to invent, and creates an incentive for continuous innovation.[29] It is also meant to boost competition in a market economy, where competitors within a specific market race to introduce new and better inventions, in an effort to attract customers. Although there are international debates on the practicality of the patent system, the purpose of the patent system remains as explained.[30]

As a preliminary point, some important terms in patent law must be clarified. The registered invention is called the patented invention, or shortly just "patent". The right holder is dubbed as the patent owner, while the term patent right refers to the exclusive right.[31]

The patent system has retained a strong and important function in western society, and has contributed to the continuous and rapid development of technology. For this reason, patent rights are widely respected, but the wide respect has also caused growing concerns. Before addressing these concerns in chapter 2.3, the next chapter will present how patent law is regulated in the EU.

[28] The specific requirements for the legal basis will be discussed in chapter 4.5.1.

[29] The economic theory involves several considerations, but the most important ones are the incentive to invest for persons, incentive to commercialize for investors, and the incentive to work around the patent for competitors: Stenvik (2020) p. 24–26.

[30] Report from WTO (2020) p. 68.

[31] Schovsbo et al. (2018) p. 29.

2.2 Fragmentation in the legal landscape of EU patent law

The EU has only partially harmonized the rules on patents, causing a fragmentation in the legal landscape due to national variations. The European instruments within the field of patent law has either aimed for minimum harmonization of national law, or provided secondary legislation about specific topics such as biotechnology. In addition, some material harmonization has been achieved by European Patent Convention (EPC) – which is a non-EU instrument. Therefore, the law on patents remains national in the EU member state – which is an essential point in this thesis. Moreover, the Unitary Patent system creates an additional layer to the fragmented landscape, since the system is not meant to replace national patents. All of these instruments will be explained in this chapter.

TRIPS and EPC concern material patent law. Material patent law encompasses rules on patentability and effects from a granted patent right to the patent owner. The main legal instrument is TRIPS (Agreement on Trade-related Aspects of Intellectual Property Rights), which is an annex to the WTO-agreement. The EU is a party to the agreement, making it an integral part of the EU legal order.[32] TRIPS aims for minimum harmonization of national IP law in the WTO member states. It does not provide for the possibility to register a patent in the WTO, but obliges WTO members to protect IPRs in their national systems. Thus, the registering and protection of patents must be done nationally. An important feature of TRIPS is that WTO members are generally free to provide more extensive protection of IP, causing a diversity in national IP law. Furthermore, the provisions of TRIPS are broadly and vaguely worded, which gives member states further flexibility in how to implement the agreement.

The European Patent Convention (EPC) provides harmonized rules on the patentability of European Patents. Although the EU is not a party to the agreement, all of the EU member states are. Thus, the importance of EPC among the member states is inevitable. Both of these instruments will be referred to in chapter 2.3 about material patent law. European Patents are in fact bundle patents, which means that one single application makes it possible to register the patent in several countries at once. The granted patent will have national protection limited to the territory of each country.[33] European Patent Office (EPO) is the official body responsible for examining and granting European Patents.

In addition to TRIPS and EPC, another significant legal instrument for patent protection in the European Union is the "Unitary Patent", which is expected to launch at June 1st 2023.[34] This

[32] TFEU Article 216 (2). This will be addressed in chapter 3.2.

[33] EPC Article 2 (2). See Pila and Torremans (2016) p. 118, and EPO European Patent (2023).

[34] European Commission (2023).

system does not aim to harmonize material patent law, but rather creates an additional system for patent protection in 25 of the EU member states. The difference between European patents and the Unitary Patent system is that the latter encompasses uniform *protection* of the patent right, whereas EPC only provides for a uniform procedure for *registering* patents.[35] Unitary patent protection entails the possibility to invoke patent infringement before the Unitary Patent Court, instead of starting litigations in several member states.[36]

Both TRIPS and EPC presupposes that national legislation grants an exclusive right to the patent owner when the patent is registered. However, only national authorities can grant a compulsory license, even under the Unitary Patent system. Thus, the national dimension of patent law becomes even more prevalent when dealing with compulsory licenses.

The law on compulsory licenses is also only partially harmonized in the EU. TRIPS Article 31 provides a list of safeguards that member states must respect if they issue a compulsory license, but as mentioned, member states can provide better protection of patent rights in national law. Additionally, it is voluntary for member states to have a compulsory licensing scheme in their national systems. Alongside the TRIPS agreement, the EU has harmonized the rules on compulsory licenses for the purpose of exporting medicines to developing countries in Regulation (EC) no. 816/2006 ("Exports Regulation"). This regulation is based on TRIPS Article 31bis, which is an exception to the main rule about national supply under a compulsory license. Both Article 31bis and the Exports Regulation (hereby export-mechanism) concern export of medicines to developing countries, and therefore fall outside the scope of this thesis. I will nonetheless refer to the legislations in chapter 4 when relevant.

The national variations in compulsory licensing schemes are the reasons why the Commission has proposed its regulation: to enhance efficiency during a Union-wide crisis.[37] However, the Proposal is limited in its scope, which will be discussed in chapter 5.

2.3 Patentability and legal effects of a patent

This chapter will discuss the main rules about patentability and the legal effects from the granting of a patent, with reference to both TRIPS and EPC. The rules on patentability provides an insight in the objectives of patent law, as the conditions makes it clear that there is a balance between the incentive for innovation on one side, with the need of keeping inventions free to use for society on the other side. The ambit of the exclusive right must also be established, in order to provide a correct analysis of how compulsory licenses limit patent rights.

[35] EPO FAQ (2023).

[36] For a simple overview of the Unitary Patent system, see EPO FAQ (2023).

[37] Commission Proposal p. 2.

There are certain conditions that must be fulfilled to patent an invention. According to TRIPS Article 27 (1) and EPC Article 52, patents shall be granted for any inventions in all fields of technology. The first precondition for registering a patent is that it concerns "inventions". The term "invention" is a legal concept: the characteristic does not rely on whether the inventor himself regards his discovery as an invention. Neither TRIPS nor EPC define what an invention is. However, EPC Article 52 (2) provides a list of activities and subject matters that are *not* considered as "inventions", such as mathematical methods and aesthetic creations. Although the provision only seems to provide a negative definition of what an "invention" is, it is nonetheless possible to say some words about the concept. According to established case law by EPO, the subject matter must have technical character in order to be categorized as an invention.[38] Inventions can overall be divided into products and processes.[39] In terms of pharmaceuticals, a vaccine can for instance be patented as product patent, whilst a manufacturing process for a medical pill can be registered as a process patent.

Not all inventions can be patented. According to TRIPS Article 27 (1) and EPC Article 52 (1), inventions must be new, involve an inventive step and be susceptible to industrial application. Additionally, EPC Article 53 provides a list of inventions which cannot be patented. These include for instance methods for surgical treatment and diagnostic methods.[40]

The criteria of newness or novelty means that the invention does not "form part of the state of art".[41] The state of art is defined in EPC Article 54 (2) and includes everything made available to the public. Thus, an invention must be kept secret upon registration: Otherwise, it is not possible to know whether the invention in fact is a new contribution of knowledge to society, or if someone wishes to monopolize an already existing invention.

EPC Article 56 provides that an invention represents an inventive step if it is not obvious to a person skilled in the art. This means that the skilled person must not be able to make the invention himself, based on elements that are already available and known in the state of art. [42] The conditions of novelty and inventive step overlap, but the latter involves a broader assessment

[38] Case G 0001/19 *Pedestrian simulation* para. 75. See also Pila and Torremans (2016) p. 173.

[39] TRIPS Article 27 (1).

[40] TRIPS Article 27 (3) makes it voluntary for member states to exclude certain inventions from patentability, including methods for treatment. EPC takes a step further: the list of patents in Article 53 cannot be patented under a European patent.

[41] EPC Article 54 (1).

[42] Chisum et al. (1998) p. 530.

that includes single elements of the invention that are individually available in the public.[43] Both the conditions about novelty and inventive step secures that not any invention can be patented. This way, knowledge stays available and free to use for society as a main rule.

A patent is granted when all the conditions are fulfilled and involves an important legal effect; the patent confers upon its owner an exclusive right to the invention, which can be described as a *negative* right. TRIPS Article 28 (1) entails what the exclusive right amounts to. If the patented invention is a product, then the patent owner can prevent third parties from the following acts: "making, using, offering for sale, selling, or importing for these purposes that product".[44] If the patented subject matter is a process, then the patent owner can prevent third parties from using the process.[45] In addition, the provision also provides for what is normally called *indirect product protection*.[46] The patent owner can prohibit third parties from the same actions concerning product patents, when these actions concern products directly obtained by the patented process. This thesis will use the term "patented product" and "medicines" for both product patents and indirect product protection, and discuss medicines as a final product.

The negative right entails two functions: freedom of contract and right to effective enforcement of the patent right.[47] The CJEU has explained the freedom of contract as a "right to determine freely the conditions under which he markets his products".[48] This means that the inventor can choose whom he wishes to engage in a contractual relationship with, and impose conditions for use of the invention.[49] The second function concerns the right to enforcement, where the inventor can take legal steps to prohibit third parties from using the invention without their consent. An important feature of the negative right is that the patent owner is solely responsible for securing his interests: national authorities do not supervise or investigate whether third parties are acting in conformity with patent rights. If the patent owner takes no actions after finding out that a third party is using the invention without his consent, the third party will be factually able to continue to use the invention. Given the "property" status of IP, it is a logical approach that patent infringement must be invoked by the right holder before the judicial system.

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[43] Ibid.

[44] Article 28 (1) (a).

[45] Article 28 (1) (b).

[46] Stenvik (2020) p. 310.

[47] This understanding is based on TRIPS Article 28 and Article 41 (1). See also C-15/74 para. 9 and C-170/13 para. 57 and 58. The latter case explains the main features of intellectual property in accordance with CFR Article 17 (2). The right to property in CFR will be discussed in chapter 4.

[48] C-19/84. This judgement concerns exhaustion of patent rights in case of a compulsory license, and will be discussed in chapter 4.4.1. Although the passage makes no direct reference to the freedom of contract, the contents express that there indeed is a right for the patent owner to control the use and placing on the market of his products.

[49] TRIPS Article 28 (2); *SIA AKKA/LAA v. Latvia*, which will be discussed in chapter 4.3.3; Correa (2020) p. 293.

Since knowledge essentially is a common good, the exclusive right is *exhausted* after the first placing of products on the market.[50] This means that that the patent owner cannot prohibit third parties from any actions that would normally infringe the patent, if the patent owner voluntarily has placed the products on the market. In the EU, the market includes the entire internal market, and will be explained in chapter 4.4.1. Although the rule is meant to limit the extent of the patent right, the CJEU has also stated that the patent owner has a *reserved right* to first placing on the market.[51] This understanding is closely connected to the economic theory behind the patent system, where the patent owner must be able to recoup his investments, while also rewarding his creative effort. The limit of first placing on the market can therefore be understood as having two roles: to limit the exclusive right, and to secure the economic benefits for the patent owner up to a certain point in the supply chain.

As previously mentioned, patent rights in the EU are national. This is due to patents being *territorial*. Patent law operates with the principle of territoriality,[52] which can also be understood as a rule and an inherent feature of the patent system: inventions must be registered in the specific country where protection is sought, and the exclusive right is limited to the territory of the authority who granted the patent.[53] This is because patents and IPRs can be understood as "privileges granted by the government". Governments or authorities can only give rights with legal effects within their territory, and is therefore a matter of sovereignty of states.[54] Thus, anyone is free to use the invention in a country where the patent is not registered. The significance of the principle of territoriality will be highlighted in chapter 4.

With all the benefits that comes with the patent system, it has its downsides as well. The monopoly status granted to the patent owner can raise concerns in a market with free competition; the patent owner can control the quantity to be placed on the market according to yielded profit. If the demand is high, then the patent owner can raise the prices to match what consumers are willing to pay. In a perfect competition, consumers would pay less for more quantity.[55] The high prices cause social concerns both in the EU and on a global level, especially with pharmaceutical products.

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[50] Stenvik (2020) p. 323–326.

[51] C-15/74 para. 9, C-187/80 para. 9, and C-19/84 para 26. The patent owner is not obligated to commercialize his patents, but this can vary depending on national law.

[52] I will not discuss whether it constitutes a general principle in EU law, or the significance of the characterization as a "principle", see Graver (2006).

[53] See for instance Dreier (2017) p. 8 and Lundstedt (2001) p. 1.

[54] Pila and Torremans (2016) p. 29.

[55] Chisum et al. (1998) p. 56–57; Eide and Stavang (2018) p. 92. The characterization of patent rights as monopolies can be contested, see the cited pages in Chisum.

Pharmaceutical companies do not find it lucrative to increase production in order to lower the prices. This is because increased production can decrease the overall profit for the patent owner.[56] During a public health crisis, the patent system may lead to a shortage of medicines if the medicines are patented. This problem became apparent during the COVID-19 pandemic, where countries raced to procure vaccine doses. This is where compulsory licensing or government-use comes in. Compulsory licenses can increase production capacity by allowing a third party to produce patented medicines. Although the compulsory licensing scheme might not solve all social problems surrounding patent rights, it can contribute by minimizing the impact of such concerns.

Therefore, member states may grant a compulsory license to a third party to increase access to medicines to solve a public health concern. However, member states must comply with the safeguards in TRIPS when issuing a compulsory license. A breach of TRIPS obligations not only affects the protection of the specific patent owner, but also has consequences for the member state. This is a matter of how TRIPS must be understood in the EU legal order, and what obligations the member states assume under the agreement towards the Union.

3 Understanding TRIPS within the European Union

3.1 Introduction

The EU, alongside its member states, has been a party to the WTO-agreement and its annexes since 1994. The status of TRIPS in the EU system has been, and still is, complicated to understand. The aim of this chapter is to highlight the main features of TRIPS in the EU *de lege lata*, without diving into the complicated case law pre-Lisbon.[57] As Advocate General Colomer stated in his opinion to case C-431/05:

> "[T]he case-law [is] copious. However, successive developments, far from offering a smooth passage, have constructed a long and winding path, whose complex route demands certain adjustments in order to help its confused users find their way."[58]

The focal point of this thesis is that TRIPS is a part of the Union's legal order, and the implementation of TRIPS by the member states is simply the implementation of EU law. When member states grant a compulsory license, they must comply with TRIPS Article 31 as EU law. TRIPS as an EU act raises several questions regarding the member state's room for action when

[56] Eide and Stavang (2018) p. 92.

[57] See for instance Dimopoulos (2008) p. 104–105.

[58] Para. 33.

granting a compulsory license, and whether they retain the right to legislate in this field. Additionally, TRIPS in the EU also raises questions regarding the interpretation of the agreement, in terms of what methodology must be used.

Chapter 3.2 will discuss whether the notion of "competence" in EU constitutional law limits the member states' room for action when legislating on and granting a compulsory license. The chapter will explore whether the coexistence of differing external and internal competences creates conflicting interests. In this case, the question is if the Union's external competence over TRIPS affects the internal competence in the field of patent law. Competence is also a decisive factor in whether the CJEU has jurisdiction to interpret TRIPS, which will be discussed in chapter 3.4.

Chapter 3.3 will explain the legal status of TRIPS in the EU. The discussion will seek to clarify whether TRIPS is binding on the member states by virtue of Union law, and if the Commission can raise an infringement procedure towards a member state for breach of TRIPS. The chapter will also discuss if private parties can rely on TRIPS before national courts. This is a question of whether TRIPS has *direct effect* in the EU legal order. The question of supremacy will also be addressed, and whether national courts are obliged to set aside a national provision which conflicts with TRIPS Article 31.

Chapter 3.4 will seek to answer whether the CJEU has interpretative jurisdiction over TRIPS, and if that very interpretation is binding upon the member states. The CJEU's methodology for interpreting TRIPS will also be established. Lastly, chapter 3.5 will provide a short summary of the key findings.

3.2 The notion of competence

3.2.1 Introduction

TRIPS was originally concluded as a "mixed agreement",[59] since the Union only had exclusive competence to conclude a binding agreement within the field of trade – which did not include intellectual property (hereafter just patent law).[60] After the Lisbon Treaty entered into force in 2009, the Union was given exclusive external competence concerning "commercial aspects of intellectual property" in TFEU article 207 – which includes TRIPS. The question remains how the shift of competence affects the internal competence of member states, and whether member states retain their freedom of legislating on patent law as they have so far. As will be observed in chapter 4, the compulsory licensing regime is not as effective and practical to increase access

[59] International agreement where both the Union and its member state are parties on one side, with third parties on the other side, see Klamert (2014) p. 183–184 and Maresceau (2010) p. 12.

[60] Opinion 1/94.

to medicines in the EU. If the member states no longer can legislate on patent law, then only the Union may provide for new legislation about compulsory licenses. In that sense, the very notion of "Union competence" must be clarified in order to answer these questions.

3.2.2 General overview

The word "competence" is not explicitly defined in the Treaties, but the context of the different Articles gives the reader a certain idea about the notion. Simply defined, "competence" can be understood as having the right to act and to perform certain tasks.[61] The notion of Union competence is an expression of the principle of conferral in TEU Article 5 (2).

In short, competence acts as both a qualifier and a limit for Union action. The notion of competence is nuanced and complicated, but Union competence can be divided into two main parts: one concerns the *extent* of the powers conferred, while the other scopes the *type* of Union action.

The *type* of Union competence entails how the Union may act. The type of Union action relies on whether it is *internal* within the EU, or *external* vis-à-vis third-party countries and entities. Internal competence entails the right to legislate and make policies within a certain area, such as customs union and monetary policy.[62] Thus, the internal competence concerns internal trade and matters within the EU. External competence encompasses the negotiation and conclusion of international agreements, and being responsible for the fulfillment of that agreement outside the Union.[63] Therefore, the external competence concerns international trade with non-member third parties. External powers can either be expressed in the Treaties, as in the case of Common Commercial Policy (CCP),[64] or implied on certain conditions according to TFEU Article 216 (1). CCP is interesting on this matter, as it also allows the Union to adopt regulations to implement the policy through an ordinary legislative procedure.[65]

The *extent* of Union competence, both internal and external, is divided in three categories: exclusive, shared with the member states, or as supporting action.[66] This chapter will not concern itself with supporting action, as it is not relevant in the case of TRIPS. If the competence is

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[61] TEU Article 5 and TFEU Articles 2–5 read in connection. This thesis will not distinguish between *competence* and *powers*, but use these expressions interchangeably; see Tridimas and Eeckhout (1994) p. 144.

[62] TFEU Article 2.

[63] TFEU Articles 205, 206, 207 and 216 (1); TEU article 3 (5); Koutrakos (2015) p. 9–10; Craig and de Búrca (2020) p. 354–355.

[64] See TFEU Articles 3, 206 and 207. The CCP is an equipment for the Union to facilitate world trade and protect its interest towards third-party countries. Article 207 entails the policy areas in CCP, and all of them are related to international trade.

[65] TFEU Article 207 (2) and (6); Craig and de Búrca (2020) p. 372.

[66] See TFEU Articles 4–6; Craig and de Búrca (2020) p. 104.

exclusive, only the Union retains the right to act, while shared competence means that both the Union and the member states can act on a certain matter. The areas where the Union has exclusive competence are listed in TFEU Article 3, whilst Article 4 clarifies when the competence is shared with the member states. Additionally, the exclusive competence can be divided in two categories: *a priori* and pre-emptive. *A priori* exclusiveness means that the exclusivity is explicitly provided for in the Treaties.[67] Pre-emptive exclusiveness is only relevant when the competence originally was shared. Pre-emption will be explained in the next chapter.

The internal and external competence can either be shared or exclusive. The different constellations are separate faculties at first glance: the external action only concerns itself with the conclusion and management of international agreements, whereas the internal action concerns making internal legislation. However, there is a connection between the internal and external competence, which is visible in the case of CCP. The external competence is said to be parallel with the internal: the so-called principle of *in foro interno in foro externo*.[68] Chapter 3.2.4 will investigate how these two types of Union competence affects the member states' ability to legislate on compulsory licenses. Before doing so, Union competence over patent law must be discussed in more detail.

3.2.3 Union competence over patent law

This chapter will give a very simplified overview of EU competence over patent law, and act as a background to the discussion in chapter 3.2.4. As a preliminary point, TRIPS was characterized by the perfectly mirrored parallelism between the internal and external competences from 1994 to 2009. This means that both the internal and external competence was shared – the *extent* of the competences was the same over patent law. Today, patent law remains under the shared internal competence, whereas TRIPS falls under the exclusive external competence under CCP.

