

THE STATUS AND LEGAL EFFECT OF COMPULSORY LICENSE IN INVESTMENT LAW

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ABSTRACT

Compulsory license is one of the main flexibilities that developing countries are allowed to use by the International Intellectual Property Law system in order to facilitate access to medicines and technology transfer. Despite the fact that this amounts to the deprivation of the right for exclusive use of the inventor, it is indeed a quite acceptable measure when it falls under the conditions set in Article 31 of TRIPS. However, the use of this flexibility might bring claims by investors before the investment arbitration, where the compulsory license is highly contested. In the current paper, we examine the status of this flexibility in both intellectual property and investment law regimes and we attempt to assess the defence of use of compulsory license before the international investment arbitration so as to examine if international investment law is true obstacle for the use of flexibilities available by the International Intellectual Property regime.

KEYWORDS

Compulsory licence, Intellectual Property, investment, access to medicines

1. INTRODUCTION

This paper provides a study on compulsory license, which constitutes a flexibility of intellectual property regime. Compulsory license is the deprivation of the right for exclusive use of a patent by a State for purposes of national emergencies or as a remedy for anti-competitive behaviour. The use of compulsory license is legally authorized by both national and international intellectual property law. The present study attempts not to examine the status of compulsory license in the intellectual property field but to present the effects of this measure in a close related field, the one of international investment law. Intellectual property rights have long been recognized as form of 'investment' entitled to protection under bilateral investment treaties (BITs) and other investment agreements. In plenty of investment agreements it is explicitly referred that the term 'investment' includes almost any kind of asset, tangible or intangible[1]. Thus intellectual property, even as an intangible asset, is a valuable part of a foreign direct investment. Since the compulsory license is an interference with the property of patent holder in the intellectual property regime already, the question is what effect has in the international investment law, when intellectual property rights are protected under the status of a foreign direct investment. In international investment law, any deprivation of property of an investor, due to state measures and policies, can be amounted in expropriation, direct or indirect, which creates the claim of adequate and effective compensation for the investor[2]. Nevertheless, in intellectual property regime, the compulsory license, which amounts to deprivation of property by state, it is a quite acceptable measure when it falls under the conditions set in Article 31 of TRIPS Agreement. One of the basic things that this study analyzes is the examination of compulsory license in relation to potential expropriation claims in international investment law.

Except of the examination of compulsory license as a form of indirect expropriation in international investment law, this study will attempt to examine also the possible claim of indirect expropriation due to issuance of compulsory license before the international investment arbitration. As it has been observed, the International Investment Field has become extremely complex[3], due to the fact of proliferation of BITs and other regional investment agreements with different kinds of provisions and investment definitions. So, the standards of protection under the International Investment Law are determined always by International Investment arbitral tribunals, whenever a specific claim is raised by the investor.

In this study, we will attempt to examine the claim of indirect expropriation due to issuance of compulsory license, before the investment arbitration. Our scope for this examination is to examine whether or not the standards of compulsory license, as they are determined at Article 31 of TRIPS can be taken under consideration by the investment tribunal. In other words, we will attempt to examine if intellectual property legal regime can be a source of law for the international investment arbitration, in case of expropriation due compulsory license.

2. THE USE OF COMPULSORY LICENSE UNDER THE INTELLECTUAL PROPERTY REGIME

2.1 The Compulsory License in National and International Intellectual Property Legislation

2.1.1 The definition and origin of Compulsory License

Compulsory license is an instrument of ambiguous character in the legal regime of Intellectual Property in both national and international level. According to a definition given by *Robert Bird*: ‘Compulsory license refers to circumstances in which a government intervenes to compel the owner of an Intellectual Property Right, normally a patent, to grant use of that right to the state or other third parties’[4]. It is quite understandable from the definition that a government willing to issue a compulsory license is able to authorize a relevant decision through its administrative or judicial authorities, without the prior consent of patent owner for the deprivation of patent use. This is normally the way for a state to respond to emergency needs or a response to an anti- competitive behaviour on behalf of the patent owner. From the abovementioned definition, it is quite clear that compulsory license is a measure that delimits a prior awarding intellectual property right and it targets the ‘use’ of this right, however, does not deprive purely the patent owner from its strict ownership right on a patent.

Internationally, the first reference of compulsory license as a measure in order to respond to abusive exercise of patent rights in cases, where the patent has failed to work successfully, has been made in article 5 of Paris Convention of 1883 [5]. According to Paris Convention, when a patent awarded is proved to be insufficient in working: ‘ *each country.....shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent...*’. Some form of compulsory license has existed also in the national intellectual property legislation of many countries, despite the fact that it has been used in very limited instances. Normally, the governments issue these licenses for purposes other than emergency needs or anticompetitive behaviours and most of these licenses are used for internal policy making reasons, such as technological development or promotion of national services and industries [6]. The most well-known example of such a national form of compulsory license is the Brazilian decree of 2007, where Brazil, for purposes of national health policy making, issued a compulsory license for Merck & Co anti-retroviral drug Efavirenz, after rejecting a reduction of a 30% of the initial price offered by the patent owner [7]. The issuing of this compulsory license under national framework

has been highly criticized by many scholars since it is considered to be outside the international standards set by TRIPS Agreement, as these standards will be discussed below and additionally to this the issuing of such a license by the Brazilian State has been interfered with the right to property, as it is embodied in the framework of intellectual property [8]. However, the most important source for the nature and content of compulsory licensing in international level today is Article 31 of TRIPS Agreement, which will be discussed thoroughly below.

2.1.2 The nature of Intellectual Property Rights and the Compulsory License under TRIPS

Since in the third section of this paper we are going to analyze the issuing of compulsory license within the legal framework existed for foreign direct investments, it is really important to examine the nature of intellectual property rights under TRIPS, before discussing the minimum conditions for compulsory licensing under this international regime. Intellectual property rights exist in order to fulfil some really important social role. These are the rights awarded to artists, inventors and scientists as a reward for their inventions [9]. Particularly for scientist and inventor, these rights are awarded at the form of a patent, which entails a twofold function for the patent owner: it is a reward for the inventor and as such gives the possibility of exclusive exploitation of the right so as the inventor to have the incentive to invest to further developments in its scientific field and on the other hand it is a contract between the state and the inventor so as the inventor to distribute all relevant information on its invention for public use. As for its first function, the patent right of an inventor excludes third parties from the use of a particular intellectual creation and this element is fundamental to the ownership of intellectual property [10]. Thus patents are negative rights, territorial in nature which arise between a state authority and a private party and in most of the cases involve registration of the right to the relevant administrative authority. The negative nature of the patents enables the patent owner to exclusively exploit, promote, sell or market its invention so as to succeed several economic advantages for himself and exercise a unique leverage in the marketplace.

The exclusivity of intellectual property rights is the core of the intellectual property system and governments are overriding this exclusivity when they authorize the use of a patent to third parties under compulsory license. Certain scholars are criticizing this measure against a private property right not only because it interferes with the security of private property as such but also because they consider it as harmful to innovation and growth. For this reason, the issuing of compulsory license by states is regulated under certain conditions in TRIPS Agreement.

In the TRIPS content, the issue of compulsory license was considered to be one of the most heated debates in the WTO, back in 1994. The existence of a 'one for all' international standard for the protection of intellectual property was well received by developed countries whose artistic and technological industries had extended to every part of this world and the existence of protection for artists and researchers was indispensable. On the other hand, for developing countries that were trying to build up the relevant industries through capacity building and importation of foreign technology and scientific achievements, the existence of a high standard protection of intellectual property would be an obstacle in their development and would constitute a strong obstacle in their policy-making in social sectors as public health and education. Except of these fundamental problems arising by an international intellectual property regime, one other structural problem between the lobby of Northern countries and the lobby of Southern countries, during the negotiations, was the completely different perception of the concept of property. The Northern countries, having kept the concept of private property as a given, wanted a protection focused on the exclusivity of intellectual property right and the exploitation of these rights by its holders for economic rewards while most of the countries of Southern lobby were perceiving intellectual property protection as an incentive for the artists and inventors so as the latter to make available their creations to the public.