Patent law is part of "the internal market" in TFEU Article 4 (2) (a), which is a shared internal competence.[69] This is because patent rights are mainly national, and in theory do not constitute a cross-border element. As was observed in chapter 2, patent rights have an economic value, and are therefore important for the member states. According to the principle of subsidiarity, "the Union shall act only if and in so far as the objectives of the proposed action cannot be

[67] Dashwood (2010) p. 356.

[68] Craig and de Búrca (2020) p. 362; Tridimas and Eeckhout (1994) p. 151–154. Tridimas and Eeckhout point out that the implied competence cannot constitute a basis for making a new external policy, similar to the CCP.

[69] See for instance TFEU Article 118, which explicitly confers a right for the Union to provide for an EU-level patent, "in the context of the establishment and functioning of the internal market".

sufficiently achieved by the Member States".[70] Thus, the member states retain the right to legislate on patent law as a general rule, whilst Union action is an exception.

It must be pointed out that when the Union legislates in accordance with the principle of subsidiarity, the member states can only legislate to the extent the Union has not exercised its competence.[71] This is called the pre-emption, where Union legislation blocks member state legislation under the shared competence: it can be said that the Union attains exclusive internal competence to the extent it has legislated on the field.[72] Union legislation has been scarce on the matter of patent law. For the sake of this thesis, it is sufficient to say that the member states in general retain the right to legislate on patent law and compulsory licenses.[73]

Also the external competence over TRIPS was shared with the member states pre-Lisbon, as observed in chapter 3.2.1. During the conclusion of the WTO-agreements in 1994, the Court decided that TRIPS did not fall under the CCP, since it was not sufficiently linked to trade.[74] The wording of CCP pre-Lisbon did not include intellectual property.[75] The Court specified that intellectual property "do not relate specifically to international trade; they affect internal trade just as much as, if not more than, international trade".[76] This is because part two of TRIPS harmonizes national IP law, in which the link to international trade is not as apparent. Furthermore, the Court also found that the Union did not have conditional exclusive competence to conclude the agreement under today's TFEU article 3 (2). Thus, TRIPS was concluded under shared competence between the Union and the member states: the competence was perfectly mirrored internally and externally. Practically, this meant that member states in principle could vote in the WTO regarding TRIPS, and were directly responsible for their compliance over the agreement vis-à-vis third countries.

However, the Lisbon Treaty expanded the scope of the CCP. TFEU Article 207, which specifies the relevant policy areas within the CCP, now includes "commercial aspects of intellectual property". In C-414/11 *Daiichi Sankyo*, the Court confirmed that the TRIPS agreement falls under the CCP. Therefore, the Union has *a priori* exclusive competence over TRIPS. Previously, the Union could only attain exclusive competence over a provision of TRIPS if it had

[70] TEU Article 5 (3).

[71] TFEU Article 2 (2). See also Craig and de Búrca (2020) p. 114.

[72] See in this direction Opinion of Advocate General Szpunar in case C-600/14 para. 77. The Court came to the same conclusion as the Advocate General proposed.

[73] See C-431/05.

[74] Opinion 1/94.

[75] EC Treaty Article 133.

[76] Opinion 1/94 para. 57.

legislated internally, which led to pre-emption of member state action. The perfectly mirrored parallelism was therefore maintained; the exclusive internal competence led to exclusive external competence.[77] Thus, the question of coexistence of differencing external and internal competence became apparent in the aftermath of *Daiichi Sankyo*, as there was no perfect reflection between them.

The intervening member states in this case argued that the Union´s exclusive external competence would lead to an indirect harmonization of national IP law, to the detriment of the shared internal competence. General Advocate Cruz Villalón also advised the Court to not include the entire TRIPS agreement under the CCP, but rather have a topological approach concerning each provision, excluding part two of TRIPS from the exclusive competence:

> "Furthermore, it is clear that the comprehensive and immediate inclusion of the field governed by the TRIPs Agreement in the concept of 'commercial aspects' tends to bring the core of industrial property law within the European Union's exclusive competence, allowing it to effect a type of 'indirect' harmonisation or even 'to deactivate' the shared competence. Moreover, subject to what is set out below, *understanding the provision as an exclusive 'external' competence, capable of existing alongside a shared 'internal' competence, leads only to a dead end*."[78] (My emphasis.)

Both the member states and the Advocate General seem to believe that an exclusive external competence "deactivates" or "consumes" the shared internal competence, in which the Union would also retain an exclusive competence over patent law internally. There seems to be a "more to the less"-logic in this argumentation. The logic seems to be based on the perfectly mirrored parallelism of Union competence over TRIPS pre-Lisbon. Furthermore, the Advocate General stated that differing internal and external competences could not be maintained in the long term.[79] The Court did not follow the Advocate General's Opinion, but the question remains if differing internal and external competences over TRIPS can exist over time.

An important point to keep in mind is that pre-Lisbon EU law also made it possible to establish differing internal and external competences for the Union. The Union could attain exclusive external competence based on the existence of an internal competence, even if it was not exclusive or exercised. This law has not been changed. However, this was only possible in very few

[77] For instance Opinion 1/03 para. 11; C-431/05 para. 34; joined cases C-300/98 and C-392/98 para. 48.

[78] Opinion of General Advocate Cruz Villalón in case C-414/11 para. 60.

[79] Ibid para. 74.

circumstances according to my understanding.[80] The point with TRIPS is that the internal and external competences in fact remained shared from 1994–2009.

The next chapter will discuss in more detail how the internal competence is linked to the external competence, and whether the concept of "parallelism" presupposes perfect mirroring between the internal and external competence. The discussion will not problematize any changes the Lisbon Treaty brought in the understanding of Union competence: I will only discuss whether differing internal and external competences can be maintained *de lege lata*.

3.2.4 Differing internal and external competences

As explained, there is a connection between the internal and external competence, in the sense that they "reflect" each other. This leads to a very important question: whether an exclusive external competence consumes the shared internal competence and vice versa. This is a matter of whether an exclusive competence automatically consumes the shared competence over the same field. This question is relevant because TRIPS pre-Lisbon conferred the same extent of competence upon the Union, internally and externally.

The discussion is relevant due to practical issues with differing internal and external competence. If a member state is in breach of the TRIPS agreement, it is in breach of its obligations towards the Union. Externally, the Union will be responsible for the conduct of its member states towards the other WTO members.[81] Since the Union is solely responsible for the compliance of TRIPS externally, it is in the Union´s interest to harmonize patent law in order to be fully in control of the execution. Furthermore, the question of coexistence is also important when discussing how member states can increase access to medicines: if national patent law cannot be changed or improved, then only the EU can make future changes.

The following chapter will firstly examine the existence of a link between internal and external competence. After that, it must be discussed whether an exclusive competence automatically consumes a shared competence over the same field.

TFEU Article 206 links the establishment of the CCP with internal customs union. The provision says that "[b]y establishing a customs union in accordance with Articles 28 to 32, the Union

[80] Opinion 1/94 and Busch (2003) p. 36–41.

[81] C-66/18 para. 80–93. There might be a mismatch between the EUs exclusive competence regarding TRIPS in EU law and international law. The WTO panel will not necessarily accept the change of competence as it is internal for the EU, which may not correspond to international rules about attribution. Since the member states are still formally parties to TRIPS, a third-party country might activate a dispute settlement towards a member state it finds to be in breach of TRIPS obligations: see Duran (2017).

shall …". The internal customs union is therefore the rationale behind the CCP, and is essentially also the reason why the CJEU over the years expanded Union competence to cover external matters.[82] Furthermore, the Union may adopt regulations to implement the policy according to TFEU Article 207 (2), but the adoption of regulations must be sufficiently connected to international trade.[83] It is therefore clear that the internal and external competence are connected.

Moreover, the Union can be given competence to conclude an international agreement even if it does not fall under CCP. The rule about implied competence can be found in TFEU Article 216 (1), and is an additional basis for external competence when it is not expressly conferred in the Treaties:

> "The Union may conclude an agreement with one or more third countries or international organisations where the Treaties so provide or where the *conclusion of an agreement is necessary in order to achieve, within the framework of the Union's policies, one of the objectives referred to in the Treaties*, or *is provided for in a legally binding Union act* or *is likely to affect common rules or alter their scope*."[84] (My emphasis.)

The provision lists three alternatives to when the Union can conclude an international agreement. All of these alternatives concern internal matters of the Union, which can constitute a basis for external action. Thus, the wording communicates that an internal competence over a field, whether exercised or not, can equip the Union with the power to conclude an international agreement.

The origin of Article 216 (1) are the *ERTA*-doctrine, *Kramer*-case and Opinion 1/76, and are therefore relevant when interpreting the provision.[85] In the *ERTA*-case, the CJEU held that "the system of internal Community measures may not therefore be separated from that of external relations". Furthermore, the CJEU specified in Opinion 1/76 that the existence of internal competence can be a basis for external competence, even if the Union has not exercised the internal

[82] Opinion 1/75 and C-41/76. See Dimopoulos (2008) p. 102.

[83] Opinion 2/15 para. 36 and C-414/11 para. 51–52. Otherwise, the competence under CCP would circumvent the allocation of competences in TFEU Article 3 and 4. See TFEU Article 207 (6), which will be discussed later in this chapter; Koutrakos (2015) p. 51.

[84] TFEU Article 216 (1). This provision is not about *exclusivity*, but only the existence of an external competence outside CCP.

[85] C-22/70 *ERTA* and joined cases 3, 4, and 6/76 *Kramer*. See Opinion 2/15 para. 170–171.

competence yet.[86] Craig and de Búrca state that this opinion endorsed the principle of parallelism – *in foro interno in foro externo*.[87] Thus, the provision and the listed judgements confirm that there is a link between the internal and external competence.

TFEU Articles 206 and 216 (1), combined with case law, shows that there indeed exists a link between the internal and external competence. This link can be characterized as expressing parallelism, in the sense that the internal competence over a field can give rise to an external competence over the same field. As for the CCP, the entire rationale behind this policy is the existence of the customs union. However, none of these provisions or the case law (as far as I can see) imply that the existence of external power can be a basis for internal powers. This is because the Union's external competence was developed from and rooted in the internal competence. Although the CCP allows the Union to adopt regulations, they must be sufficiently connected to international trade: the possibility to adopt regulations does not extend to matters internal for the Union.[88] This finding indicates that differing internal and external powers over patent law can co-exist at the same time, since there seems to be no legal basis for making or changing the internal competence due to the existence of an external competence.

This chapter has so far demonstrated that the internal competence in itself can give rise to external competence. The external competence over TRIPS may therefore not affect the internal competence over patent law. However, the question remains if "parallelism" indicates that both the internal and external competence over the same field must confer the same *extent* of power. This is a question of whether exclusive competence over TRIPS automatically consumes the "lesser" internal competence over patent law. In order to answer this question, it must be established when the Union is conferred exclusive competence.

As mentioned, the areas where the Union has exclusive competence are listed in TFEU Article 3 (1), which also includes CCP and thus TRIPS. Aside from the CCP, all of the other listed areas concern the internal competence. Article 3 (2) is about conditional exclusivity:

> "The Union shall also have exclusive competence for the conclusion of an international agreement when its conclusion is provided for in a legislative act of the Union or is necessary to enable the Union to exercise its internal competence, or in so far as its conclusion may affect common rules or alter their scope."[89]

[86] See in this direction Craig and de Búrca (2020) p. 362–363.

[87] Craig and de Búrca (2020) p. 362; Tridimas and Eeckhout (1994) p. 151–154.

[88] C-414/11 para. 50 and C-137/12 para. 56.

[89] TFEU Article 3 (2). This provision also originates from case law, see C-22/70 para. 17–19, Opinion 1/94, and Opinion 1/03 para. 113–116.

The provision only concerns exclusive competence to conclude an international agreement, which is an *external* action. The conditions for conferring exclusive external competence rely on the existence of internal competence, very similarly to TFEU Article 216 (1). The wording of the provision makes it clear that only the internal competence can be a basis for exclusive external competence, and not the other way.

However, the exclusive competence over TRIPS arises from the CCP, and not the conditional exclusiveness under Article 3 (2). The question is if the CCP can be a reason for conferring exclusive internal competence over patent law.

Neither Article 3 (2) nor the rest of Article 3 gives rise to an exclusive internal competence on the basis of an external competence. The shift of competence internally is provided for in TFEU Article 2 (2) which envisages the rule on pre-emption. If the Union has satisfied the conditions for providing legislation under the shared competence, then member states cannot legislate on this matter – unless the legal act itself gives the member states the opportunity to do so.[90] This is usually the case with secondary law which aims for minimum harmonization. The point is, only exercised internal action can give rise to exclusive internal competence over the same field. This strongly suggests that exclusive external competence over TRIPS *per se* does not automatically consume the shared internal competence over patent law. The Union must legislate on patent law internally in order to pre-empt member state action.

As mentioned above, the CCP allows the Union to adopt regulations under Article 207 (2), but the regulations must be sufficiently linked to international trade with non-member states.[91] On this matter, the Union enjoys exclusive internal competence. However, a completely internal harmonization of patent law is not allowed. This understanding is confirmed by TFEU Article 207 (6), which provides for an important limitation of the exercise of its exclusive competence:

> "The exercise of the competences conferred by this Article in the field of the common commercial policy *shall not affect the delimitation of competences between the Union and the Member States*, and shall not lead to harmonisation of legislative or regulatory provisions of the Member States in so far as the Treaties exclude such harmonization." (My emphasis.)

An everyday understanding of "shall not affect the delimitation of competences between the Union and the Member States" suggests that the Union cannot circumvent the shared internal

[90] See for instance C-373/11 para. 26–29.

[91] Opinion 2/15 para. 35–36 and C-414/11 para. 50–52.

competence over patent law. The Union must adhere to the principle of subsidiarity in TEU Article 5 (3) if it wishes to harmonize the law on patents or compulsory licenses, when the regulation is not specifically linked to international trade.[92] Thus, the exclusive competence over TRIPS does not consume the shared internal competence over patent law – and definitely does not confer a general exclusive internal competence for the Union over intellectual property.

It can be contested that the inclusion of TRIPS under CCP means that the entire agreement becomes binding on the member states by virtue of Union law, and not just the provisions where the Union has legislated on internally. This argument presupposes that TRIPS in its entirety was not binding on the member states as EU law since its conclusion, see chapter 3.3.1. Thus, the substantive patent rules in TRIPS, including Article 31, becomes an integral part of the EU legal order. It can therefore be argued that since member states are obliged to comply with the patent rules in TRIPS towards the Union, the binding effect leads to pre-emption internally – and indirect harmonization to the "detriment" of the shared internal competence.

Although it is true that member states must comply with TRIPS as Union law, it does not mean that the Union acquires a general exclusive competence to legislate on patent law. Again, Article TFEU 207 (6) supports this finding. The provision says that exercise of competences conferred in Article 207 cannot affect the allocation of competence provided for in the Treaties. The wording suggests that the exclusive competence over CCP does not have a contagious effect on other areas of competence; the allocation of competences remains as provided for in the Treaties. It is worth noting that the previous Article 133 EC provided that the Union could not conclude an international agreement if it included provisions "which would go beyond the Community's internal powers". The Lisbon-treaty left out this expression of mirroring between internal and external competence. This may indicate that the change was intentional. The historical development of an EU provision can be a relevant interpretative factor, which in this case confirms the overall findings.[93]

Lastly, TFEU Article 207 (1) expressly recalls that the CCP "shall be conducted in the context of … the Union's external action". Read in conjunction with Article 207 (6), the provision also suggests that exclusive competence over TRIPS does not affect the shared internal competence over patent law. The CJEU has confirmed this stance in *Daiichi Sankyo* by stating:

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[92] See also Opinion 2/15 para. 164; Opinion of Advocate General Sharpston to Opinion 2/15 para. 106–109.

[93] See in this direction Koutrakos (2015) p. 51. Koutrakos does indeed characterize the CCP as being close to supranational international action. However, he also explains that the conclusion of an international agreement does not confer a more extensive internal competence over the subject matter – in this case, patent law. Dimopoulos and Vantsiouri are also of the same understanding regarding TFEU Article 207 (6): Dimopoulos and Vantsiouri (2014).

> "Admittedly, it remains altogether open to the European Union, after the entry into force of the FEU Treaty, *to legislate on the subject of intellectual property rights by virtue of competence relating to the field of the internal market*. However, acts adopted on that basis and intended to have validity specifically for the European Union *will have to comply with the rules concerning the availability, scope and use of intellectual property rights in the TRIPs Agreement*, as those rules are still, as previously, intended to standardise certain rules on the subject at world level and thereby to facilitate international trade."[94] (My emphasis.)

The Court explains that the Union is bound by its TRIPS obligations when it legislates in accordance with its internal competence. The passage also confirms that the Union must legislate according to its shared internal competence, by adhering to the principle of subsidiarity. Therefore, the inclusion of TRIPS in CCP is an external matter.

Both the listed Treaty provisions, historical development of CCP and *Daiichi Sankyo* makes it clear that the CCP and exclusive external competence do not automatically consume the shared internal competence. This is because an exclusive external action does not affect the shared internal competence, albeit member states must comply with TRIPS in its entirety as EU law. Furthermore, the possibility for the Union to adopt regulations under CCP is strictly reserved for matters that are sufficiently linked to international trade, and does not give rise to harmonizing purely internal matters – which would be the case with harmonizing national patent law. Furthermore, there are no examples in the Treaties or case law where external action became the basis for expanding the Union's internal competence.

Additionally, there is no consistent "more to the less"- approach between the competences, as in the external competence automatically "consuming" the shared. This is illustrated by the conditional exclusive competence in Article 3 (2). The wording does not specify that the internal competence must be exclusive or exercised: A non-exercised internal competence can give rise to an exclusive external competence. In my opinion, the terms "parallel" and "mirroring" are misleading, and may lead to a wrong assumption that the *extent* of the internal and external competences must be the same over a field.

Differing internal and external competences can therefore coexist at the same time; they are, *in their nature*, different from each other. Thus, the member states still retain the right to legislate on compulsory licensing, despite the change in CCP and external action. However, the member states must respect the obligations assumed by the Union under the TRIPS agreement: TRIPS

[94] C-414/11 para. 59.

Article 31 must be complied with when granting a compulsory license to increase access to medicines.

3.3 Legal status of TRIPS in the EU

3.3.1 TRIPS in the EU legal order

The question in this chapter is whether TRIPS is binding on member states by virtue of Union law. Whether and how international agreements of the EU are binding upon the member states, and thus become a part of the EU legal order, are addressed in the Treaties and the case law of CJEU. This chapter will not endeavor to answer the question of how international law has normative effect on States, neither will this chapter touch upon the fragmentation of international legal systems. The question is how the EU's external actions affects the internal obligations between the EU and the member states. That is to say, what status does TRIPS have in the EU legal order?[95]

TFEU Article 216 (2) states that international agreements concluded by the Union are binding upon the member states and the EU institutions. The provision codified pre-Lisbon case law. In C-181/73 *Haegeman II*, the CJEU found that "[t]he provisions of the [Athens] Agreement, from the coming into force thereof, *form an integral part of community law*".[96] This stance has been repeated by the CJEU in subsequent cases, and the Court has also explicitly stated TRIPS is a part of the EU legal order.[97] Thus, international agreements have normative effect by virtue of Union law, and not by international rules.

That being said, the TRIPS agreement was not solely "concluded by the Union", since the Union did not have exclusive external competence over TRIPS during the Uruguay rounds in 1994. A preliminary question is if the binding effect of international treaties rely on whether the Union had exclusive competence to conclude it. That is to say, whether the Union must conclude the agreement without the member states' co-conclusion in order for the agreement to be binding as EU law.

The wording of Article 216 (2) does not mention competence, which may suggest that "concluded by the Union" is a matter irrespective of exclusive or shared competence. The case law of CJEU can indicate the same finding. The CJEU found that the Athens Agreement was an integral part of the EU legal order in *Haegeman II*, even though it was a mixed agreement. Similarly, the legal character of pre-Lisbon TRIPS was outlined in C-431/05, while it was still considered a mixed agreement:

[95] Koutrakos (2015) p. 209.

[96] C-181/73 para. 5, my emphasis.

[97] C-431/05 para. 31; C-66/18 para. 68–71; C-583/12 para. 48.

> "The WTO Agreement, of which the TRIPs Agreement forms part, has been signed by the Community and subsequently approved by Decision 94/800. Therefore, according to settled case-law, *the provisions of that convention now form an integral part of the Community legal order*".[98] (My emphasis.)

None of the cases distinguishes the binding effect of agreements according to Union competence, in which only the parts that fall under the exclusive competence of the Union, become an integral part of the EU legal order. [99]

The Court has reasoned its finding with the fact that agreements are concluded by the Council, thus representing "an act of one of the institutions of the community".[100] According to TFEU Article 218 (6), an agreement is concluded in terms of EU law when the Council adopts a decision. The decision by the Council includes the entire agreement as an annex – as in the case of Decision 94/800, which concluded the WTO-agreements. Thus, "concluded by the Union" may encompass all agreements which the Union is a part of, regardless of exclusive or shared competence over it.