As a result of these negotiations, the TRIPS Agreement contains a very important provision for issuing of compulsory license in Article 31 of the TRIPS Agreement. We have to underline here that article 31 is one of the more detailed provision within the Agreement so as to satisfy the Northern lobby which supports the existence of exclusivity in intellectual property [11]. The provision does not refer explicitly to the notion 'compulsory license' but instead it uses the expression 'without authorization of the right holder' [12]. The provision allows for the grant of compulsory license by WTO Member States, however, it sets a number of conditions that should be fulfilled and are mentioned below. First of all, the compulsory license 'shall be considered on its individual merits'. In addition to this the compulsory license should be decided as a measure only if negotiations with the right holder, for authorization of the patent on reasonable commercial terms and conditions, have not ended up successfully. The compulsory license granted should contain explicitly the scope and duration of deprivation of use and of course should explicitly analyze in its body the purpose for which it was authorized. In any case, the compulsory license must cease if the purpose of its issuing has been succeeded. The compulsory license has to be limited geographically for the supply of the domestic market product of the authorizing State. Finally and most importantly, the right holder must be paid '*adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization*'.

In comparison with what we have already mentioned in the subsection one of this Chapter that compulsory license could be justified only on the ground of failure of working for a patent under Paris Convention, the provision of Article 31 of TRIPS Agreement leave the substantive justification for the issuing of compulsory license upon to the WTO Member States. However, the provision makes reference to several potential reasons that could justify the grant of compulsory license without of course providing an exhaustive list of reasons. In Article 31 (b) is mentioned that a national emergency or circumstances of extreme urgency could justify authorization of a compulsory license. In addition to this, the same article refers to compulsory license for public and non commercial use. Moreover, Article 31 (k) recognizes the compulsory license as remedy for previous anti-competitive behaviour of the right holder and article 31 (l) justifies the compulsory licensing when this is necessary for the exploitation of a patent based on the patent of the right holder.

Even if the compulsory license is granted by a WTO Member State for a national emergency or as anti- competitive measure, still the loss of exclusivity in use for the right holder is a highly contested issue. As we mentioned above, the compulsory license violates the core of private property for the inventor since the loss of use of a patent means also economic losses from the exploitation of the patent. However, as we will see in the following subsection, the compulsory licence is perceived as a useful flexibility for public health issues, particularly after the Doha Declaration, in 2001. It is really important to examine the important status of Article 31 under Doha Declaration before we continue with the examination of compulsory license within the framework of Investment Law and arbitration.

2.2 The compulsory license for health emergencies under Doha Declaration

As we mentioned above, the compulsory license nowadays is considered to be an efficient flexibility for states in order to protect health, however, scholarship has faced the issuance of compulsory licensing for health emergencies quite differently. Scholars, such as Carlos Correa, have argued that compulsory licensing is a beneficiary flexibility that is possible to increase the efficiency of a State in dealing with public health emergencies and practices of pharmaceutical companies that would result in breaking down of prices and access to medicines for all [13]. On the contrary there are scholars that have argued that the compulsory license does not only harm the property right of right holders but also harms the pharmaceutical sector by discourage

initiatives for research and development in pharmaceutical industry of developing countries and enhance the illegal copying of patented drugs [14]. In practice, the debate about the efficiency of compulsory license for health emergencies has been tested in late 1990s, when South Africa issued compulsory license for anti- retroviral medicines in order to deal with the outbreak of AIDS HIV in the country. According to its Constitution, South African Parliament passed the Medicines and Related Substances Control Amendment Act in order to facilitate access to cheap anti- retroviral drugs and allow the parallel importation. Despite the reactions of pharmaceutical companies in relation to the harmful effect to their property rights, the important public health reason behind this legislation was enough to justify the issuance in this case and the mediation of international organizations so as to resolve the tension between South Africa and the home states of pharmaceutical companies has managed to succeed a compromise in favour of South Africa, without reference of the case to the dispute settlement body of WTO [15].