However, the CJEU has in other cases held that mixed agreements "have the same status in the Community legal … in so far as the provisions fall within the scope of Community competence".[101] In my opinion, there seems to be a lack of consistency in case law. Supposed that the latter case law applies to TRIPS, the question is if a shift in competence after the conclusion of TRIPS can change the binding effect of the agreement, in the sense that the entire agreement is a part of the EU legal order.

The Court has stated the following about pre-Lisbon TRIPS:

> "[W]hen the field is one in which the Community has not yet legislated and which consequently falls within the competence of the Member States, the protection of intellectual property rights and measures taken for that purpose by the judicial authorities do not fall within the scope of Community law."[102]

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[98] Para. 31.

[99] See also C-344/04 para. 36, C-386/08 para. 39, and C-410/11 para. 20.

[100] C-181/73 para. 4 and C-431/05 para. 31.

[101] C-239/03 para. 25 with the cited case law; C-459/03 para. 82–86; C-13/00 para. 14–17; Opinion of Advocate General Kokott in case C-66/18 para. 42.

[102] C-431/05 para. 34.

The judgement can be understood as to relying on whether the Union has exercised its internal competence, in order for a TRIPS provision to be binding as EU law.[103] This understanding may refers to the "parallelism" of pre-Lisbon TRIPS, where the notion of pre-emption internally led to a "mirrored" external competence. The judgement suggests that changes in competence after the conclusion of TRIPS also changes the status of a provision in EU law.

It can be contested that the case law concerning Union competence over mixed agreements is connected to the Court's interpretative jurisdiction over the agreement.[104] The CJEU has mainly jurisdiction to interpret an agreement if the Union has exclusive competence, either internal or external. Whether or not the Court's jurisdiction over an agreement is synonymous with the binding effect of that agreement under EU law, is not easy to ascertain.[105] The CJEU can only interpret EU law, in which it is natural to think that the interpretative jurisdiction also reflects what parts of the agreement is considered as EU law. However, some agreements under the Common Foreign and Security Policy (CFSP) are binding on the member states, but the Court may not have jurisdiction to interpret them.[106] Without diving into the very complicated case law concerning the interpretative jurisdiction of the Court over TRIPS as a mixed agreement,[107] TRIPS falls under the exclusive competence of the Union now. The CJEU found that it had interpretative jurisdiction over TRIPS in *Daiichi Sankyo*, which also underlines that the entire agreement under all circumstances is considered as EU law.

The same finding is supported by the Opinion of Advocate General Kokott in case C-66/18. This case was about Hungary's breach of GATS (General Agreement on Trade in Services). GATS is an annex to the WTO-agreement alongside TRIPS, and was originally entered into as a mixed agreement due to Opinion 1/94.[108] The Union has now exclusive competence over GATS under CCP. The Advocate General explicitly held that "[t]he obligation at issue under GATS, which was originally entered into by Hungary, was therefore transferred to the European Union by the Treaty of Lisbon at the latest and thus constitutes an obligation under EU law".[109] The Court confirmed this stance in C-66/18 by simply stating that GATS is EU law, and the

[103] See also C-414/11 para. 41–42.

[104] C-414/11 para. 41–42. See Busch (2003) 49–51 and 92–95.

[105] See Neframi (2010) p. 331–337 on whether mixed agreements bind the member states by virtue of EU law in their entirety. Dimopoulos and Vantsiouri (2014) holds that only the provisions that fall under the Union's exclusive competence (either *a priori* or due to pre-emption internally), binds the member states by virtue of Union law in a mixed agreement.

[106] Koutrakos (2015) p. 443 and Wessel (2021) p. 71–72.

[107] See for instance Opinion of Advocate General Ćapeta in case C-500/20 and Opinion of Advocate General Ruiz-Jarabo Colomer in case C-431/05 concerning the difficulties in establishing interpretative jurisdiction over mixed agreements and pre-Lisbon TRIPS.

[108] The same Opinion ruled that the Union did not have exclusive competence over TRIPS, see chapter 3.2.3.

[109] Para. 47.

commitments in GATS fall under the CCP. Thus, the Union is responsible for the conduct of its member states externally, whilst any breach of GATS by the member states is a breach of EU law.[110]

It can be concluded that TRIPS in its entirety forms an integral part of the EU legal order. This can either be established on the fact that TRIPS as a whole became an integral part of the EU legal order from the conclusion in 1994, or due to the shift of competence post-Lisbon. Therefore, the Commission might start an infringement procedure against a member state in breach of TRIPS obligations. This could be the case if national legislation about compulsory licenses is in conflict with TRIPS Article 31. The judgement C-66/18 is so far the only example of a Commission infringement procedure for the breach of WTO-law.

3.3.2 Direct effect and supremacy

The question in this chapter is if TRIPS prevails over national law before national courts. This question concerns two topics: direct effect and supremacy, which are two central aspects of the EU legal order. [111] These two faculties both created and rationalized the EU legal order as its own, distinct from the national legal orders of the member states and the overall international order(s).[112] The rules on direct effect and supremacy follow from case law.

The expression "direct effect" has cited criticism by legal scholars, as the term is vague and not used uniformly.[113] Without dwelling on the impreciseness of the term, "direct effect" encompasses two aspects: whether TRIPS confers individual rights that can be invoked before the courts, and whether secondary Union legislation can be challenged because of a possible breach of TRIPS obligations.[114] Whether secondary Union legislation can be challenged is an extensive topic and falls outside the scope of this thesis. The question to be answered is whether individuals can rely on TRIPS before the Court. For the sake of this thesis, the question is if a patent owner can challenge national law about compulsory licenses for breaching TRIPS article 31.

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[110] C-66/18 para. 68–75.

[111] Mendez (2013) p. 64

[112] Mendez (2013) p. 12.

[113] Advocate General Cruz Villalón even stated that " it is questionable whether the order for reference is correct in using the expression 'direct effect', despite its widespread use … the distance between the 'direct effect' of treaties and the 'direct effect' of European Union law is so great, 'in both concept and scope', that it would be advisable 'to use different terms to describe them in future in order to avoid any unfortunate confusion, and hence to speak only of the possibility of relying on international agreements'", see para. 84 in his opinion to the *Daiichi Sankyo*-case. See also Craig and de Búrca (2020) p. 218–219 about the different approaches in understanding "direct effect".

[114] As will be illustrated by the case law in this chapter.

The topic of "direct effect" is provided for in case law and not the Treaties. In C-26/62 *Van Gend En Loos*, the Court stated three conditions for according direct effect to an international agreement; the obligation must be clear, precise and conditional.[115] It is established case law that TRIPS does not have direct effect:

> "… the provisions of TRIPs, an annex to the WTO Agreement, are not such as to create rights upon which individuals may rely directly before the courts by virtue of Community law".[116]

The Court's conclusion about direct effect of TRIPS was done in the context of TRIPS mixity. Pre-Lisbon, the Court could only decide if TRIPS could be given direct effect if a provision fell under the Union's exclusive competence, or in fields in which the Union had legislated. If the Union had not legislated on the matter internally, then it was up to the member states to decide if TRIPS could be given direct effect.[117]

Since TRIPS now falls under the exclusive external competence of the Union, the national courts can no longer decide to give TRIPS direct effect in their own legal systems. This approach was confirmed by the Court in *Daiichi Sankyo*, as the referring court asked if it still could choose to give TRIPS Article 33 direct effect. This question initiated the analysis of CCP and exclusive competence. Since the Court found that TRIPS fell under CCP, it did not find it necessary to answer whether national courts retained the choice of giving direct effect. Although it is a pity that the judgement did not spell out the consequence of exclusive competence on direct effect, the silence confirms that the established case law about TRIPS remains good law. Therefore, patent owners cannot challenge national law about compulsory licenses if it is in breach of TRIPS Article 31. However, the Commission may still open an infringement procedure against the member state for the misconduct.[118]

Whilst TRIPS does not have direct effect – in which it cannot be relied on by private parties – the Court has confirmed that the principle of indirect effect still applies. This means that national legislation ought to be interpreted harmoniously with the TRIPS agreement as far as possible.[119]

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[115] See Craig and de Búrca (2020) p. 225 for a thorough analysis of the case law.

[116] Joined cases C-300/98 and C-392/98 para. 44; C-431/05 para. 35;

[117] Joined cases C-300/98 and C-392/98 para. 48.

[118] It can be discussed whether TRIPS can be given direct effect through a topological approach, since the Court consistently has held that WTO-agreements "in principle" do not have direct effect, see C-149/96 para. 47.

[119] Joined cases C-300/98 and C-392/98 para. 47. See also C-105/21 para. 82 and 83 about Framework Decision 2002/584 which the Court held does not have direct effect. Nonetheless, member states are required to interpret national law in conformity with the Framework Decision.

Although the TRIPS agreement cannot be relied on before the courts, it maintains its position in the EU legal order. This matter prompts the question of supremacy, and whether TRIPS has primacy over national legislation. EU law, as in the rights and obligations in the Treaties, has primacy over national law and measures.[120] Since TRIPS is EU law, it has primacy over national legislation.[121] As the Court stated in C-430/21, a national court must disapply any national rule or practice that cannot be interpreted in compliance with the requirements of EU law.[122]

However, there has been a discussion among legal scholars whether direct effect acts as a trigger for supremacy, or whether they are completely separated from each other.[123] If they are connected, then national courts cannot set aside a national provision to repair the illegality in a specific case, if the international agreement does not have direct effect. The alternative understanding is that it is the principle of primacy *itself* which is being invoked, and not the international agreement.[124]

In C-261/20, the Court clarified that national courts only have an obligation to disapply EU law with direct effect.[125] However, national courts may set aside national law in breach of TRIPS, if the domestic system so provides.[126] If the national law is not set aside, the member state would nevertheless be in breach of EU law. Direct effect being a "trigger" for supremacy does not take away the legal character of the principle of primacy: it simply means that the principle cannot be activated in a specific case. Furthermore, the patent owner affected by a national compulsory license in breach of EU law is not entitled to compensation. This is because a condition for non-contractual State liability is that the EU law must confer rights upon individuals.[127]

In conclusion, individuals cannot rely directly on TRIPS to challenge national legislation about compulsory licenses. Member states must nonetheless interpret national law harmoniously with TRIPS as far as possible. If the national provision conflicting with TRIPS is not set aside, and the law has not been changed domestically, then the Commission may start an infringement procedure against the member state.

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[120] C-6/64, C-11/70 para. 3, and C-430/21 para. 47–50.

[121] See for instance C-66/18 para. 69–71.

[122] Para. 53.

[123] Mendez (2013) chapter 3.1, Koutrakos (2015) p. 14–15, and Craig and de Búrca (2020) p. 309.

[124] Mendez (2013) p. 14–15.

[125] Para. 33.

[126] Para. 40.

[127] Para. 44.

3.4 Interpretative jurisdiction of the Court over TRIPS

3.4.1 Interpretative jurisdiction

It has been established that TRIPS is Union law in the context of the EU legal order. According to case law, the question of the Court's interpretative jurisdiction relies on whether the Union has competence over it. In the case of mixed agreements, the road to establish jurisdiction is rockier. Since TRIPS falls under the CCP, the Court has interpretative jurisdiction to interpret the entire agreement, as illustrated by the *Daiichi Sankyo*-case.

The Court can rule on TRIPS in two ways: in a preliminary ruling on interpretation, and in an infringement procedure. Since TRIPS does not have direct effect, there are no other judicial measures available. The preliminary ruling procedure is laid down in TFEU Article 267. Last instance courts are obliged to seek an interpretation on TRIPS Article 31 by the CJEU.[128] Since the Court is the responsible and authorative interpreter of EU law, the interpretation becomes binding on the referring court.[129] It can be presumed that the interpretation also binds other national courts.[130] However, the Court's interpretation of TRIPS does not bind third country WTO-members: the rulings strictly concern TRIPS as EU law.[131]

Since the Union is externally responsible for the rightful execution of TRIPS, and the agreements is binding on the member states, the *legal methodology* of the CJEU when interpreting TRIPS is also important to consider. This is the topic of the next sub-chapter.

3.4.2 Interpretation of TRIPS

Since TRIPS is EU law, the question is how the agreement is ought to be interpreted. Since the CJEU is the authorative interpreter of EU law, I will base the discussion in chapter 4 on the CJEU's methodology when it interprets TRIPS.

The Court has used the VCLT as a starting point for interpreting international agreements of the Union. The Court has specifically stated that the VCLT Article 31, which lays down the main principles for interpretation, is a part of the EU legal order.[132] This is because the Union may be in breach of its international obligations if it interprets the agreement differently from international rules. However, the Court has not been consistent on this matter when interpreting TRIPS. The Court rather interprets the agreement without reference to the methodology. Whether or not the interpretation of TRIPS is a deviation from the general interpretation of

[128] TFEU Article 267 (3).

[129] C-430/21 para. 72 and 74, C-181/73, and Mendez (2013) p. 69.

[130] C-430/21 para. 64.

[131] C-66/18 para. 89.

[132] C-111/21 para. 22 with the cited case law.

international agreements, or if the Court *in reality* uses the same methodology without explicit reference to VCLT, will not be discussed. For the sake of this chapter, it is sufficient to establish how the Court has proceeded when interpreting TRIPS provisions. In general, the Court has stated the following on the interpretation of TRIPS:

> "[S]ince the European Union is a party to the TRIPS Agreement, it is under an obligation to interpret its trade-mark legislation, so far as possible, in the light of the *wording* and *purpose of that agreement*".[133] (My emphasis.)

Although the Court mainly refers to the rule of interpreting secondary law harmoniously with international agreements, it also states the most important factors in interpreting TRIPS itself. Case law shows that the Court relies on the wording of the provision in the same way as it does with EU law in general.[134] The purpose, or the objectives, of TRIPS are also an important source for interpretation. Not only are the specific objectives of the provision important, but also the general objectives of TRIPS in Article 7. I will therefore rely on TRIPS Article 7 when interpreting Article 31.

Furthermore, I will consider the context of TRIPS – especially the structure and the connection between the different provisions. The Court has relied on the context when interpreting TRIPS in addition to the wording and the objectives.[135] Furthermore, the Court has also relied on an interpretation that does not render another provision ineffective.[136] The latter point is important if a provision constitutes an exception to the main rule. An interpretation which renders an exception ineffective, or if a broad interpretation of the exception renders the main rule ineffective, cannot be chosen.

Case law from the CJEU will be relied on when interpreting TRIPS Article 28, see chapter 1.3 about the significance of case law. As far as I can see, there have been no cases before the CJEU and the WTO Panel concerning the interpretation of TRIPS Article 31. Thus, the analysis will mainly rely on the wording, context and purpose.

Since TRIPS is an EU act, EU primary law also constitutes the context for TRIPS. Due to the hierarchy of norms, primary law prevails over TRIPS in case of a conflict between them.[137] In

[133] C-809/18 P para. 64 with the cited case law.

[134] C-347/03 para. 105–107, C-414/11 para. 66, and C-355/21 para. 44.

[135] C-414/11 para. 67, 80 and 82.

[136] C-414/11 para. 67.

[137] See for instance C-352/19 P para. 25, and Tridimas (2006) p. 51 with cited case law.

cases concerning secondary law, the Court has stated that secondary legislation must be interpreted harmoniously with legal acts hierchically above it.[138] Deriving from this logic, I find that TRIPS must be interpreted harmoniously with primary law, in so far the interpretation does not lead to a breach of the Union's international obligations.[139]

The Court has not, according to the case law I have found, explicitly mentioned a rule of harmonious interpretation of international agreements with primary law. However, the logic in the hierarchy of norms, as well as the established rule of harmonious interpretation of secondary law with primary law, strongly indicates that this rule also applies to international agreements. For this reason, TRIPS Article 31 will be interpreted in line with and supplied with primary law, since TRIPS allows WTO members to provide for better protection of patent rights. Chapter 4 combines the safeguards of TRIPS with the right to property in CFR Article 17, especially since it elevates the protection of the patent owner.

Chapter 4 will refer to a WTO Appellate Body report. The CJEU has held that it takes account of the interpretation by the Dispute Settlement Body (DSB) when interpreting a GATS provision.[140] The Appellate Body is the panel that reviews DSB-reports in an appeal. Thus, I assume that Appellate Body reports are equally as relevant as DSB-reports.

The thesis will also rely on the Doha Declaration when interpreting TRIPS Article 31.[141] The Doha Declaration is a waiver made by the WTO members in 2001, and states how TRIPS can be interpreted to provide access to essential medicines. Although I have not found a case where the EU relies on the Declaration when interpreting TRIPS, I find that it is a relevant source for interpretation: especially since TRIPS must be interpreted according to the principle of *pacta sund servanda* and implemented in good faith, see C-66/18 para. 92.

The Exports Regulation will also be referred to. It is not a relevant factor when interpreting TRIPS, since it is hierarchically below the agreement. Nonetheless, it can provide a valuable reference point to how national law can be implemented within the limits of TRIPS and CFR article 17. Lastly, travaux préparatoires will be referred to. The CJEU has not relied on travaux préparatoires as a legal source when interpreting TRIPS as far as I can see. Such documents only constitute a supplementary mean to support the overall findings according to VCLT Article 32.

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[138] See chapter 1.3.

[139] C-66/18 para. 81 and 92; Busch (2003) p. 43–44 with cited case law.

[140] C-66/18 para. 92. As previously mentioned, GATS is also annex to the WTO-agreement alongside TRIPS. The DSB deals with disputes between the WTO members, see WTO DSB (2023).

[141] Declaration on the TRIPS Agreement and public health of 14. November 2001 (Doha Declaration). See chapter 4.9 about waivers.

3.5 Key takeaways

It is now established that the Union has exclusive external competence over TRIPS, which means that only the Union is a party to the agreement vis-à-vis the other WTO members. The member states' compliance with TRIPS is an obligation towards the Union only. A breach of TRIPS would be a breach of EU law, since the agreement is an integral part of the EU legal order. Externally, the Union is responsible for the conduct of its member states. At the same time, the member states retain their right to legislate on compulsory licenses. Thus, the internal and external competences do not affect one another.

Furthermore, TRIPS does not confer rights upon individuals. Patent owners cannot challenge the national legal basis for compulsory licenses by claiming a breach of TRIPS Article 31. Rather, patent owners must either wait for the member state to change the law itself, or for the Commission to start an infringement procedure. If a national court reviews the legality of a granted compulsory license against national law, then it must interpret national law harmoniously with TRIPS as far as possible. Furthermore, a last instance court has an obligation to request a preliminary ruling on TRIPS Article 31 from the CJEU – an obligation which ensures uniform and autonomous interpretation of the agreement within the Union. Now that the constitutional questions regarding TRIPS are established, the material conditions concerning compulsory licenses must be discussed in the following chapter.

4 Compulsory licenses to increase access to medicines

4.1 Introduction

If a third party wishes to use someone's patent, they must obtain authorization to do so. The main rule in patent law is that authorization is obtained by consent from the patent owner. However, there are circumstances where it is not possible to obtain a voluntary license agreement. In such circumstances, national legislation may allow the government to either grant a compulsory license or to use the patent itself. The latter is called "government-use", and is a compulsory license specific for the government. This chapter will mainly deal with compulsory licenses to non-government parties, but will address government-use when relevant.

TRIPS Article 31 provides an extensive list of different safeguards that must be guaranteed when national authorities consider and grant a compulsory license. In addition, the right to property in CFR article 17 must be respected at all times, and imposes additional safeguards that member states must comply with. Only the most relevant safeguards concerning compulsory licenses to address public health concerns will be discussed.

Chapter 4.3 will discuss compulsory licenses as an interference to the right to property, and thereby supply the safeguards in TRIPS with the proportionality test in CFR. Chapter 4.4 will

thoroughly discuss the principle of territoriality and highlight the challenges of territorial restrictions in the internal market. Safeguards *prior* to granting a compulsory license will be discussed in chapter 4.5, whilst safeguards concerning the *contents* of the license will be discussed in chapter 4.6. The procedural safeguards will be shortly commented in chapter 4.7. Lastly, chapter 4.8 will comment on the compatibility of the safeguards in TRIPS with the proportionality test in CFR, whilst the challenges with the compulsory licensing scheme will be reflected on in chapter 4.9. Before that, the next chapter will comment on whether member states have a human rights obligation to supply medicines to its population during a public health crisis.

4.2 Access to medicines as a human right

The international debate during COVID-19 discussed access to medicines as a human right.[142] Thus, the question is if member states have a positive duty to ensure sufficient supply and stockpiling of medicines to cover national needs. If the answer is yes, then it must secure its own population by granting a compulsory license. In addition, member states must secure domestic needs before sharing medicines with other EU member states.