For the years to come, a lot of cases of issuance of compulsory license have been occurred based on a public health emergency. As a result, the adverse impact that the pharmaceutical patents regime might bring on public health has been brought into the light and countries have started the lobbying for how to make TRIPS Agreement friendlier to the public health issues. These processes have finally led to the adoption of a declaration on TRIPS Agreement and public health. According to the Doha Declaration, it is understandable from the Member of the Agreement that the patents regime embodied in TRIPS sometimes constitutes an obstacle for the public health policies in some countries [16]. In paragraph 4 of the Declaration it is stated that TRIPS Agreement does not and should not come in way of Members fulfilling their public health needs. Additionally to this, at the same paragraph, it is underlined that Member States should be encouraged to interpret the TRIPS Agreement in a way which would be supportive to the promotion of access to medicines and to public health in general. In the same text it is recognized that access to medicines is one of the most important priorities in order to safeguard public health. For first time in the WTO regime, it is acknowledged that flexibilities such as the compulsory license, afforded by TRIPS Agreement, should be used by Member States for the fulfilment of their obligations related to public health. It is explicitly referred in paragraph 5 (b) of the Doha Declaration that *'Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted* [17]. This freedom to determine the grounds on which compulsory license is possible to get issued transforms the measure to an important flexibility since the member state can decide on its own the circumstances and situations under which a license will be granted, instead of waiting for a national emergency. Moreover, paragraph 5(c) of the Declaration gives the right to WTO Members to determine what constitutes national emergency and if a current situation in a State can be qualified as emergency or not.

From what was mentioned above concerning the Doha Declaration, we understand that compulsory license has become important right- flexibility for the Member States in order to succeed public health policies and promotes access to medicines. Despite the fact that the legal text has no binding effect on the application of TRIPS Agreement, we have to keep in mind that it still constitutes an important legal document for the interpretation of TRIPS. The fact that compulsory licensing has been used in many cases, such as in Brazil in 2007, in Thailand the year after and recently in India [18], for promoting access to medicine might have transformed the limited use of the measure under TRIPS to a policy making tool used by States in any occasion that could amount as emergency. Thus, the violation of the right to property for the right holders and the removal of exclusivity of patents' use might become a mainstream for States in the name of public health.

3. THE STATUS OF COMPULSORY LICENSE UNDER INTERNATIONAL INVESTMENT LAW

3.1 The difficulties in defining compulsory license as indirect expropriation

Most of legal scholars, who have dealt with the issue of compulsory license as a claim of expropriation under international investment law, have focused their considerations on indirect expropriation [19]. Under the intellectual property regime, the issuance of compulsory license does not amount in a total transfer of legal title to the State and this might imply that patent holder's ownership rights are not really violated. Given that a direct expropriation under investment law standards means the transfer of the legal title of investor's property to the State or to a third party, the compulsory license does not fall under the scope of direct expropriation [20]. The reasonable result would be that compulsory license would amount to indirect expropriation under International Investment Law, however the lack of clarity concerning the degree of interference with rights of ownership that is required for an act or series of acts to constitute an indirect expropriation has been one of the most controversial issues [21]. There are a lot of ways for a measure taken by state so as to have a negative impact in an investment and thus there is no certain formula that can address directly what constitutes an indirect expropriation. Since the decision whether or not a compulsory license interferes with investor's property rights at a level that it can be considered as indirect expropriation, it is has to be examined in a case by case basis and under the context of recent cases addressing issues of indirect expropriation in investment law.