This chapter will apply the European Convention on Human Rights (ECHR). The Union is not a party to the Convention, but all member states are – which makes it an important instrument in the EU.[143] The ECHR does not contain any provisions about the right to health. Thus, a duty for member states to provide medicines to the population must be established under Article 2 about the right to life and the prohibition against torture in Article 3.[144] CFR will not be discussed, as it is not clear when member states "implement" Union law if they have a constant obligation to stockpile and acquire medicines for their population.[145] The result may not be different even if CFR is applicable, since CFR Article 2 and Article 4 have the same scope and meaning as ECHR Article 2 and 3.[146]

For a member state to have a duty to ensure a sufficient supply or stockpiling of medicines to cover its population during a health crisis, someone must be affected by the "neglect" of the member state.[147] It is established case law that the ECHR neither allows an application to be lodged as *actio popularis* – an action taken by any person in the name of public interest – or an

[142] See for instance Hathaway et al. (2021).

[143] Council of Europe (2023).

[144] These provisions will not be discussed extensively, as it would fall outside the scope of this thesis.

[145] See chapter 4.3.2.

[146] Explanations to Article 52. CFR article 35 will be commented in chapter 4.3.4.

[147] ECHR article 34; *Vallianatos and others v. Greece* para. 47.

abstract review of a national measure.[148] In case *Le Mailloux v. France*, a French man lodged an application concerning the domestic handling of the COVID-19 pandemic by the French government.[149] The applicant complained that the French government did not do enough to safeguard the lives and health of its citizens, and claimed that France had an obligation to provide surgical face masks and testing facilities to the entire population. The application was deemed inadmissible, since it fell under the category of *actio popularis*. The man had not proved that he indeed was directly or indirectly affected by the lack of face masks and testing facilities.[150]

The case illustrates that it is difficult to impose a positive duty for member states to provide medicines to the entire population during a health crisis, since the alleged "victim" status would be tricky to prove. A person must have been denied medicines or medical care in order to bring the case before the ECtHR, as that seems to be the only plausible way to be considered a direct victim in this case.

If the victim-status is established, Article 2 and 3 may project a duty to provide medicines to the population. Article 2 grants the right to life. Although the wording suggests that the provision only comes into play when a person dies, the ECtHR has held that it is not a requirement in certain circumstances.[151] Furthermore, the ECtHR has ruled that a member state may breach Article 2 if the State denies an individual health care, by not taking "appropriate steps to safeguard the lives of those within its jurisdiction".[152] However, the ECtHR was more concerned with whether the government "deliberately withheld medical treatment from the population".[153] Other cases establishing a breach of Article 2 have been about negligence on the part of health care professionals. The breach has been established due to the lack of a regulatory framework for ensuring the protection and integrity of patients. I have not found any case law which establishes a breach of Article 2 because of a shortage of medicines, no less during a health crisis.

As for Article 3, the provisions prohibits torture, inhuman or degrading treatment or punishment. In the context of this thesis, it is sufficient to say that I have not found case law where a

[148] *Roman Zakharov v. Russia* para. 164; *Practical Guide on Admissibility Criteria* (2022) p. 15 with cited case law.

[149] *Le Mailloux v. France* and EU Law Live (2020).

[150] *Vallianatos and others v. Greece* para. 47.

[151] See *Guide on ECHR art. 2* (2022) p. 6–7.

[152] *Cyprus v. Turkey* para. 219.

[153] Ibid.

state became responsible for the shortage of medicines.[154] A denial of medicines due to a shortage might be considered to be an inhumane treatment of a patient, but the assessment would rely on the specific circumstances of the case.

Thus, it is difficult to establish whether member states have a positive duty to provide medicines to the entire population, or to prevent shortage of medicines. The assessment would rely on the circumstances of each case, and be specific for the alleged victim. For this reason, the rest of chapter 4 will not consider access to medicines as a human right.

4.3 The interface between primary law and international agreements of the Union

4.3.1 Introduction

The purpose of this chapter is to highlight how EU primary law affects the level of protection in TRIPS. The right to property in CFR Article 17, which is primary law, may entail a higher degree of protection than the safeguards in TRIPS Article 31 alone.-Since CFR is considered as primary law, it is hierarchically above TRIPS. If there is a potential conflict between TRIPS and CFR, then CFR has primacy. If there is no conflict however, then member states must respect the obligations in both TRIPS and CFR at the same time.

There are two ways to avoid a potential conflict between TRIPS and CFR Article 17. This can either be done by interpreting TRIPS harmoniously with primary law, in which the safeguards in Article 31 must be interpreted in line with CFR Article 17 as far as possible.[155] Another way of ensuring harmony between TRIPS and CFR, is by understanding the right to property as a minimum threshold that must be respected at all times. The latter solution means that CFR Article 17 elevates the degree of protection in the Union, and constitutes an additional restriction on member states when they issue a compulsory license. Whilst the first solution ensures that the contents of TRIPS in themselves comply with the right to property, the latter solution makes sure that member states are aware of CFR Article 17 in addition to TRIPS.

Both approaches must lead to the same conclusion, since the right to property has primacy over TRIPS. The difference in the approaches does not constitute a specific problem for member states, but the distinction may be of significance when addressing the legality of TRIPS against CFR. This is an important observation, since the Union could possibly be at a risk of breaching its international responsibilities under TRIPS if there is a conflict between the agreement and CFR. However, then it can be assumed that there is no conflict: TRIPS only requires a minimum

[154] See *Guide on ECHR art. 3* (2022).

[155] See chapter 1.3 and 3.3.2.

level of protection for IP, whereas CFR requires more strict conditions concerning a compulsory licenses in the interest of the patent owner. I will therefore interpret the wording of TRIPS in line with the right to property where it is possible. Otherwise, the safeguards in TRIPS will be supplemented with additional conditions imposed by CFR Article 17.

4.3.2 Application of CFR

According to Article 51 (1), the provisions of CFR are only addressed to the member states when they "implement" Union law. The question is if member states implement Union law when they legislate on compulsory licenses.

The term "implement" Union law indicates that secondary Union legislation is being included or executed in national law, which includes regulations and directives. In terms of the TRIPS agreement, the question of whether member states have "implemented" it by virtue of Union law is more complicated. I assume that some member states already had legislation about compulsory licenses before the conclusion of the WTO agreements, and thus did not need to change their national law. In that case, the CJEU has interpreted "implemented" broadly to include national acts and legislation which fall within the *scope* of Union law.[156] It has furtherly held that it is "nevertheless necessary that, in the area concerned, *EU law imposes specific obligations on Member States with regard to the situation at issue* in the main proceedings".[157]

Since TRIPS is an integral part of the EU legal order and is binding upon the member states in accordance with TFEU Article 216 (2), national legislation about compulsory licenses must be in compliance with TRIPS Article 31. Article 31 states that when member states have a compulsory licensing scheme in their national legal system, then certain safeguards must be respected. Thus, the provision imposes specific obligations concerning national legislation and therefore decisions about compulsory licenses. Member states are therefore considered to implement Union law by having a compulsory licensing system in national law.

If anyone is in doubt as to whether member states implement Union law when fulfilling obligations under an international agreement concluded by the EU, C-66/18 is of interest. This case was an infringement procedure against Hungary for breaching GATS, as observed in chapter 3.2. CJEU generally held the following:

> "[T]he GATS forms part of EU law. It follows that, when the Member States are performing their obligations under that agreement, including the obligation imposed in Article

[156] C-617/10 para. 21.

[157] C-223/19 para. 79, my emphasis.

XVII(1) thereof, they must be considered to be implementing EU law, within the meaning of Article 51(1) of the Charter".[158]

The judgement confirms that member states implement Union law when international agreements become a part of the EU legal order, and the agreement imposes obligations on the member states. This means that national legislation about compulsory licenses must respect the right to property in Article 17. This also means that member states must interpret and apply national legislation in line with CFR when granting a compulsory license to a third party.

4.3.3 Compulsory licenses as an interference with the right to property

CFR Article 17 entails the right to enjoy one's property, and Article 17 (2) explicitly refers to the protection of intellectual property. According to the Explanations, the reference to intellectual property makes it clear that IP is recognized as a property, and thus falls within the scope of Article 17 (1).[159] The Explanations also clarify that the protection of intellectual property includes patent rights.[160] The question is whether a compulsory license breaches the right to property. This question actualizes two sub-questions: whether the granting of a compulsory license constitutes an interference with the right to property, and whether the interference can be justified. The latter question also concerns whether the compulsory license fulfills the proportionality test. This chapter will answer the first question.

In order to provide a correct analysis of CFR Article 17, it must be established whether this provision corresponds to a human right in the ECHR. This is because CFR Article 52 (3) provides that the meaning of a provision in CFR must be given the same scope and meaning if it corresponds to a right in ECHR.[161]

The right to property is protected under ECHR protocol 1 Article 1 (hereafter P1-1). According to the Explanations, CFR Article 17 corresponds to P1-1 in both meaning and scope.[162] The CJEU has confirmed this stance.[163] Additionally, the ECtHR has interpreted the provision as to

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[158] Para. 213.

[159] Explanations to Article 17. See chapter 1.4 about the interpretative value of the Explanations. See also C-477/14 para. 163. Some legal scholars describe the protection of intellectual property as a *lex specialis*, with reference to the explanations, since they explain that the guarantees in Article 17 (1) apply *mutatis mutandis* to IP; see Christoffersen et al. (2018) p. 206. I cannot see that the protection of IP constitutes *lex specialis*, since there is no conflict with Article 17 (1). As will be observed below, ECHR P-1 also considers IP as "possessions".

[160] Explanations to Article 17.

[161] According to the Explanations to Article 52, the reference to ECHR also includes its protocols.

[162] Explanations to Article 52. Although the wording of CFR Article 17 and P1-1 are not identical, they seem to communicate the exact same contents.

[163] Joint cases C-798/18 and C-799/18 para. 35; C-235/17 para.72.

protect intellectual property as well, which also includes the protection of registered patents.[164] The protection provided under P1-1 constitutes a minimum threshold under the CFR, which means that CFR can entail a higher degree of protection of patent rights.[165]

P1-1 establishes three ways an infringement of a property right can take place: deprivation of property in the second sentence of the first paragraph (deprivation-rule), control of property in the second paragraph (control-rule), and the general principle about peaceful enjoyment of one's possession in the second sentence of the first paragraph (principle-rule). These three categories are provided for in the wording of the provision, and confirmed in case law of the ECtHR.[166] In addition, the wording of CFR Article 17 also contains these three rules. According to the case law of the ECtHR, the existence of an interference is done by assessing whether the property owner has been negatively affected by the State action.[167] The assessment is done by considering whether the situation at hand fits into one of the three infringement-categories.[168]

A compulsory license can either be regarded as a deprivation or control of the patent right. The distinction between these rules is important. If a compulsory license is considered as a deprivation of the patent right, then the patent owner must for instance be compensated. Under the control-rule, there is no requirement of giving compensation, see chapter 4.3.4 and 4.6.2.

Before discussing whether a compulsory license constitutes deprivation or control of the patent right, we must trace back to what a patent right entails. As was observed in chapter 2, a granted patent confers upon its owner an exclusive right to use the invention. The exclusive right is *negative* in its nature, in the sense that the patent owner can prohibit third parties from using their invention. One of the key functions of a patent right is freedom of contract: the patent owner can choose to allow others to use the invention, to whom, and subject the use to certain conditions. A compulsory license severely disturbs the freedom of contract, since national authorities allow a third party to use the invention without consent from the patent owner, as well as decide the contents of the license in accordance with legal criteria. Another aspect of patent rights is that patent owners have a reserved right to place a manufactured product on the market

[164] See for instance *Anheuser-Busch Inc v. Portugal* para. 72; *Lenzing AG v. the United Kingdom*; *Tokel v. Turkey* para. 56. I will not problematize whether a patent application, or a rejection of a patent application, is considered as a "possession", since it is not relevant for this thesis.

[165] See CFR Article 52 (3) last sentence and C-235/17 para. 72.

[166] *Sporrong and Lönnroth v. Sweden* para. 61; Jorem (2021) p. 89–90. The principle rule is mostly used as a category for situations that naturally do not fit into the abovementioned rules, see for instance *Tokel v. Turkey* para. 72.

[167] Jorem (2021) p. 87. It is not necessary for the purpose of this thesis to discuss the State's positive obligations under the Convention.

[168] Jorem (2021) p. 90.

for the first time. This aspect is also disturbed by a compulsory license. With this in mind, it must firstly be established whether a compulsory license constitutes a deprivation of the exclusive right of the patent owner.

The wording in "deprivation" indicates that the possession has been transferred from the property owner to someone else – so called formal expropriation.[169] By doing so, the property owner can no longer legally and actually dispose of their property. Additionally, "deprivation" also includes *de facto* expropriation according to case law from the ECtHR. A property is *de facto* expropriated when the property right becomes practically useless, in a way that the property owner no longer can enjoy his possession in a meaningful way.[170] In this case, the question is if the compulsory license expropriates the patent right, in which the patent right is either extinguished from the patent owner, or the patent owner no longer can enjoy the patent right in a meaningful way.

A granted compulsory license restricts the exclusive right of the patent owner: The patent owner cannot prohibit "the licensee" from using its patent without its authorization.[171] "The licensee" refers to the actual or legal person who has been granted a right to use the patented invention by national authorities. Furthermore, the restriction is limited to a specific applicant if the license is non-exclusive in accordance with TRIPS Article 31; the patent owner retains the freedom of contract towards other third parties. At first glance, compulsory licenses may not constitute neither a formal nor *de facto* expropriation of a patent right.

It can be argued that the very essence of a patent right is to effectively execute the negative right towards third persons. A compulsory license can be considered as an "expropriation" of the patent owner's right to stop the specific licensee from using its invention. As was observed above, one of the key functions of the exclusive right is the freedom of contract. The exclusive right of a patent owner can be said to have its reality towards each and every third party, in which a compulsory license deprives the patent owner's possibility to exercise its exclusive right towards the specific licensee. Additionally, it no longer retains the right to place on the market the specific products which the third party has manufactured.

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[169] See for instance *Sporrong and Lönnroth v. Sweden* para. 62.

[170] *Papamichalopoulos and others v. Greece* para. 43. The ruling seems to indicate that the entire property must become practically useless. See also Kjølbro (2023) p. 1366 with the cited case law; Jorem (2021) p. 89; *Guide on P1-1* (2022) p. 22. Although legal literature is not considered as a legal source for determining the meaning of a provision, the cited literature provide an observation based on an induction of case law.

[171] TRIPS Article 28 (1), which states that the patent owner can prevent third parties from certain acts relating to the patented subject matter.

However, this approach can be too formalistic. The facts of the case, and the contents of the specific license, will determine whether a compulsory license constitutes deprivation. If there are very few potential licensees, then a compulsory license may amount to a *de facto* expropriation. For the purpose of this thesis, it can be said that a compulsory license *may* constitute deprivation, albeit in very few circumstances. If member states comply with TRIPS Article 31, then a compulsory license is most likely not a deprivation of patent rights. Thus, the next question is whether a compulsory license can be considered as "controlling" patent rights.

The control-rule is provided for in P1-1 (2), where States can enforce such laws "as it deems necessary to control the use of property". The wording in "control the use of property" indicate that the property is still in the possession of the property owner, but its disposal is being limited by law. Such an interpretation is logical, since "control" cannot constitute a "deprivation". Otherwise, the deprivation-rule would become superfluous. Thus, the question is if a compulsory license constitutes a control with the patent owners' exclusive right.

The term "control" does not give any substantial guidance on the threshold. Case law from ECtHR evidences that the control-rule has been used for diverse situations.[172] Thus, the vagueness of the term "control" can indicate that any negative effect due to the State control is considered as an interference. A preliminary observation implies that a compulsory license constitute a "control" with the patent owner's exclusive right to enjoy its invention, since the compulsory license restricts the exercise of the exclusive right. The impact of a compulsory license will differ depending on the specific case. Nonetheless, the case *SIA AKKA/LAA v. Latvia* can provide some guidance on whether compulsory licenses normally constitute a "control" with patent rights.

SIA AKKA/LAA ("SIA") is a non-profit organization made by the Latvian Authors Association, consisting of various Latvian artists. SIA was tasked to manage the copyrights of the musical works of over two million artists, by entering into licensing agreements with broadcasting stations in Latvia. Many of these agreements expired between 1998 and 1999, and SIA was not able to reach new agreements due to the terms, especially on remuneration. As a result, some broadcasting stations used the protected works without an agreement, and without paying remuneration. SIA brought two civil cases before Latvian courts, and there were several claims brought up in these cases. Relevant for this thesis is that the Latvian Supreme Court ordered the parties to enter into license agreements. The reason behind this decision was that the parties were interested in entering into an agreement, but simply could not agree on the royalty rate. The Supreme Court also fixed the royalty rate.

[172] *Guide on P1-1* (2022) p. 23–24.

The ECtHR was to consider whether the obligation to enter into a license agreement was contrary to P1-1. The organization held that the Supreme Court decision amounted to a compulsory license. To this, the ECtHR held that the measure restricted the applicant's freedom to enter into contracts.[173] Thus, the ECtHR found that the obligation to enter into license agreements constituted a "control" of the use of property.

Although the case is about copyrights, it is nevertheless about economic rights deriving from an intellectual property. The ECtHR did not formally acknowledge the Latvian Supreme Court decisions as compulsory licenses, but this was perhaps not necessary. Numerous case law on the application of ECHR shows that the ECtHR has a dynamic approach to the Convention, and is more concerned with the realities of a situation than the label of a measure.[174] The judgement suggests that a compulsory license can be considered as a restriction of the key functions of the exclusive right: freedom of contract and the right to effectively prohibit a third party from using its invention. For this reason, a compulsory license can also amount to "control" with the use of a patent right.

It can be discussed whether all compulsory licenses only constitute control of an IP right due to *SIA AKKA/LAA v. Latvia*. However, the ECtHR did not name the measure in the case as a compulsory license, and the facts in that case where a bit special. The Latvian Court had ordered the parties to enter into an agreement, but did not set the terms of the license besides the royalty rate. In typical cases about compulsory licenses, the national authorities also determine the scope and contents of the license. It can nonetheless be concluded that a compulsory license will constitute control with the patent right rather than a deprivation, but it will depend on the facts of the specific case.

4.3.4 Justification of a compulsory license

An expropriation or control with a property right must be justified, in the sense that it must fulfill certain conditions in order not to breach CFR Article 17 and P1-1. The following text will give a general overview of the different conditions. For the sake of simplicity, I will refer to control and deprivation as just "interference". "Interference" in this thesis does not mean the principle-rule in the first sentence of P1-1, which is usually used when a state action does not naturally fit into the deprivation- or control-rule.

CFR Article 17 must be read in conjunction with Article 52 (1). A compulsory license must be provided for by law, pursue objectives of general interest recognized by the Union or needed to

[173] *SIA AKKA/LAA v. Latvia* para. 58, my emphasis.

[174] *Sporrong and Lönnroth v. Sweden* para. 63 and *Schembri and Others v. Malta* para. 29.

protect the rights and freedoms of others, be subject to the principle of proportionality, and respect the essence of patent rights.[175] Similar to P1-1, compensation must be paid to the patent owner if the compulsory license amounts to expropriation.[176]

The proportionality-test requires that the compulsory license must be appropriate, necessary and proportional *stricto sensu* (or a fair balance between the right to property and the right to health care, see below).[177] Although many cases on CFR Article 17 do not explicitly provide for this three-step test as far as I can see, these three steps are in line with how the CJEU assesses the general principle of proportionality.[178] The reference to the principle of proportionality in CFR Article 52 is general, and indicates that it must be given the same meaning as in TEU Article 5 (4) and case law. Thus, I assume that the proportionality test is the same and coherent in CFR and the Treaties.[179]

Furthermore, I find that the justification assessment under CFR provides a better protection of the right to property than ECHR. Case law from the ECtHR does not make it clear whether it follows a three-step proportionality test, or if it does a broad assessment of the interests at issue.[180] Case law on P1-1 shows that there must be a fair balance instead of a strict proportionality test.[181] The requirements of appropriateness and necessity are therefore just factors in the overall assessment, whereas they constitute conditions in the EU proportionality test.

The EU proportionality test under CFR also requires a broad assessment of the different interests at play, where the interests of the patent owner is weighed against other relevant interests. This is the *stricto sensu*-test, and the last step when considering whether an interference is proportional. I will apply the same factors as in the broad assessment under ECHR. Some relevant factors in the broad assessment is whether it is possible to review the national decision which grants the compulsory license,[182] remuneration,[183] procedural factors and other specific factors

[175] For instance C-220/17 para. 92–96. See also in this direction Christoffersen et al. (2018) p. 570.