One of the main disadvantages that investment law presents in determining indirect expropriation is the language and definitions of investment law itself. In most of the cases, BITs or other investment agreements contain provisions that regulate the status of expropriation. As Lowenfeld has stated ; ' Standard terms establish what constitutes lawful expropriation under the BIT.....expropriation is not necessarily conflict with BITs where expropriation i) is carried out for a public purpose; ii) is non- discriminatory; iii) is carried out in accordance with due process, and iv) is accompanied by payment of compensation.' [22]. In the majority of these provisions, the inclusion of indirect expropriation is explicitly referred or clearly implied, however there is no guidance on how this treaty standard of protection should be applied in specific circumstances such as a government authorization of compulsory license.

The compulsory license as a form of indirect expropriation has an additional difficulty that has to be taken under serious consideration when we examine its status under investment law. In case we accept that it is an indirect expropriation under investment law that amounts to compensation claim for the investor, we need to keep in mind that in the intellectual property framework it is still a legitimate regulation that needs no compensation. Thus in the case of compulsory license there is the extra problem of the applicable law in order to determine the expropriation status. The ICSID Convention in Article 42 provides that unless the parties agreed on applicable law, the tribunal will apply the law of the host state and the rules of international law that might be applicable in every case [23]. The meaning of this provision, for many scholars including myself, is that international law can have a corrective effect for the gaps in the host state's domestic law, whenever these gaps constitute violation of international investment law [24]. However, still it is not clear if the regulatory framework of international law regimes and in particular the international intellectual property legal regime can constitute an appropriate source of law for determining the status of compulsory licensing as indirect expropriation.

Even if we accept that only international standards related to investment law are only possible to be concerned in determining the compulsory license as indirect expropriation, the only criterion that we have in relation to what constitutes internationally an expropriation is a part of the decision of *Starrett Housing Corporation vs Islamic Republic of Iran* that states :

‘It is recognized in international law that measures taken by a state can interfere with property rights to such an extent that these rights are rendered so useless that they must be deemed to have been expropriated, even though the state does not purport to have expropriated them and the legal title to the property formally remains with the original owner’ [25]

From what it has been stated in the text of the decision, there are two elements that need to be addressed in the case of compulsory license, in order to claim that compulsory license constitutes an indirect expropriation, we need to examine two particular elements which are: the level of deprivation of rights under compulsory license that constitute a taking and the level at which this taking constitutes an indirect expropriation. In my analysis I will examine one more factor which is the justification behind compulsory license, since as we have mentioned in chapter two, the compulsory license has normally the character of a regulatory action for a policy making purpose.

3.2 The potential status of compulsory license as an indirect expropriation

As I implied in the previous section, the sole effect doctrine expressed by the *Iran- U.S.* investment arbitration during the 1980s, has set two very important factors so as to examine the possibility of indirect expropriation in the case of compulsory license. These two factors are the level of deprivation of right that constitute a taking and the level under which a taking constitutes an indirect expropriation. Additionally to this, in this section we will analyze an extra factor, namely the purpose behind the issuing of compulsory license, since compulsory license is normally a regulatory measure used by governments in certain circumstances.

3.3 The Level of Deprivation of the Right that constitutes Taking

As it has been stated by Paulsson and Douglas, the key function of property is not the tangibility of things as such but the capability of rights providing exploitation of the thing for commercial or marketing purposes so as to succeed a commercial rate of return. [26] Thus, a compulsory license may operate to undermine an essential element of a patent right as investment. The patent rights are granted in order to support the exclusive commercial leverage of the right holder to exploit the invention in the market. So, as patent is not considered only the right of ownership over the patent but also the economic return that will come up after the exclusive exploitation of the patent by the patent holder. The grant of compulsory license is quite possible to have negative effects on this economic return of the right holder since there is no more exclusivity in exploitation. Thus, from what was mentioned above, the value of the patent- based investment will be decreased due to the issuance of compulsory license and so that constitutes *prima facie* a taking.