[176] CFR Article 17 (1).

[177] See for instance C-580/21 para. 531, C-401/19 para. 65, C-97/21 para. 56, and C-331/88 para. 13

[178] The Court referred to the three-step test under CFR article 17 and 52 in C-580/21 para. 531. Case law on proportionality shows that the CJEU does not always assess the last step, see Harbo (2021) p. 327. Since ECHR P1-1 presupposes a broad assessment of different factors, I find it correct that the last step in the proportionality test applies when assessing if a compulsory license can be justified under CFR article 17.

[179] See also C-601/15 para. 54; Wollenschläger (2021) p. 510.

[180] Jorem (2021) p. 94, Harbo (2021) p. 341–344, and Kjølbro (2023) p. 1353–1354.

[181] See *Guide on P1-1* (2022) p. 30–39 for an overview of case law.

[182] See for instance *G.I.E.M. S.r.l. and others v. Italy* para. 302 and *Shorazova v. Malta* para. 105. See also *Guide on P1-1* (2022) p. 31–32.

[183] See for instance *The Holy Monasteries v. Greece* para. 71.

in the case concerned. Furthermore, the ECtHR has held that a measure (in this case, a compulsory license) is not proportional if "the person concerned had to bear a disproportionate and excessive burden".[184] I will use "fair balance" and *stricto sensu* interchangeably in this thesis, because I find that the exercise and the result is the same: The rights of the patent owner must be balanced against the need to protect health, which is also a principle in CFR. As a preliminary point, the safeguards in TRIPS operationalize the broad assessment.

CFR Article 35 entails the principle of health protection.[185] Member states must weigh the interests of the patent owner against Article 35.[186] I will not make a distinction between public health issues as a general interest or as a matter falling under Article 35. This is because the assessment is the same, at least in the context of patent rights against health concerns. Furthermore, member states seems to enjoy a wide margin of appreciation when addressing a public health concern, such as a pandemic or epidemic.[187] This means that member states have some freedom in assessing whether the compulsory license is justified, as the intensity of the judicial review is less stringent in such cases.[188]

Lastly, I will not discuss in detail what the essence of intellectual property is, and have not found any case law about this either. Considering that the CJEU has found that the essence of CFR Article 16 encompasses freedom of contract,[189] it can be assumed that the essence of intellectual property entails the main functions of IP as explained in chapter 2. This includes freedom of contract and the right to effective enforcement of the patent right.[190]

The following text will examine the safeguards provided for in TRIPS Article 31, and supply the safeguards with the conditions of lawfulness, public health concerns as a general interest and the principle of proportionality. The balancing of different interests will be shortly commented in chapter 4.8, since the safeguards in TRIPS can be understood as to operationalize this assessment. Before doing so, the next chapter will provide an extensive review of the implications of the principle of territoriality in the EU, especially concerning cross-border supply in the internal market.

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[184] See for instance *Hutten-Czapska v. Poland* para. 167.

[185] The Explanations to Article 35 refer to the entire Article as "principles". See by analogy C-176/12 para. 44–48; Christoffersen et al. (2018) p. 379.

[186] Explanations to Article 52 and C-547/14.

[187] *James and others v. The United Kingdom* para. 46. See also *Guide to P1-1* p. 29–30, Wollenschläger (2021), and Christoffersen (2018).

[188] Jorem (2021) p. 94.

[189] C-426/11 para. 35–36.

[190] For a discussion about the essence of IP, see Husovec (2019).

4.4 Principle of territoriality

4.4.1 Actions that necessitate authorization

Article 31 states that when the law of a member state "allows for other use" without consent from the patent owner, then certain safeguards must be satisfied. "Other use" is a reference to actions that constitute a patent infringement when authorization is not obtained from the patent owner. In such cases, it is necessary with a compulsory license. In order to map out what actions necessitate authorization within the framework of patent law, the exclusive right of the patent owner must be established.[191] The chapter reflects an important aspect of the principle of territoriality: a third party needs a compulsory license in every country where the patent is registered. The overall question is what the different patent–infringing actions entails, and how the principle of territoriality affects cross-border supply chains of companies in the EU, as was mentioned in chapter 2.

This chapter will discuss several questions. Firstly, it must be established whether the use of the patent must be done in a commercial context. Secondly, the different patent-infringing actions before placing the products on the market will be discussed. Lastly, exhaustion of patent rights will be shortly commented.

The different patent-infringing actions were explained in chapter 2. Article 28 (1) prohibits the following actions concerning patented products: "making, using, offering for sale, selling, or importing for these purposes that product". Since the list covers actions between making and selling the patented product, the aim seems to be to prohibit third parties from utilizing the patent as early as possible. Furthermore, the provision seems to prohibit actions which have a commercial potential.[192] On that note, a preliminary question is if patent infringement only takes place if the listed actions are done in a commercial context. "Commercial" in this thesis refers to activities with the aim of gaining economic profit, and does not refer to any legal concept of commercial activity. This is an important question when discussing compulsory licensing for the purpose of addressing a public health concern: companies or governments may for instance find it correct to donate medicines instead of selling them.

[191] For a more extensive understanding of the different patent-infringing actions, literature on national patent law can be recommended. Such works are more extensive and detailed than commentaries based on TRIPS. This chapter will not deal with national patent law in the different member states.

[192] A separate question is if private use of a patented protection is excluded from the exclusive right of the patent owner in TRIPS. This discussion is not relevant in this thesis, since the point is to discuss compulsory licensing for the purpose of addressing a public health concern. This thesis presupposes that only companies and governments will seek a compulsory license to address such concerns.

Article 28 is silent on this matter, and none of the other Articles in TRIPS part 2, section 5 explicitly addresses this question. The silence in the provisions can indicate that non-commercial use of the patent, with the aim of donating or giving the products for free, is also considered to infringe a patent. However, when interpreting a provision of TRIPS, it is important to consider the objectives of the agreement as well. Article 7 provides, amongst other things, that intellectual property "should contribute to the promotion of technological innovation" and be of advantage "in a manner conducive to social and economic welfare". When it comes to economic welfare, the provision seems to embody the economic explanation to the patent system.[193]. Therefore, due regard must be given to the economic function of patent rights, as was described in chapter 2.1.

It can be argued that since the patent system provides an economic advantage for the patent owner, then only a commercial "use" of the patent by a third party disturbs the exclusive right. However, this would be a narrow understanding of the economic perspective behind the patent system. The CJEU has held that "the substance of a patent right lies essentially in according the inventor an exclusive right of first placing the product on the market".[194] Although the referenced judgements came before the making of TRIPS, the passage confirm the overall economic rationale behind the patent system, and is therefore relevant when interpreting TRIPS provisions. Since the aim of patent rights is to make it lucrative to invest in new technology and incentivize innovation, the patent owner has the right to put its products on the market for the first time. Even if a product is made available to the market for free by a third party, the patent owner will miss the potential profit which originally should have contributed to the recoupment of his investments.[195] Thus, non-commercial activity can also disturb the economic advantage of the patent owner.

Furthermore, Article 31 (b) states that compulsory license can only be granted if the third party has made prior efforts of obtaining a voluntary license. The provision makes an exception for situations where a compulsory license is meant for public noncommercial use. A normal understanding of the wording "public noncommercial" indicates that the patent-infringing actions in Article 28 are provided to the public for a non-commercial purpose. "Noncommercial" means that the aim of the activity is not to earn a profit. Article 31 (c) also mentions public noncommercial use as a specific purpose for the compulsory license. If only commercial actions were caught by Article 28, then the reference to public noncommercial use in Article 31 would become illusory.

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[193] See in this direction Gervais (2021) p. 244.

[194] C-187/80 para. 9.

[195] The CJEU also explained that the point is to protect the potential profits of the patent owner: there is no guarantee that he will obtain a reward in all circumstances, see C-187/80 para. 10.

In addition, Article 26 about industrial designs explicitly states that the listed actions infringe the exclusive right "when such acts are undertaken for commercial purposes". For this reason, the silence about commercial use in Article 28 (1) appears to be intentional. Thus, the lack of any express requirement of commercial use in Article 28 (1), combined with the objectives of TRIPS as well as Article 31, strongly indicate that non-commercial use is also covered by Article 28.[196] The following chapter will include both commercial and non-commercial use of the patent by third parties.

Another point to keep in mind is that patent rights are *territorial*.[197] Thus, making and selling medicines are only considered to infringe a patent in those countries where the invention is registered. This is usually not a problem if manufacturing capacity is placed in the same country in which the medicines will be sold. However, many businesses have their supply chain spread out in different EU member states. The different components of a medicine or a vaccine could perhaps be produced in different factories in totally different countries, assembled and stockpiled in another, whilst sold in another country. Although the accuracy of this example can be challenged, it serves as a way to understand that supply chains can involve several countries within the Union. As will be observed in chapter 4.4.2, TRIPS and EU law does not allow a national compulsory license to have extraterritorial effects, in the sense that the license is valid in all EU member states. Thus, a license is needed in all respective countries where manufacturing and sale will take place.

Now that the nature of patent-infringing actions has been clarified, the specific actions concerning supply of medicines must be analyzed further. It is clear that producing and selling medicines is covered by Article 28 (1). If both of these actions take place in one country, then only one license is needed. However, if the manufacturing and sale of medicines happens in two separate member states, then the third party must seek a compulsory license in both countries. Cross-border supply chains in the EU raises several questions regarding the need for separate licenses. Supply chains usually involve other activities between the producing and selling of patented products. The most practical activities in terms of cross-border supply is physical transfer of products. Article 28 (1) explicitly names "importing" a patented product as an action falling under the exclusive right of the patent owner. The question is when "import" of products is considered to be a patent-infringing action.

[196] See in this direction Correa (2020) p. 289. Member states can limit the exclusive right to only cover actions by third parties in a commercial context, in accordance with Article 30 about exceptions to rights conferred.

[197] See chapter 2.

According to the wording of the provision, import is not a patent infringement *per se*: import is only considered an infringement if the purpose is to make, use, offer for sale, or sell a patented product. Import is therefore only a complementary action. As explained above, Article 28 (1) seems to make it possible for patent owners to prohibit third parties from actions which may lead to placing products on the market.[198] If a patent owner has knowledge of a company that imports medicines from third countries for the purpose of selling them in an EU member state where the patent is registered, then the patent owner does not have to wait until the products are put on the market. By this, the patent owner can prevent the economic damage from happening.

A specific question arises in terms of importing medicines for the purpose of donating medicines to an EU member state. The question is if import of patented products for the purpose of donating them is a patent-infringing action. As mentioned, import of patented products only infringe a patent when the purpose is to produce, use, offer for sale or sell the product. The list does not include donations. It has already been established that Article 28 (1) considers any of the listed actions as infringing a patent when done for noncommercial purposes as well. Donation is a noncommercial purpose, since the aim is not to gain any profit from the activity. However, a distinction must be made between donations *per se*, and noncommercial *purposes* concerning the listed actions. As will be examined below, the list of patent-infringing actions in Article 28 (1) is exhaustive. Since donations is not listed as a patent-infringing action, import for the purpose of donating products does not infringe a patent. Regardless, donations presuppose use of the products. Since "use" infringes a patent, donations can be impractical.

There are also other activities involved when supplying medicines through a cross-border supply chain. Three actions will be discussed: export, transit and stockpiling. In order to find out whether these actions can infringe a patent, it must be established whether the list of actions in Article 28 is exhaustive.

The wording of Article 28 indicates that it is indeed exhaustive. It first states that "a patent shall confer on its owner the following exclusive rights". Furthermore, it describes that the patent owner can prevent third parties "from the acts of", and then proceeds to list different actions with a full stop at the end. The provision does not use phrases such as "amongst others" and "or similar actions". Thus, the wording strongly indicates that the list of patent-infringing actions is exhaustive.

[198] This does not mean that the third party must have engaged in the listed actions with the purpose of placing the patented products on the market. This is because the listed actions, excluding import, infringe a patent *per se* – regardless of the purpose. The point is rather to prohibit any potential placing on the market, and to protect the creative effort of the patent owner according to the natural law perspective on the patent system.

As for the objectives of TRIPS, Article 7 states that the protection of intellectual property must be balanced with other rights and obligations, and that it should contribute to social and economic welfare. Article 7 is illustrative of the fact that patent rights are not absolute rights, as was observed in chapter 2. It is possible to argue that the balance between the interests of the patent owner and social interests can be achieved through other means, and therefore allowing a more extensive exclusive right to begin with. Two examples of such means are compulsory licensing in Article 31, and the possibility to limit the extent of the patent right in Article 30.

However, a more extensive right conferred to the patent owner can be contrary to the aim of social and economic welfare. Since a patent in fact is new knowledge or information, then it is essentially a common good. The society must benefit from new information, but also carefully balance the interests of the patent owner. Since the list of actions in Article 28 covers the most important actions regarding using and placing patented products on the market, the list itself can be understood as providing an extensive protection to the patent owner. Furthermore, a restrictive reading of Article 28 is makes it possible to meet the common objectives in Article 7 and the overall aim of the patent system: to incentivize innovation without severely restricting the free use and enjoyment of new knowledge in society.

Both the wording of TRIPS, combined with Article 7 and economic theory behind the patent system strongly indicate that the list of actions in Article 28 (1) is exhaustive. Correa also supports this interpretation, explaining that "the granting of exclusive rights represents a drastic derogation to the principle of free access and usability of knowledge as a public good".[199] He holds that Article 28 (1) should be interpreted narrowly for this reason.

Since the list of actions in Article 28 (1) is exhaustive, export is not considered as a patent-infringing action. This is because manufacturing and sale of patented products infringe the patent – and these activities would have to take place before the export. Chasing export as an independent patent-infringing action would therefore be impractical. This is important to note, given that Article 31 imposes limits to export of patented products, see chapter 4.4.3.

As for transit, Article 28 (1) makes no reference to this action. Thus, it cannot be considered as a patent-infringing action. It can be argued that transit is "import" in a strict sense: the products are brought into the territory of a member state, albeit for a limited time. However, import does not infringe a patent *per se.* Since the purpose of the transit is not to use or sell medicines in any of the countries it is passing by, it does not amount to a patent-infringing action.

[199] Correa (2020) p. 289.

Article 28 (1) does not mention stockpiling or storing of patented products either. The explanation is the same as to why Article 28 (1) is exhaustive: the listed actions are sufficient to protect the interests of the patent owner. There will most likely be a patent-infringement prior to the stockpiling, which is why it would be superfluous to prohibit this action. As an additional point, the drafting history of the provision shows that the parties deliberately left out stockpiling from the wording.[200] Although travaux préparatoires have limited importance when interpreting TRIPS provisions according to VCLT Article 32 (and EU law in general), the drafting history supports the finding that stockpiling does not infringe a patent. Thus, a third party does not need a compulsory license if it only stockpiles medicines in one member state before exporting them to another.

In conclusion, the list of actions in Article 28 (1) is exhaustive. Therefore, actions such as export, transit or stockpiling do not necessitate a compulsory license according to TRIPS. This is useful information for third parties who have cross-border supply chains in the EU.

The discussion until now has only concerned itself with patented products which are not yet placed on the market. In EU primary law, intellectual property rights to a physical exemplary of a product are exhausted after the first placing on the internal market.[201] This means that the patent owner cannot invoke patent infringement after he has willingly placed the products on the market. This is due to the free movement of goods, where intellectual property rights essentially act as trade barriers.[202] Third parties can therefore obtain medicines already available on the internal market in order to resell them. However, the rules on exhaustion do not apply when the patented products have been placed on the market due to a compulsory license.[203]

This chapter has concerned itself with patent-infringing actions in TRIPS. Since the matter of infringement is not harmonized in EU law, the specific patent-infringing actions must be considered according to the legislation in each member state. However, the Unitary Patent system will launch in June 2023. With the possibility to register a European patent with unitary effect in 25 of the participating EU member states, the rules on patent infringement will be common for such patents. The question is what actions are considered to be patent-infringing according to the Unitary Patent system.

Article 25 in Agreement on a Unified Patent Court ("AUPC") states when the patent owner can prevent third parties from directly using their invention. The provision considers the following

[200] The drafting history is provided for in Gervais (2021). See pages 463–464: draft of 23 July 1990 (W/76), draft of 1 October 1990, and draft of 25 October 1990.

[201] C-19/84 and C-539/13 para. 24 with the cited case law.

[202] TFEU article 36, see for instance C-147/20 para. 46–47; C-191/90 para. 22–23; C-187/80.

[203] C-19/84.

actions to infringe a patent: "making, offering, placing on the market or using a product which is the subject-matter of the patent, or importing or storing the product for those purposes". In addition to use of processes, the provision also provides for indirect product protection. "Placing on the market" can be understood as "selling" in TRIPS Article 28 (1). The interesting part about this provision is that it includes storing as a patent-infringing action, if the purpose is making, offering, placing on the market or using the product. Thus, when the Unitary Patent System launches in June 2023, third parties must also be aware that storing patented products might be problematic. However, for a third party who seeks to produce and sell medicines, the prohibition against storing is of limited significance. The company still has to apply for a license concerning the production, importing and sale of the medicines.

In conclusion, this chapter evidences that the same company might have to apply for a compulsory license in different EU member state, even though the purpose might be to supply one specific country. Although export, transit or stockpiling of patented products do not infringe a patent, national legislation might prohibit these actions.[204] One can wonder whether the leeway to provide a more extensive protection of the exclusive right in national legislation is limited, due to the reasons why the list in Article 28 (1) is exhaustive. Adding more patent-infringing actions to the list in national legislation might impair the balance between the aim of the patent system to incentivize innovation, and the economic understanding of knowledge as a public good, see Article 7 and Article 1 (1). The same can be said about AUPC Article 25, which includes "storing" as a patent-infringing action. However, I will not dwell on this matter any further.

The complexity of the patent system, where different actions might infringe the exclusive right depending on the member state in question, can be challenging for a company to handle. Furthermore, the requirement of predominantly supply to the national market makes it even more challenging to make use of compulsory licenses. This point will be discussed in chapter 4.4.3.

4.4.2 Issuing member state: geographic jurisdiction

It has already been established that patent rights are territorial in chapter 2, in which a patent owner can only prohibit actions within the territory where the patent is registered. The principle of territoriality is inherent in the patent system.[205] If the patent is registered in several EU member states, then a third party must apply for a compulsory license in every country where the use of the invention might infringe the patent. This chapter will mainly address two questions.

[204] The rules on enforcement of intellectual property are harmonized in Directive 2004/48/EC. See Article 2 (1) about the scope, where it is held that the directive applies to any infringement of IP provided for in EU law or national law of the member state concerned. The directive does not concern itself with what actions are considered to infringe a patent.

[205] See chapter 2.

Firstly, it will be discussed whether a national compulsory license can have EU-wide effects. Secondly, the Commission Proposal concerning an EU-wide compulsory license will be discussed.

The need for separate licenses in a cross-border supply can be time-consuming, challenging, and lead to unwanted results. If one member state refuses to grant a compulsory license, then the entire production might stop, even if the license was granted in the other member states. Additionally, the rule about predominant national supply can make it almost impossible to execute a compulsory license in the case of a cross-border supply chain, as will be observed in chapter 4.4.3. Thus, the question is whether a national compulsory license can cover the internal market of the Union. This is a matter of whether the principle of territoriality in TRIPS means that a national compulsory license only can address a national patent.

The principle of territoriality as has been known so far, primarily deals with national borders. A reading of different provisions of TRIPS can explain how the agreement addresses the principle of territoriality. Article 1 (1) provide that "Members shall give effect to the provisions of this Agreement". Article 31 states that when "the law of a Member" allows for other use, and Article 31 (f) states that the compulsory license must be used to predominantly supply the domestic market "of the Member authorizing such use". These provisions indicate that patent rights are contained within the borders of where the patent is registered. Since it is not possible to register an EU-wide patent right as of May 2023, such rights only have a national dimension in the Union.

However, the term "Member" in TRIPS indicates that it refers to the contracting parties of the WTO agreements. TRIPS was originally concluded as a mixed agreement, as was observed in chapter 3. Thus, both the EU itself and the individual member states have signed the agreement. With the changes brought by the Lisbon Treaty, the Union was given exclusive competence over TRIPS – thereby making the signatories of the member states illusory from the perspective of EU law. The change in competence can make one wonder whether the term "Member" must be understood as the entire Union, in which the principle of territoriality refers to the internal market. A consequence of such an interpretation is that a national compulsory license will apply in the other member states as well. This also raises the question of whether there is sufficient legal basis in EU law to give a national compulsory license EU-wide effects.

The wording of the different provisions in TRIPS do not support such a finding. A combined reading of Article 1 with Article 31 provides that the member who has provided for patent rights, is responsible for giving the legislation effect within its territory. This also means that the authority who has provided for a compulsory licensing regime within its territory, can only issue a compulsory license that has domestic effects. The Union has not provided for an EU-

wide effect of national compulsory licenses, and has yet to legislate on compulsory licenses issued by an EU institution. Although the Commission has proposed a regulation for an EU-wide compulsory license, it is not adopted yet.[206] Thus, compulsory licensing regimes are completely national in the EU, and cannot have extraterritorial effects by covering the internal market. A contrary answer would meddle with the sovereignty of the member states.

It can be argued that TRIPS itself can constitute a sufficient legal basis for allowing a national compulsory license to have EU-wide effects. This argument is based on the thought that the actions of a specific member state must be understood as the actions of the Union, in relation to TRIPS. However, the right to property in CFR Article 17 provides that a limitation in the exclusive right of a patent owner must be prescribed in law. As will be observed in chapter 5.4.2, the legal basis "must itself define, clearly and precisely, the scope of the limitation on its exercise".[207] A compulsory license which has effects in the entire Union, severely limits the exclusive right of a patent owner, since its patent rights are registered individually in different member states.[208] No provision in TRIPS part 2 chapter 5 expressly provides that a national compulsory license is valid in all EU member states. Therefore, TRIPS itself cannot be regarded as being a sufficient legal basis.

In addition, the Union being the sole party to TRIPS on behalf of the member states is only relevant in terms of *external* action. The external competence under the CCP means that only the EU votes in the WTO in regards to TRIPS, and only the EU is internationally responsible if a member state breaches a provision of TRIPS. It is not meant to disturb the shared internal competence over intellectual property, in which the member states retain the right to legislate on patent law according to the principle of subsidiarity in TEU Article 5 (3). Since the Union has not provided for an EU-wide compulsory licensing regime, the member states are responsible for legislating on this matter. Thus, the effects of a compulsory license is contained within the borders of the member state who has issued the license.

Case law from the CJEU supports the abovementioned findings. The rules on exhaustion reflect that IP rights are contained within the national borders of a member state. Since IP rights can act as potential barriers to free movement of goods in the internal market, the rights are exhausted when they are placed on the market in a member state. In C-19/84, the Court held that

[206] COM(2023) 224 final.

[207] C-265/19 para. 86 with the cited case law.

[208] This argument relies on a presumption that a patent owner has wished to protect its invention in all of EU, or at least several member states. This is not given: some patent owners may not find it necessary to protect its invention in more than one country. In such a case, the question of extraterritorial effects of a compulsory license becomes irrelevant: third parties can freely use the invention in the other countries where the invention is not patented.

patent rights are not exhausted if patented products are placed on the market due to a compulsory license. This means that the patent owner can invoke patent infringement in the other EU member states where the patent is registered, and a third party has used the invention in these countries. The judgement affirms that a national compulsory license does not have EU-wide effect. Although this case came before the making of TRIPS, it underlines the attitude of the Union regarding the principle of territoriality: patent rights and compulsory measures only have an effect within the territorial borders they are provided for.

The conclusion is that national compulsory licenses do not have EU-wide effects. This is because EU law does not provide a sufficient legal basis for such effects.

The discussion so far has been about national patents. Due to the principle of territoriality envisaged in TRIPS, national compulsory licenses concerning *national* patents cannot have EU-wide effects without a sufficient legal basis saying otherwise. The same cannot be said about the Unitary Patent system. The question is whether the introduction of the Unitary Patent will have as a result that compulsory licenses can be given EU-wide effect. According to the Unitary Patent Regulation Article 3 (2), a European patent with unitary effects "may be licensed in respect of the whole or part of the territories of the participating Member States". The question is if "licensed" only refers to voluntary licensing, or if it also includes compulsory license. If the wording includes both types of licenses, then a national compulsory license decision might be given extraterritorial effects, within the territory of the 25 member states who are parties to the Unitary Patent system.

The legislative framework of Unitary Patens does not contain any provisions regarding compulsory licensing, and the UPC is also not given any competence to issue a compulsory license. Rather, the preambles of the Unitary Patent Regulation state that "[c]ompulsory licences for European patents with unitary effect should be governed by the laws of the participating Member States as regards their respective territories".[209] Thus, the Unitary Patent system leaves the question of compulsory licenses to national legislation. A national compulsory license concerning a Unitary Patent can hardly have effect in the 25 participating member states. This is because the framework about the Unitary Patent does not comment on the question of compulsory license, and therefore cannot constitute a sufficient legal basis for allowing extraterritorial effects. Although the license will concern a patent which has extraterritorial effect, the matter of compulsory licenses is not governed by the legislation. It can therefore be concluded that a national decision concerning a compulsory license only has national effects, regardless of whether the patent is national or with unitary effects.

[209] Preambles para. 10.

The Commission has proposed a regulation which gives it authority to issue an EU-wide compulsory license.[210] The license can address both national and Unitary Patents. The question is if TRIPS allows the Commission to provide a compulsory license concerning a national patent, considering that it is the member state in question that has provided for this patent right.

It can be argued that the principle of territoriality means that only the authority who has provided for a patent right, can issue a compulsory license concerning the patent. This means that only member states can issue a compulsory license concerning a national patent, whereas the Commission can only deal with Unitary Patents. However, TRIPS does not seem to provide such an understanding of the principle of territoriality. As discussed above, "members" in TRIPS refers to the WTO members. In terms of EU law, only the EU is considered as a member of TRIPS. Therefore, the member states are identified with the EU: and national territory is identified with the internal market. The only reason why national decisions granting a compulsory license do not have EU-wide effects, is because there is no legal basis for this. The Commission has competence under TFEU Article 26 and 114 to provide harmonizing rules on the internal market, and can therefore legislate on an EU-wide compulsory license. The principle of territoriality does not seem to act as a barrier to the proposal.

The point is that as of now, there is no legislation that allows a national compulsory license to have effect in the entire Union. The principle of territoriality must be understood as giving patent rights effects within the borders of the authority which has provided for the patent rights to begin with. It also means that the effects of compulsory license based on national law is contained within this specific member state. It is up to the EU to provide rules on EU-wide compulsory license, either by allowing national compulsory licenses to be valid in the entire Union, or by authorizing the Commission to issue such licenses.[211] The Commission has proposed the latter solution.

4.4.3 Supply of national market as a main rule

TRIPS Article 31 (f) entails a safeguard specifically concerning the geographical scope of the use of a patent: "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use". As was established in chapter 4.4.1, export of patented products is not a patent-infringing action. The rule of national supply is therefore not an expression of the exclusive rights of the patent owner, but rather a safeguard meant to limit

[210] Commission Proposal COM(2023) 224 final.

[211] The secondary legislation has to satisfy the principle of proportionality and the right to property in CFR. This means that the legislation somehow must be limited in scope, or in other ways compensate for the further limitation of a patent owner's exclusive right.

the scope of a compulsory license. This safeguard could therefore have been discussed in chapter 4.6 about the contents of the license, but I find it suitable to discuss this condition here, as it is closely connected to the principle of territoriality. The rule on national consumption shows that the use of a compulsory license is also limited to the country where the patent is registered, and where the "use" will take place.

Article 31 (f) states that the license must be "predominantly" used to supply the domestic market. An everyday-language understanding of "predominantly" suggest that not the entire production must be supplied to the national market. There seems to be an opening for exporting products, but the wording makes it clear that supplying foreign markets cannot be the main purpose of the license.[212] Export as the main purpose of the license is regulated by Article 31bis, which is an exception to the rule of predominant supply to the domestic market. This exception does not apply for EU member states, since they are not considered as eligible importing countries.[213] Therefore, a member state can only rely on Article 31 (f) to grant a compulsory license to export some medicines to another member state.

The wording gives little guidance on what exactly constitutes "predominantly", and whether it must be understood as communicating the special needs of a member state. On that note, the first question is if the provision requires that national needs must be covered before any export can be allowed.

The rule about national supply must be read in the context of Article 31 (c), which provides that the scope and duration of the license must be limited to its purpose. Since export cannot constitute the main purpose of the license, there must be some kind of a need in the domestic market. The domestic needs can amount to either addressing public health concerns, or in a wish of building local industry. The quantity produced under the license must therefore be adjusted accordingly: Only the necessary amount to cover national needs can be produced. Since public health concerns in another member state is also a general interest pursued by the Union, see chapter 4.5.4, the license may allow for an extra quantity to be produced in order to export them. The size of the quantity will be discussed below.

The next question is how much of the supply is considered to be "predominantly". This is a question of which parameters the amount of supply is to be calculated by in order to ascertain how much can be exported to other member states.

[212] See also in this direction Correa (2020) p. 311 and Gervais (2021) p. 499.

[213] Annex to the TRIPS Agreement para. 1 (b), footnote 3.

The wording of the provision strongly indicates that it refers to a quantitative threshold of the total supply under the license agreement. In order to understand what the total supply will be under the license agreement, the national authority must consider the specific application and the grounds applicable to issuing a license. In terms of addressing a public health concern, a compulsory license for the purpose of supplying the national market can be issued for producing a fixed amount of medicines within a certain timeframe. In this case, it is easy to predict what the total supply of the products will be.

In the case of a pandemic, it might not be easy to ascertain what the total production under the license would be. One way of interpreting "predominantly" when it is not possible to pre-determine the total supply, is that only the surplus may be exported. This could be the case if the third party overestimates the amount needed. The surplus of the production would be established after the public health concern ends in the country in question. This way, it is also clear that the main purpose of the license was to supply the national market. Additionally, member states may calculate extra medicines for the purpose of addressing a public health concern in another member state, which is a general interest pursued by the Union – as long as most of the production is not exported.

As to the exact threshold, the wording provides little guidance. It is possible to understand "predominantly" as a reference to a percentage or similar ratios.[214] The wording indicates that the lower threshold cannot be less than 50%. As for the interval between 50% and more, the provision seems to give the members freedom to determine the exact threshold. Neither the context nor the objectives of TRIPS gives a detailed answer to this question.[215]

4.4.4 Challenges with the territorial conditions

Territoriality is an inherent feature of the patent system, and the territorial restrictions are due to the sovereignty of states: One member state cannot decide what rights a person can have in another state. The national limitations of the patent system has become apparent in a globalized trade, and especially in the internal market of the EU. The problem is reinforced by the rule about predominant national supply, which is a challenge for companies with cross-border supply chains. This provision makes it clear that the compulsory licensing rules presume that

[214] See in this direction Correa (2020) p. 311, who mentions the possibility of interpreting "predominantly" as referring to net sales or income under the license. However, the wording gives no guidance as to whether it can be understood like this. Rather, "predominantly for the supply of the domestic market" most likely refers to the quantity produced and placed on the market in the member state in question, as has been explained in this chapter.

[215] The Commission Proposal Article 5 (1) (e) and Article 11 state that the license is limited to the Union, and all export is prohibited. The proposal elevates the protection of the patent owner than what is provided for in TRIPS, but also makes it seamless to address a Union-wide crisis.

manufacturing capacity is placed in the issuing member state. The reality is rather that the manufacturing capacity is placed in a few countries.

If a cross-border supply chain involves two countries, then the rule about predominant supply means that only a limited amount of the total supply under the license can be exported to another country. This constitutes a challenge to address the public health concern in the country where the license is mainly sought for.

The matter becomes even more complicated if the supply chain involves more than two countries where the patent-infringing actions take place. As was observed in chapter 4.4.1, "making, using, offering for sale and selling" are *per se* patent-infringing actions. If a third party engages in any of these actions in different countries before selling them to one specific member state, then a compulsory license is necessary in all relevant countries. The requirement of predominant national supply makes it almost impossible to reach the destination member state where the medicines are meant to be sold – especially given that there must be a need for the license in every country.

Furthermore, neither TRIPS nor other EU law has a coordination mechanism between member states, if they receive an application for compulsory license from the same third party, concerning the same patent. A lengthy application process in one member state may affect the entire supply chain, and delay the supplying of medicines. This can especially become a challenge if a compulsory license from one country only is valid for a short time. As will be pointed out in chapter 5, I find that the Union should provide a solution for the lack of coordination.

4.5 Safeguards prior to granting a compulsory license

4.5.1 Legal basis for a compulsory license

TRIPS Article 31 states that when the law of a member state allows for other use of the patent, then certain safeguards must be satisfied. "Law of a member" communicates two messages. First of all, it says that member states are not required to provide for a compulsory licensing regime in national law. Secondly, a compulsory licensing regime must have a legal basis in the respective member state. Three questions will be answered in this chapter. The first question concerns what a sufficient legal basis is under TRIPS. The second question is if CFR Article 17 places any additional requirements regarding the legal basis. Lastly, I will comment on whether EU law places requirements regarding the implementation of TRIPS provisions when they are transposed to national law, similar to the conditions regarding transposition of secondary law.

A normal everyday understanding of "law" in TRIPS Article 31 indicates that at least written legislation satisfies the condition of sufficient legal basis. The question is if "law" also encompasses non-written documents such as case law, and other legal documents such as travaux préparatoires.

The wording of Article 31 provides no answer. When interpreting the term "law" in Article 31, due regard must be given to Article 1 (1) last sentence, which states the following: "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice".

Article 1 (1) gives member states a wide flexibility in how the agreement must be implemented in their national legal systems. The provision seems to demand that the agreement must be implemented in such a way as to give the contents *a legal reality*, in the sense that it actually creates enforceable rights and obligations within the national legal system. This is because the first sentence of Article 1 (1) establishes that member states "shall give effect to the provisions of this Agreement". The case *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* also underlines this interpretation. India had implemented Article 70 (8) by administrative instructions. The Appellate Body found that the implementation was insufficient, as the instructions were contrary to the Indian Patent Act. Thus, an Indian court could overrule the instructions if a competitor of the inventor challenged the patent application.[216] The case highlights that the method for implementation must give the agreement a legal reality in the WTO member.

Otherwise, the provision does not name specific methods for implementation, and does not demand any qualitative requirements for the national legal basis for granting a compulsory license.

However, as was described in chapter 3.4.2 and 4.3, member states must respect the right to property in CFR Article 17 when issuing a compulsory license. The question is if the right to property places additional requirements regarding the legal basis of the granting of compulsory licenses.

CFR Article 17 (1) and ECHR P1-1 use the following phrases to describe the condition of lawfulness: "provided for by law", "regulated by law", and "enforce such laws". The ECtHR has held that this condition is based on rule of law, and must be understood in the same way as in other ECHR-provisions which allows for an interference of the specific human right.[217] An

[216] Para. 63 and 69–71.

[217] *Lekić v. Slovenia* para. 94–95.

everyday understanding of the wording implies that there must exist a legal basis in the national legal system of the member state in question. Secondly, the ECtHR's reference to rule of law implies that the legal basis must be correct and not amount to arbitrariness. Thus, the analysis of whether there exists a sufficient legal basis, can be done by using a two-step test. The ECtHR has not explicitly provided for such a test, but I find it correct given the wording of the provision and case law. The first test is about finding out whether the basis for a compulsory license is recognized as a legal basis in the domestic legal system of the member state in question. If the answer is yes, then the second test requires the legal basis to satisfy certain qualitative criteria. Both of these tests will be explained respectively.

According to the case law of the ECtHR, "law" means that there must exist a "legal basis in domestic law".[218] Domestic law must therefore consider the acclaimed "law" as a proper legal basis. This condition can be explained by the ECtHR's reference to rule of law, in which an interference with a human right cannot be done arbitrarily.[219] If the legal system of a member state does not consider case law as a binding legal instrument, then it does not constitute "law" in the sense of CFR and ECHR. The first step of the test can be understood as to rule out obvious breaches of rule of law, where the member state in question did not have any legal basis for their decision about a compulsory license.

Thus, "law" in the context of CFR must be understood as Union law, and national law which implements Union legislation. This would at least cover any binding act in the EU legal order such as: the Treaties, regulations, directives, decisions and international agreements of the Union. As for national legislation which implements Union law, the member states have different legal systems, and therefore different approaches as to what constitutes binding law. Whether the first step of the test is satisfied, relies on an interpretation and understanding of a member state's legal system.

When it is established that the compulsory license indeed has a legal basis in national law, then the task in the second step is to ascertain the qualitative requirements of the legal basis.[220] A preliminary question is if only formal legislation is recognized as a sufficient legal basis for an interference of the right to property.

[218] *Vistiņš and Perepjolkins v. Latvia* para. 96.
[219] Ibid.
[220] Ibid.

As previously noted, the member states have different legal systems. This means that even if one country regards a certain instrument as a source of law, another country might think contrarily. The ECtHR has therefore established that the concept of "law" comprises statutory and case law.[221] Thus, there is no requirement that a compulsory license must be prescribed in formal legislation. The CJEU has not placed any additional requirements on national legislation other than what is provided for by the ECtHR, as far as I can see.[222]

Rather, the ECtHR has expressed that the legal basis must be "sufficiently accessible, precise and foreseeable in their application".[223] The CJEU has similarly held "the interference with that right *must itself define, clearly and precisely, the scope of the limitation on its exercise*" (My emphasis.)[224]

Both judgements read in conjunction require that the legal basis must be accessible, clear and precise in their scope, as well as foreseeable in their application. This requirement can also be said to be rooted in the rule of law. In terms of the scope of the limitation, the CJEU has pointed out that the basis for calculating the remuneration must be clearly provided for in the legal basis.[225] This rule is important if the interference amounts to deprivation given the facts of the case, in which the patent owner must be granted a compensation. Thus, it is clear that CFR Article 17 is stricter concerning the legal basis for granting a compulsory license than TRIPS.

It has now been established that whilst TRIPS Article 31 only requires its provisions to have a legal reality in the member state in question, CFR Article 17 also requires the legal basis to be of certain quality. A member state may not comply with CFR Article 17 if they only rely on the implementation rule in TRIPS, since the quality of the legislation can be contested. If the legal basis does not meet the criteria laid down in CFR Article 17, then the compulsory license is not justified under any circumstances. A lack of sufficient legal basis cannot be repaired by the proportionality-test, since it constitutes a separate and absolute condition.[226]

The next question is whether there are additional requirements in EU law regarding the implementation of TRIPS in national law. This question raises the issue of how international agreements must be given effect within domestic legal orders, in order to comply with TFEU Article 216 (2) and the principle of sincere cooperation in TEU Article 4 (3). The case law regarding

[221] *Špaček, s.r.o. v. the Czech Republic* para. 54.

[222] See in this direction Peers and Prechal (2021) p. 1626.

[223] *Lekić v. Slovenia* para. 95 and *Vistiņš and Perepjolkins v. Latvia* para. 97.

[224] C-265/19 para. 86 with the cited case law.

[225] C-235/17 para. 126–127.

[226] See in this direction Peers and Prechal (2021) p. 1634 about T-187/11.

implementation of EU acts mainly concern secondary legislation. The CJEU has for instance held that directives must be transposed in a clear and transparent framework, and usually not accepted implementation through travaux préparatoires or by administrative instructions.[227] However, TRIPS is not secondary legislation, but rather has primacy over them. The matter of implementation seems to rely on TRIPS itself, supplied with the requirement of a sufficient legal basis in CFR.

4.5.2 Eligible licensees

In order for a license to be issued, someone has to apply for a compulsory license. Article 31 does not state who the applicants must be. Rather, the provision provides that governments or third parties authorized by the government can use a patent without consent from the patent owner. Thus, both public and private entities can apply for a compulsory license.

In the case of governments, the first question is if only the government itself can use the patent, or if it can be interpreted as any official body of the state. The wording simply states when the law of a member allows for other use without consent from the patent owner, "including use by the government or third parties authorized by the government", then the safeguards in the provision must be satisfied. "Government" can either exclusively refer to the executive power of a member state, or be understood as any official body of the State. The term itself does not give any answers as to which alternative is correct. "Including" indicates that the named entities are merely examples of who can use the patent. Thus, "government" can be understood as any official body of the member state, including the Parliament, judicial courts and administrative bodies.

The phrase "third parties authorized by the government" refers to any non-governmental bodies, since the government must authorize the use. The provision does not specify who these third parties can be. The silence of the wording indicates that both legal and actual persons can apply for the license.

As for the qualifications of these third parties, the provision is also silent on this matter. It is possible to think of scenarios where a third party very obviously does not have the expertise to produce or use the patented invention. A third party may also be financially unstable, in which there can be uncertainty as to whether the third party will be able to fulfill the license by supplying medicines to an EU member state. This is matter of the appropriateness of granting a compulsory license, and will be discussed in chapter 4.5.5.2.

[227] See for instance C-206/16 para. 41 and 46; C-143/83; Fredriksen and Mathisen (2022) p. 400–401 with cited case law.

4.5.3 Subject of the application

It is natural that the subject of the application must be the patent which the third party intends to use. This includes a product patent, process patent and products derived from a patented product, see Article 28 and chapter 2. A single patent application may also cover multiple patents.[228] On that note, the granting of a compulsory license only authorizes the third party to use the patented subject matter, and does not entail the sharing of know-how and trade-secrets from the patent owner. This can become a problem in the case of complicated vaccine-technology, such as the mRNA-vaccine.[229] Even if a third party can apply for a license, they may not be able to actually produce the vaccines due to the difficulties with not having access to know-how. This matter will be discussed in chapter 4.5.5.2 and 4.9.

4.5.4 Purpose and objectives of the license

A compulsory license can only be issued on eligible grounds. A meaningless license will always be unjustified and disproportional in the eyes of CFR Article 17. Since the topic of this thesis is access to medicines during public health concerns, the question is if public health concerns are an eligible ground for a compulsory license. As was observed in chapter 4.3.4, CFR Article 35 entails the principle of health protection. However, the scope of this Article is difficult to ascertain. The point of this chapter is therefore to highlight that public health concerns also constitute a general interest recognized by the Union. Two questions will be answered. The first question is whether public health concerns is generally an eligible ground for granting a compulsory license, and whether the concerns must be limited to specific diseases. The second question is whether public health concerns in *other* countries also is an eligible ground. Both of these questions will discuss TRIPS and secondary law before CFR.

TRIPS Article 31 does not contain any eligible grounds for a compulsory license. Rather, some examples are provided in the provision. Thus, the entire provision read in conjunction indicates that member states have freedom in determining grounds for issuing a compulsory license. This understanding is highlighted by the fact that countries can choose to have a compulsory licensing scheme in national law, and that Article 31 only imposes safeguards to ensure that compulsory licenses are proportional to the aim. Article 31bis (5) provides context to Article 31, and underlines this interpretation by referring to the Doha Declaration on the interpretation of TRIPS: Paragraph 5 (b) of the Declaration confirms that member states are free to determine the grounds for a compulsory license. It can therefore be concluded that any public health concern is an eligible ground for a compulsory license under TRIPS Article 31.

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[228] The Commission Proposal Article 2 encompasses patents, utility models and supplementary protection certificates. The subject matter of the license is therefore broader. The products produced under an EU-license must be "crisis-relevant" products.

[229] Gaviria and Kilic (2021).

As discussed in chapter 3.4.2 and 4.3, member states must respect CFR when granting a compulsory license. This means that CFR may confer more strict safeguards than what is provided for in TRIPS. According to CFR Articles 17 and 52 (1), a compulsory license must "genuinely meet objectives of general interest recognized by the Union". The question is if a public health concern is a general interest recognized by the Union.

The explanations to CFR clarify that the general interests can be found in both TEU Article 3, and other provisions in the Treaties which communicate specific interests.[230] Public health is addressed in TFEU Article 168, which states in first paragraph that "[a] *high level of human health protection* shall be ensured in the definition and implementation of all Union policies and activities".[231] The second paragraph of the provision among other things expresses that Union action shall be directed towards improving public health, preventing diseases, obviating sources of danger to physical health and cover 'the fight against the major health scourges". The provision strongly suggest that public health concerns, such as an epidemic and a pandemic, is a general interest recognized by the Union. In addition, TFEU Article 9 also provides that the Union must take into account the protection of human health when defining and implementing its policies and activities. TFEU Article 36 lists protection of health and life of humans as a reason for limiting the free movement of goods. Public health is also a reason for limiting the free movement of workers and establishments in TFEU Article 45 (3) and Article 52. It is clear that the Union recognizes member states' measures for addressing national public health concerns. Case law from CJEU also underlines this interpretation.[232]

The listed provisions in the Treaties do not list what diseases are covered under public health concerns, but rather seems to provide for a broad interpretation. Thus, it can be assumed that most diseases and health concerns are general interests recognized by the Union. In addition, the Treaties do not seem to require that the public health crisis constitute an emergency, as prevention of diseases is covered by TFEU Article 168 (2). This understanding is in line with P1-1, which constitutes the minimum protection. The ECtHR has held that the notion of "general interest" is extensive, and it is for the member states "to make the initial assessment as to the existence of a problem of public concern warranting measures interfering with the peaceful

[230] Explanations to Article 52.

[231] My emphasis.

[232] See C-183/95 para. 43 and 57, C-547/14 para. 152, C-579/19 para. 96, and C-220/17 para. 97. In terms of general interests that can justify an interference under ECHR P1-1, the provision does not list the different interests as in ECHR Articles 8–11. Protection of health is a legitimate interest according to Articles 8–11. The context of the Convention strongly suggests that "general interest" in ECHR P1-1 as a minimum includes the listed legitimate reasons in Articles 8–11, including protection of health. Therefore, there is no deviation between the CFR and P1-1, and the minimum protection provided by ECHR is intact.

enjoyment of possessions".[233] Additionally, the ECtHR has given member states a wide margin of appreciation in assessing what constitutes a general interest, especially if the infringement pursues an aim of political, economic and social goals.[234] A compulsory license for the purpose of addressing public health concerns is meant to cover social needs, as well as combat high prices causing lack of access to medicines.

It can be concluded that CFR Article 17 acknowledges public health concerns as a reason for issuing a compulsory license. The notion can be understood as to being wide, in which member states have a flexibility in deciding what constitutes a public health concern.

The next question is whether public health concerns in other member states is also an eligible ground for issuing a compulsory license. It has already been established that TRIPS Article 31 does not impose any restrictions regarding grounds for issuing a compulsory license. Thus, TRIPS Article 31 certainly considers public health issues in other countries as an eligible ground for a compulsory license. The question is rather if CFR Article 17 accepts public health concerns in a fellow member state as a general interest recognized by the Union.

The general values of the EU are provided for in TEU Article 2, whilst TEU Article 3 contains the general objectives of the Union. Although the objectives in TEU concern the *Union's* action, the provision can nonetheless be understood as general objectives recognized by the Union: if member states pursue the objectives named in TEU Article 3 (or 21, see below), then they are acting within the framework and values which the Union itself complies with. This is more so a logical approach, since the Charter only addresses member states' action when they implement Union law.

TEU Article 2 states among other things that the Union respects human dignity. Furthermore, TEU Article 3 (1) explains that the Union aims to promote the well-being of its peoples: the Union citizens. Paragraph 3 entails the establishment of the internal market, as well as the promotion of solidarity among member states. The objectives of the Union indicates that public health concerns in other member states is recognized by the Union, given that exporting medicines to another member state is an act of solidarity and addresses the well-being of other Union citizens. The objectives of EU can be read in conjunction with TFEU Article 168, which encompasses a wide notion of public health concerns. Given that the purpose of the EU is continuous integration, it can be concluded that public health concerns in another member state is an eligible ground for issuing a compulsory license. However, EU member states cannot receive medicines through the export-mechanism, see chapter 4.4.3. Thus, the export must happen in

[233] *Béláné Nagy v. Hungary* para. 113 and *Vistiņš and Perepjolkins v. Latvia* para. 106.

[234] *Vistiņš and Perepjolkins v. Latvia* para. 106 and *R.Sz. v. Hungary* para. 46.

line with the rule of national supply in Article 31 (f), which may be counter-intuitive: a member state must ensure predominant supply to its national market, even if the purpose is to address health concerns in another member state. This is the consequence of Article 31 (f), which is meant to limit the scope of the license.

It is now established that CFR Article 17 recognizes public health concerns as a general interest, which can justify a compulsory license. The concerns can be national and regional for the EU.

4.5.5 Appropriateness and necessity of a compulsory license

4.5.5.1 Introduction

As was observed in chapter 4.3.4, a compulsory license must be proportional according to CFR Article 17. Amongst other things, the license must be appropriate and necessary to address the public health concerns in question. These conditions are cumulative: if one of them is not satisfied, then the compulsory license is disproportional and unjustified under all circumstances.

TRIPS Article 31 does not explicitly provide for a condition about appropriateness and necessity, but has one condition which can be understood as partly satisfying these requirements: the applicant must have made efforts to obtain authorization from the patent owner prior to applying for a compulsory license This chapter will firstly discuss what the requirement of appropriateness entails. Secondly, it must be discussed when a compulsory license is absolutely necessary. In the latter discussion, TRIPS Article 31 (b) will be elaborated. The aim of this chapter is to make it clear that the safeguards in TRIPS must be supplied with the general proportionally-test, in order for the granting of a compulsory license to be valid under CFR Article 17.

4.5.5.2 Appropriateness

The condition about appropriateness means that the license must actually be an appropriate and right tool to solve the problem. The CJEU has held that the national legislation or measure must attain the pursued goals in a consistent and systematic manner.[235] It can be assumed that a compulsory licensing scheme in general is an appropriate measure in itself, since it enables the authorities and third parties to use a patent in order to address a public health concern.

However, the appropriateness of a compulsory license in a specific case can be discussed. As was observed in chapter 4.5.2, TRIPS Article 31 does not contain any requirements concerning eligible licensees. There might be instances where a third party clearly does not have the manufacturing capacity or know-how to produce medicines. There can also be instances where a

[235] See for instance C-190/16 para. 48.

third party is not financially stable. The common feature of these scenarios is that national authorities might predict that the applicant is not able to actually make use of the compulsory license. The question is, can the compulsory license be granted in such situations?

The wording of CFR Article 52 (1) states that the compulsory license must genuinely meet the objectives of addressing a public health concern. Although TRIPS Article 31 does not state that a license must be executed, or that the execution must be successful, it would be disproportionate to grant a license when it is somewhat clear that the third party will not be able to use it for the purpose it was granted for. In such situations, a compulsory license would genuinely not meet the objectives of supplying medicines.

Deriving from the condition of appropriateness, an additional safeguard can be established alongside the ones provided for in TRIPS Article 31: The applicant must actually be able to execute the license for the purpose it was granted for.[236] This can be a challenge during a pandemic where newly developed vaccine doses are needed, as was the case during COVID-19. Many vaccines are protected by multiple patents, including trade secrets and production know-how. Third parties might have the prerequisites for producing vaccines, but not the specific know-how for producing *this* specific vaccine. Since a compulsory license does not impose an obligation for the patent owner to share know-how and trade secrets, the license might not be the most effective tool for addressing a specific health crisis. This point will be discussed in chapter 4.9.

It is difficult to establish a rule that says that the license must be executed *successfully*, since the consideration of the application is *ex ante* to the actual use of the patent. The purpose of the patent system suggests that national authorities must at least expect a successful outcome. However, member states have a wide margin of appreciation when granting a compulsory license for the purpose of addressing a public health concern. For this reason, it is not possible to provide an absolute rule about the successfulness of the license.

4.5.5.3 Necessity

A compulsory license must be necessary. The CJEU has held that "when there is a choice between several appropriate measures recourse must be had to the least onerous".[237] "Onerous" in this context seems to refer to how the measures affect the patent owner. The availability of different options relies on what is actually possible for the member state in question. Thus, the

[236] The Commission Proposal Article 5 (1) (f) states that the third person must be "deemed to be in a position to exploit the protected invention in a manner that permits the proper carry out of the relevant activities". The Proposal is therefore in line with CFR Article 17 on this matter.

[237] C-189/01 para. 81 and T-256/11 para. 205.

different appropriate options must be real and not just theoretical options. This chapter will provide some scenarios to when a compulsory license might not be necessary at all, before discussing the specific requirement in TRIPS about prior efforts of obtaining consent from the patent owner. It can be noted that the scope and duration of the license is also a consideration in whether a license is necessary, but will be discussed in chapter 4.6.1.

It might not be necessary with a compulsory license if there are enough medicines on the market of another member state, which are willingly placed by the patent owner. Firstly, because acquiring medicines already available on the market is a less onerous option for the patent owner. Secondly, since the patent rights are exhausted for these medicines, the applicant does not need a compulsory license for selling medicines to the member state in question. However, the proportionality test must be assessed accordingly to the facts of the case. The medicines placed on the market of another member state might be very expensive. In such cases, there might be necessary with a compulsory license.

Additionally, if there are several applications concerning the same patent, then it might not be necessary to grant all of them. Whether or not it is necessary with compulsory licenses to more than one applicant, would rely on the needs of the member state, access to medicines already on the market, and the manufacturing capacity of the different applicants.[238]

Whether there are other options available to supply medicines, is also a matter of whether the patent owner is willing to authorize the third party to use his invention. TRIPS Article 31 (b) therefore partially addresses the necessity of a compulsory license in a given situation. According to the provision, a compulsory license can only be granted if:

> "[T]he proposed user has *made efforts* to obtain authorization from the right holder *on reasonable commercial terms and conditions* and that such efforts have *not been successful within a reasonable period of time*".[239]

This provision contains three conditions that must be satisfied in order to grant a compulsory license.[240] First of all, the applicant must have made efforts of obtaining a voluntary license.

[238] The Export Regulation Article 6 (2) requires member states to consider the necessity of a compulsory license if the applicant has submitted applications to more than one country.

[239] My emphasis.

[240] The Commission Proposal has opted for a different approach. It seems like a third party can apply for a compulsory license without documenting prior efforts of reaching a voluntary agreement. The Commission shall give the patent owner and the licensee the opportunity to comment on the possibility to reach a voluntary agreement. Since the scope of the proposal is limited to Union-wide crises or other emergencies, the exception in TRIPS Article 31 (b) second sentence is applicable.

The first conditions simply means that the applicant actually has made efforts of reaching out to the patent owner. If the applicant has done nothing, then the condition is not satisfied.

Secondly, the proposed voluntary license agreement must not have been on "reasonable commercial terms and conditions". The provision indicates that the proposed terms and conditions must be similar to what is normally obtained on the market. "Reasonable" suggests that the patent owner is not discriminating between third parties without reason. If the patent owner is placing more stringent conditions than usual for no particular reason, then it can be concluded that the license agreement does not place reasonable commercial terms and conditions.

It can be discussed whether the commercial terms must be consistent with other license agreements from the patent owner, or whether the assessment must be done objectively by considering the market value of the patent. The assessment can be tricky with the first solution. The patent owner has a monopoly over the market. Thus, the "market conditions" in reality refers to the conditions which the patent owner imposes on everyone who seeks to obtain a license from him. From an objective standpoint, the patent owner might be imposing far more stringent conditions compared to the nature of the patent. Thus, the use of "reasonableness" may suggest an assessment based on conditions imposed by a hypothetical patent owner, given the value and necessity of the patent. The assessment could also be done by comparing license agreement from comparable fields of technology.

However, such an understanding of "reasonable commercial terms and conditions" could impair the purpose of the patent system, where the whole point is to grant the patent owner a monopoly status. It can be contested that the monopoly status is meant to recoup investments, and the market value of the patent must be established by considering the actual costs of the patent owner during the inventive phase. Yet, such a rule would make it extremely difficult to assess the market value of the patent in reality, since the third party would have to seek financial statements from the patent owner. Furthermore, recoupment of investments is not the only explanation to the patent system. The natural law perspective says that the inventor must be rewarded, in which it is natural for the patent owner to expect commercial profits from his invention.

In addition, there are already remedies in place for addressing competition concerns in EU law, and the conditions for obtaining a license due to an abuse of dominant position in TFEU Article 101 are very strict.[241] It can therefore be concluded that the assessment of "reasonable terms and conditions" must be made by comparing other voluntary license agreements concerning the

[241] C-418/01 para. 35 and 38.

same patent. If the patent owner never has granted a license before, then recourse to a more objective assessment might be necessary.

The third condition in Article 31 (b) is that the applicant must not have been successful within a reasonable period of time. "Reasonable period of time" is not defined, and the wording does not provide any clear answers. The lack of any specific time suggests that the assessment must be done by considering the circumstances of the case.[242] Nonetheless, "period of time" seems to indicate that at least *some* time must have gone. On that sense, the Exports Regulation can be mentioned. Article 9 (1) has substituted "reasonable time" with 30 days. This rule provides foreseeability for all parties involved and makes the rule more effective. However, the regulation cannot be a source for interpreting TRIPS. Since TRIPS is above the regulation in the EU legal hierarchy, it is rather the regulation that must be interpreted in line with TRIPS. 30 days can nonetheless be a "guideline" or a benchmark for third parties, although the assessment must be done individually. If the applicant has failed to get any response from the patent owner for more than 30 days, then it can be concluded that he failed to reach an agreement. If the negotiations already have started, then the timeline can for instance be compared to how long it usually takes for the patent owner to negotiate a contract.

Article 31 (b) second sentence makes an exception to the rule of prior effort to obtain a voluntary license agreement, in cases of a national emergency or other extreme cases of emergency. The wording of "emergency" suggests that the matter is urgent and of a large scale, perhaps even life-threatening. The Doha Declaration paragraph 5 (c) provides that public health concerns such as epidemics can constitute a public health concern. Furthermore, it is stated that member states are free to determine what constitutes a national or other extreme case of emergency. Although the Declaration seems to communicate that member states freely can assess when a public health concern is an emergency, the wording itself requires that the concern must be of a certain scale and urgency. If any public health concern, such as increased obesity in the population, would be understood as an emergency, then the rule of prior efforts of obtaining a voluntary agreement would become illusory. It can be concluded that TRIPS Article 31 requires that the emergency must be of a certain degree of urgency and scale, in order to derogate from the rule about prior efforts of obtaining a voluntary license.

In terms of compatibility of this exception with CFR Article 17, it can be understood as a reference to the wide margin of appreciation granted to states during a national emergency.[243] During an epidemic or pandemic concerning a contagious disease, there may not be time to

[242] See in this direction Gervais (2021) p. 497.

[243] See chapter 4.3.4 about margin of appreciation.

negotiate a license agreement with the patent owner. The level of urgency must be assessed considering the facts of the case.

The exception in TRIPS Article 31 (b) second sentence also applies to "public non-commercial use". The phrase can be understood as government-use for non-commercial purposes.[244] The wording suggests that the purpose is not to gain any profit, see chapter 4.4.1. It is difficult to reconcile this exception with the proportionality requirement in CFR Article 17. As was observed in chapter 4.4.1, non-commercial use of the patent also infringes a patent right. Thus, any interference must be in compliance with Article 17. I cannot see why the rule about necessity should be waived because the government itself is using the patent. It can therefore be concluded that governments in EU member states may not use a patent without prior efforts of obtaining a voluntary license agreement, unless there is a national or extreme urgency.

It can be concluded that member states must assess on a case-by-case basis whether the granting of a compulsory license is necessary. If it is possible to obtain medicines already on the market, or the patent owner is willing to enter into a voluntary license agreement on reasonable commercial terms, then the compulsory license is not necessary as a main rule.

4.5.6 Consideration of the application: on individual merits

TRIPS Article 31 (a) states that "authorization of such use shall be considered on its individual merits". "Individual merits" means that a decision must be taken according to the facts of the case.[245] It is therefore clear that member states cannot generally allow certain categories of patents to automatically be licensed upon request.[246] Such a rule would rather be covered by Article 30, and may conflict with CFR Article 17 and ECHR P1-1 which require an individual assessment of each case.

A medicine or a vaccine can be protected by several patents. The first question is if an application can state that it wishes to produce and sell a medicine, and therefore needs a compulsory license concerning all patents that protect the product. The wording does not give any definitive answers to this question. I cannot see that CFR Article 17 requires that separate applications must be submitted concerning each patent. Correa and Gervais also suggest that the provision indeed allows such applications to be granted, especially in the case of pharmaceutical products.[247]

[244] TRIPS Article 31 (b) fourth sentence.

[245] The Law Dictionary (2023).

[246] Gervais (2021) p. 496.

[247] Correa (2020) p. 310 and Gervais (2021) p. 496–497.

The second question is if it is necessary with a compulsory license per action, if more than one action concerning the same patent will take place in the same country. Neither the wording of TRIPS Article 31, nor any rules in EU primary law (as far as I can see), necessitate separate licenses per action. It can therefore be concluded that only one application is needed.

4.6 Safeguards regarding the contents of the license

4.6.1 Scope and duration limited to the purpose

According to TRIPS Article 31 (c), the scope and duration of the license must be limited to the purpose it was authorized for. This condition also expresses whether the license itself is necessary to address the specific public health concerns in question. The CJEU has held that the measure cannot go further than what is necessary to obtain the objectives.[248] This chapter will comment on what this condition entails under TRIPS.

Given that an application for a compulsory license must be assessed on individual merits, the scope and duration will therefore vary depending on the facts of the case. During an epidemic or pandemic for instance, the scope and duration of the license must be established concerning the quantity of medicines needed. As for the duration, there can be various factors which can influence the duration, such as uncertainty in when the health crisis will end. Neither the wording of TRIPS nor CFR specify that there must be an absolute time-limit to the license: As long as the need exists, the necessity of the license persists. This understanding is also in line with TRIPS Article 31 (g), where the patent owner must in principle be able to terminate the license when "the circumstances which led to it cease to exist". This safeguard will be shortly commented in chapter 4.6.4 and shows that the interests of the patent owner are protected.

The rule of necessity can become tricky if the purpose of the license is to address public health concerns in another member state. The rule about predominant national supply means that the quantity must mainly be sent to the national market in question. If there is no need for a license in the national market, then the quantity and scope of the license must be adjusted accordingly. In reality, this means that no license can be obtained in such a case, since the license would be meaningless in the context of national supply. Thus, although there is a theoretical possibility to address public health concerns in a fellow member state, this cannot be executed in practice unless there is a domestic need for the medicines as well.

If the scope and duration goes beyond what is necessary to address the specific public health concerns, then the license does not fulfill the requirement of necessity. Whether the entire license or only the "excess" is considered disproportional is a separate question, and will not be pursued.

[248] C-419/14 para. 74.

An interesting rule in TRIPS Article 31bis and the Exports Regulation can be mentioned. Both legislations require the licensee to publish the quantity supplied and distinguishing features of the product on a website.[249] This rule makes it easy for both the national authorities and the patent owner to control how the license is being executed and is a testimony of the scope of the license. A similar requirement in national law can be a relevant factor in the *stricto-sensu* assessment, as it is beneficial for the patent owner to overlook the activities of the third party. The Commission has also proposed this solution in its Proposal.[250]

4.6.2 Adequate remuneration

TRIPS Article 31 (h) states that the patent owner must be paid "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization". The wording provides that remuneration must be established on a case-by-case basis. Furthermore, the economic value of the license must be considered, but the use of the phrase "taking into account" suggests that this is not the only factor. Nevertheless, it is an important factor. The question is how the economic value of the license must be established.

The use of the word "adequate" suggests that a fixed sum may not be enough to compensate for the use: the amount must be established based on the scope and quantity produced under the license. This understanding is in line with one of the key functions of patent law, where the patent owner has the right to place the patented product on the market for the first time, as well as recoup his investments. For every product produced and sold under the compulsory license, the patent owner "loses" his possibility to gain profit from these products.

Additionally, the provision does not state how the economic value of the license must be calculated. Given the discussion in chapter 4.5.5.3 about "reasonable commercial terms and conditions", it is natural to believe that the calculation of remuneration must be based on other license agreements concerning the same patent. If there are no prior license agreements, then the assessment must be based on the objective economic value of the license in the member state concerned, which would depend on the product itself and the demand for a license. [251] This understanding is based on the wording "economic value", and the purpose of TRIPS in Article 7 which states that the protection of IP should be contribute to the promotion of innovation. If the remuneration does not align with what the patent owner could at least expect to get under a

[249] Annex to TRIPS paragraph 2 (b) (iii) and Exports Regulation Article 10 (6).

[250] Commission Proposal Article 10.

[251] See in this direction Gervais (2021) p. 499–500.

voluntary license agreement, then the incentive for investing in new technology could be weakened.

The provision opens up for other factors which can be considered when calculating the remuneration. What the different factors are, depend on the circumstances of the license, and the specific public health concern in question.[252]

If some of the products will be exported to another member state, then the third party might need a license to sell the products in the importing country given that the patent is registered there as well. TRIPS Article 31 does not provide any answers as to how the remuneration must be calculated in such situations. It can be wondered whether the member state, where the medicines are being manufactured, can take into account that some of the products will be exported and therefore lower the amount of total remuneration. In this situation, it would be up to the importing country to set the amount of remuneration concerning the import and sale of medicines. Since there can be local variations concerning the market value of the patent, the patent owner can either come better or worse off by not receiving full remuneration in both countries.

On this matter, Article 31bis may be relevant to consider as a context to Article 31 (h). Article 31bis (2) states that remuneration must be paid under the compulsory license issued by the exporting member state, whereas the importing state does not need to pay remuneration. This solution suggests that the patent owner is not entitled to remuneration in both countries. However, this provision can be understood as a *lex specialis*, and specifically addressed to help developing countries. This is highlighted by the fact that the exporting country must take into account the economic value of the patent in the importing country, when calculating the remuneration. Thus, Article 31bis seems to have a social dimension to it, where the aim is not to put a burden on developing countries. Therefore, Article 31bis may not be completely relevant when deciding how remuneration must be calculated if some medicines are to be exported under TRIPS Article 31 (f).

The objectives of TRIPS in Article 7 may indicate that full remuneration must be paid in the producing country, regardless of whether some of the medicines will be exported. The exclusive right is the main rule when the patent is granted, and the point of the patens system is to provide an economic benefit for the patent owner. Furthermore, the patent-infringing actions are taking place in both countries: both production and sales infringe a patent *per se*. Thus, it can be concluded that the patent owner is entitled to full remuneration in all countries where the patent will be infringed, even when the patent-infringing actions take place due to a cross-border supply chain.

[252] See in this direction Correa (2020) p. 312.

Now that the rules on adequate remuneration under TRIPS and the regulation have been examined, it must be assessed whether CFR Article 17 places additional safeguards concerning the remuneration. As was observed in chapter 4.3.4, a third party or the government are only required to pay compensation if the compulsory license amounts to deprivation. It can be assumed that the calculation of the remuneration under TRIPS satisfies the condition about compensation in CFR.[253]

If the granting of the license constitutes "control" with the patent right in the specific case, then the patent owner does not have any right to compensation. In that situation, TRIPS provides for a better protection of the patent owner, which is an important factor in the *stricto sensu*-test.[254] If compensation has been given in accordance with TRIPS, then the compulsory license is likely proportional.[255]

4.6.3 Other third parties' access to the patented invention

TRIPS Article 31 (d) states that the license must be non-exclusive, which means that the patent owner can license to other third parties. This is an important safeguard, since it ensures that the patent owner in theory retains his freedom of contract towards other third parties. If this safeguards is respected by the member states, then a compulsory license might not be considered as a deprivation of property – resulting in most compulsory licenses being "control" of the patent right.

Additionally, Article 31 (e) provides that the license must be non-assignable, which means that the licensee cannot sell the license right to others. The latter safeguard can also be understood as to limiting the scope of the license, in which national authorities and the patent owner can control how the license is being executed. This safeguard is also a relevant factor in the *stricto sensu*-test: a non-assignable license is in the interest of the patent owner. [256]

Article 31 does not prohibit sub-licensing, which means that the licensee may outsource parts of the production or sale.

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[253] See Wollenschläger (2021) p. 508 and Christoffersen (2018) p. 205 with cited case law.

[254] See for instance *Papachelas v. Greece* para. 48.

[255] The Commission Proposal Article 5 (1) (d) generally states that adequate remuneration must be paid to the right holder. Article 9 lays down the criteria for calculating the remuneration, which shall not exceed 4% of revenue generated under the license. The Proposal also refers to public funding during R&D as a relevant factor for calculating the remuneration. The calculation of remuneration is therefore more detailed than in TRIPS, and more in line with the requirement of "provided for by law" in CFR Article 17.

[256] The Commission Proposal Article 5 (1) (a) also states that the license must be non-assignable and non-exclusive.

4.6.4 Termination of license

TRIPS Article 31 (g) provides that the license must be liable to be terminated "when the circumstances which led to it cease to exist and are unlikely to recur". The legitimate interests of the licensee must be protected adequately. This means that whether the license can and should be terminated, relies on the interests of the licensee as well. The provision states that national authorities must be able to review the existence of the public health concerns in the specific case, upon motivated request. It is sufficient to note that TRIPS requires that a compulsory license can be terminated, which protects the interests of the patent owner. This condition is a relevant factor in considering whether a compulsory license is proportional in the *stricto sensu*-test.[257]

4.7 Procedural safeguards

4.7.1 Notification to the patent owner

As was observed in chapter 4.5.5.3, TRIPS Article 31 (b) requires that the applicant has made prior efforts of a voluntary license as a main rule. When the exception concerning national or other urgent emergency applies, the patent owner must be notified. TRIPS does not state that the patent owner must be notified about the granted license. However, given that the patent owner must be given the right to terminate the license, as well as the right of review (see chapter 4.7.2), he must have knowledge of the license. Thus, in order for the named safeguards to be effective, it can be concluded that the member states must always notify the patent owner about the granting of a compulsory license. This understanding is also in line with TRIPS Article 7 and the rationale behind the patent system, in which the reference to continued innovation and balancing of rights means that the interests of the patent owner must be respected.

Another question is if the patent owner should be notified *before* the granting of a license. In light of the necessity-requirement in CFR Article 17 and TRIPS Article 31 (b), notification should be sent in time for the patent owner to propose a voluntary agreement. In addition, since the application must be considered on its individual merits, the notification should enable the patent owner to comment on the facts of the situation.[258] Whether or not the patent owner has been notified, either before or after granting a license, is a relevant factor in the *stricto sensu*-test.

[257] The same is provided for in Article 14 of the Commission Proposal.

[258] The Commission Proposal Article 7 (3) states that the patent owner and the licensee shall be given the opportunity to comment on the possibility to reach a voluntary agreement, the necessity of a license, and conditions for a license. In addition, the Commission shall notify both parties that a license may be granted, and as a main rule notify them individually, see Article 7 (4). This is an important factor in the *stricto sensu*-test, which likely could lead to the license being proportional.

On a side note, the Exports Regulation Article 7 contains a general notification rule when a member state receives an application. In addition, the patent owner must be given the opportunity to comment on the application before the compulsory license is granted. The Exports Regulation is not a relevant factor when interpreting TRIPS, but provides a rule which secures the interests of the patent owner. Thus, notification in line with the Regulation increases the chances of the license being proportional.

4.7.2 Judicial review

TRIPS Article 31 (i) and (j) provide that the legal validity of the decision which granted the compulsory license, and the decision relating to the remuneration, must be subject to review. The review can either be done judicially by the courts, or as an independent review by distinct higher authority. For the purpose of this thesis, it is sufficient to know that the possibility to review a decision which interferes with the property right, is an important factor in the *stricto sensu*-assessment.[259] Since judicial review is a requirement in TRIPS, then a compulsory license is more likely to be proportional.

I will not comment on CFR Article 47 about the right to an effective remedy and fair trial. It can also be noted that the patent owner cannot rely on TRIPS Article 31 directly for judicial review, since TRIPS does not have direct effect in the EU, see chapter 3.3.2.

4.8 Compatibility of TRIPS Article 31 with the right to property

The discussion so far has shown that CFR Article 17 provides for a more extensive protection concerning the interpretation of some safeguards. This is the case for the safeguards such as lawfulness, efforts of obtaining a voluntary license prior the application, and the limitations on geographical jurisdiction. Moreover, CFR Article 17 provides for additional safeguards that must be considered, namely the conditions of appropriateness and necessity for granting a compulsory license. Although the rule on prior efforts of obtaining a voluntary license communicates when a compulsory license is necessary, TRIPS Article 31 does not address the possibility of there being several appropriate measures to choose between. Member states must therefore keep the elevated protection of patent rights in mind when they consider and grant a compulsory license to address a public health concern.

As was observed in chapter 4.3.4, a fair balance must be struck between the principle of health and the interests of the patent owner. In this assessment, several factors are relevant. The different conditions in TRIPS Article 31 can be understood as to operationalize this assessment. This is more so because TRIPS Article 31 provides for both material and procedural safeguards,

[259] See for instance *G.I.E.M. S.r.l. and others v. Italy* para. 302 and *Shorazova v. Malta* para. 105. See also *Guide on P1-1* (2022) p. 31–32. The same is provided for in the Commission Proposal Article 14.

in which the latter makes it possible for the patent owner to have the decision about a compulsory license reviewed. Furthermore, the patent owner is also given the possibility to terminate the license, although whether the termination actually can be put into action, must be assessed based on the interests of the licensee. The fact that the safeguards operationalize the *stricto sensu*-test in CFR Article 17, means that the member state can rely on the conditions in TRIPS, accompanied with the additional safeguards and interpretation provided for in this thesis.

As a last point, the discussion in chapter 3 showed that TRIPS does not confer rights upon individuals. The stance of the Court has been criticized in legal literature.[260] Regardless, patent owners retain the right to challenge national law about compulsory licenses against CFR article 17. However, the level of protection could differ depending on whether the license constitutes deprivation or control of the patent right: The patent owner is only entitled to compensation in the former case, whereas TRIPS Article 31 requires that remuneration must be payed regardless of how onerous the license is.

4.9 Challenges with compulsory licenses in the EU

The analysis in chapter 4 has identified several shortcomings of the compulsory licensing system. The territorial restrictions have been discussed in chapter 4.4.4, and will not be repeated here. Compulsory licenses as a tool for increasing global access to medicines may not be as effective with the current EU legislation.

First of all, a compulsory license only allows third parties to use a patented subject matter, and does not impose an obligation for the patent owner to share know-how and trade secrets – unless specifically provided for in national law. This is usually not a problem for producing more simple medicines. The matter becomes complicated with medicines protected by multiple patents, which also may involve trade-secrets. Some medicines or vaccines are more complex to produce, where specific know-how is needed. A third party might not have the know-how to produce a specific vaccine: a problem which was highly discussed during the COVID-19 pandemic.[261] A member state who seeks to address a public health concern, might not be able to do so, because only the patent owner is able to manufacture the medicines. Furthermore, the condition about appropriateness in CFR article 17 underlines that only a third party with the ability to produce the medicines are eligible licenses.

Another issue with TRIPS is that the wording is abstract. The choice of wording is likely intentional, in order to give the WTO members leeway during the implementation of the agreement

[260] See for instance Mendez (2013) p. 207–208.

[261] See for instance David (2021), Gubby (2020) p. 53, Mermelstein and Stevens (2021) p. 2, and Wang (2014) p. 95.

in national law, as well as the interpretation. The lack of clarity can constitute a problem in terms of foreseeability for member states, since the exact obligations under the agreement are not easy to ascertain. The problem is amplified by the lack of jurisprudence from CJEU and the DSP about TRIPS Article 31. The lack of clarity may lead to a reluctance in using the compulsory license system effectively. The Commission has for instance reported that the exports-mechanism under the Exports Regulation has never been used.[262]

Aside from compulsory licenses, a waiver can also be a remedy to increase access to medicines. A waiver of TRIPS is provided for in the WTO-agreement Article IX. WTO defines a waiver as "[p]ermission granted by WTO members allowing a WTO member not to comply with normal commitments. Waivers have time limits and extensions have to be justified".[263] A waiver can be directed to one specific WTO member, or all of the members combined. The latter solution was used with the Doha Declaration, which is a waiver concerning the interpretation of TRIPS. A waiver allows WTO members to not respect certain safeguards in TRIPS, or provide a specific interpretation of the wording.[264]

The significance of a TRIPS waiver in the EU can be discussed. A waiver will be legally binding for the member states under TFEU Article 216 (2) if the Union adopts a position in favor of it. However, a waiver might not be compatible with CFR Article 17. Furthermore, although a waiver can be a handy tool in combatting public health concerns, it requires a lengthy procedure in the WTO. For member states who are experiencing a local epidemic, or wish to address an emerging health concern as quickly as possible, a waiver might not be the solution. In such circumstances, member states must rely on compulsory licenses.

5 Concluding remarks and Commission Proposal

The thesis has made some key findings concerning compulsory licenses in order to increase access to medicines in the EU. Compulsory licenses can be used to address a public health concern in the member state in question, as well as to export a limited amount of medicines to another member state. The granting of a license is subject to several safeguards. Therefore, the patent owner enjoys a high level of protection in the EU.

[262] European Commission (2021) p. 4.

[263] WTO (2023).

[264] At the end of the COVID-19 pandemic, the WTO members adopted a waiver concerning COVID-19 vaccines and diagnostics, but this waiver only applies to developing countries: Ministerial decision on the TRIPS agreement of 17. June 2022 (WT/MIN(22)/30 WT/L/1141).

As for the constitutional questions, TRIPS is first of all binding on the member states by virtue of EU law. This means that member states must fulfill its obligations under the agreement towards the Union. Non-compliance with the agreement can lead to an infringement procedure against the member state in question. Interesting about TRIPS is that the Union is externally responsible for the conduct of its member states towards third country WTO-members.

Although TRIPS imposes EU law obligations on the member states, it does not confer rights upon individuals. This means that a patent owner cannot rely on TRIPS to challenge national law in breach of the agreement. However, member states must interpret national legislation about compulsory licenses harmoniously with TRIPS article 31 as far as possible, and last instance courts must request a preliminary ruling on the interpretation of TRIPS from the CJEU.

When member states grant a compulsory license, they cannot solely rely on the safeguards in TRIPS Article 31 – they also have to respect the right to property in CFR Article 17. The compulsory license must be proportional, which means that the license must be appropriate, necessary, and not put an excessive burden on the patent owner. The first two conditions supply the safeguards in TRIPS, whereas TRIPS operationalizes the last condition in the proportionality test.

The thesis has also shown that member states retain their right to legislate on patent law, and that the Union has not harmonized national law about the exclusive rights of the patent owner or compulsory licenses. Thus, patent rights continues to be a national barrier in the internal market, where the patent is protected in every member state where the invention is registered. This also means that a third party who wishes to produce and sell medicines in the internal market must seek a compulsory license in each member state – which is a challenge for companies with cross-border supply chains. On that note, an EU-act that either coordinates compulsory licensing decisions between the member states or provides for an EU-wide compulsory licensing scheme can be beneficial. The Commission has proposed the latter solution.

The Commission Proposal seeks to establish an EU-wide compulsory licensing scheme to be used during a Union crisis.[265] The proposed regulation gives the Commission authority to grant a compulsory license for supplying the internal market. The license can concern both national and Unitary Patents. Chapter 4.4.2 discussed the question of the compatibility of the Proposal with the principle of territoriality in TRIPS. Furthermore, the references to the Proposal throughout chapter 4 indicates that the Commission Proposal is in line with both TRIPS Article 31 and CFR Article 17. However, this is just a preliminary impression of the Proposal: an in-depth analysis was not possible due to the time the Proposal was released.

[265] Commission Proposal Article 1.

The Proposal has many interesting features that may solve some of the challenges with national compulsory licensing schemes. The most important feature is the EU-wide compulsory license, which directly solves the problems surrounding cross-border supply chains. Secondly, the subject matter of the license does not only cover patents, but also published patent applications and supplementary protection certificates.[266] Thus, third parties will be better equipped to produce the patent. The proposal also provides extra leeway for the Commission by widening the scope to cover patent-like protections. Furthermore, both the licensee and the patent owner shall act in good faith and cooperate with each other "when performing rights and obligations under this Regulation".[267] This provision can indicate an obligation for the patent owner to share trade-secrets and know-how, in order for the third party to successfully manufacture medicines.

Another interesting part of the proposal is that the Commission can impose fines and periodic penalty payments on *both* the licensee and patent owner for breaching obligations under the Regulation. Thus, the third party and the patent owner must cooperate in order to execute the license efficiently, and is a clear signal for patent owners that they have a responsibility in ensuring that public health concerns are being properly addressed.

The Proposal makes it possible to grant a compulsory license without identifying the patent owner, with the consequence that they are not notified prior or after the granting of the license. The lack of notification is relevant when assessing if the measure is proportional under CFR Article 17.

The scope of the Proposal can be contested. It is only limited to a Union-wide crisis. This is an understandable approach given that the Commission can grant a compulsory license concerning a national patent. However, the Proposal should extend the scope if the license concerns a Unitary Patent. The challenges with the national compulsory licensing scheme identified in chapter 4.9 are not limited to public health issues, but are also general in character. A wider scope of the Regulation could help the Commission in addressing wider problems concerning patents and make it easier for third parties to apply for a compulsory license in the case of cross-border supply chains. In addition, the Commission should facilitate coordination between member states when they consider national applications for compulsory licenses concerning the same patent.

[266] Article 2.

[267] Article 13.

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TFEU	*Treaty on the Functioning of the European Union*, consolidated version 2020, (2016/C 202/01)
CFR	*Charter of Fundamental Rights of the European Union*, (2012/C 326/02)

International agreements of the EU

TRIPS agreement or WTO agreement	Decision 94/800/EC: Council Decision of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994)
TRIPS Article 31bis	Decision 2007/768/EC: Council Decision of 19 November 2007 on the acceptance, on behalf of the European Community, of the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005
COVID-waiver	Council Decision (EU) 2022/1293 of 17 June 2022 on the position to be taken on behalf of the European Union within the 12th Ministerial Conference of the World Trade Organization

Other agreements

UPC Agreement	Agreement on a Unified Patent Court, (2013/C 175/01)

Regulations

Exports Regulation	Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems
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