However, this taking does not mean that we have also an expropriation. From the analysis of the expropriation content, the taking should be a substantial deprivation to the investor’s property right. The criteria that assess this gap between a taking and an expropriation are no placed in the investment law for the compulsory license but in Article 31 of TRIPS, where it is assessed the degree of interference under the compulsory license. As it is stated in TRIPS agreement, the compulsory license’s terms will determine the legality and the degree of interference of a taking. Consequently, if the scope and duration of a license is in conformity with the standards set in TRIPS agreement and adequate remuneration has been paid to the right holder, the taking could

be legal and does not reach the level of expropriation in investment law. However, the lack of relevant decisions by arbitral tribunals makes the abovementioned consideration still a potential and not a given. What it is possible, then, to extract from this subsection is that compulsory licensing, indeed, constitutes a taking in investment law. However the level of interference with the investor's rights lies upon criteria by the intellectual property regime and the assessment of arbitral tribunal so as to consider this taking as indirect expropriation.

3.2.1. The Level under which a taking constitutes indirect expropriation

We have to underline that there is no provision in the main body of international investment law that determines which is the level that a taking is alike to an indirect expropriation. However, we have an extract form by the decision of *Metaclad Corp. Vs The United States of Mexico* [27] that determines two important factors that might transform a taking to an indirect expropriation. The first one is the specific undertakings or representations on the part of the state and the second one is the legitimate or reasonable expectations of the investor. In this way, the arbitral tribunal tries to distinct the cases where certain representations and expectations are existing by both sides from the cases that derive from policy changes on the behalf of the state, which most of the time, are part of the investment risk and no claim of expropriation can be raised, such as tax fee changing.

Regarding the first factor set by the decision in the case of compulsory license, namely the undertakings and representations on the part of the state, we need to assess the followings. The government's grant of patent rights confers a legal monopoly within the host state for a particular invention. This legal exclusivity is considered to be the return of the government for the inventor's agreement to share information on its creation with the public [28]. The award of a patent to the inventor is the result of a specific application procedure that the State has already approved, so the specific legal right is obtained by the patent based investor under the approval of the State. Thus, there are certain undertakings on the behalf of the state for the awarding of the patent and for this reason a compulsory license could be amount as indirect expropriation of the patent- based investment.

Regarding the second factor set by the decision, namely the legitimate expectations of patent holder we need to assess that, first of all, in an international level, a patent provides the right to exclude others from making, using, offering for sale, selling or importing the patented invention for the term of the patent, which is exactly twenty years from the filing date of the patent for Member countries of WTO. Unlike other law areas, the patent protection term is something that is harmonized not only in national but also in the international level and this well established term for the protection of a patent, creates to the patent- based inventor the security that his invention would be protected by the state awarding the patent throughout the entire term of these twenty years. So, it is understandable from the abovementioned considerations that the patent- based investor has legitimate expectations for the protection of his exclusivity on his patent for the entire term of twenty years.

However, the state cannot be always bound by the twenty years protection under TRIPS, when he designs social policies that are in danger due to the patent regime protection. In this case, the national patent legislation of a country is possible to include certain limitations of this twenty year patent protection. However, these limitations should be always prescribed by the national legal framework and should not be in conflict with the relevant international minimum standard. In these cases, the legitimate expectations of a patent- based investor should derive from both the international patent protection standard of twenty years and the national patent legislations with its delimitations. Consequently, a compulsory license that is granted by State outside the international and national framework of protection is against the reasonable and legitimate

expectations of a patent based investor and in this case the compulsory license again should amount to an indirect expropriation.

3.3. The Regulatory Purpose of Compulsory License

It is this particular factor in assessing a compulsory license as an indirect expropriation, where we have a certain intersection of investment law and intellectual property law. I have to state that no relevant decision has assessed ever the regulatory purpose of Compulsory License, so the analysis will be based on reasonable conceptions related to the nature of compulsory license as it has been stated in the second part of this study.

As we have already mentioned in the second chapter, the compulsory license in the intellectual property legal regime is normally a measure taken by a State in order for the State to regulate circumstances that might be of great importance for the public coherence. Particularly, after the Doha Declaration, we have seen that compulsory license is a valuable flexibility for States in order to face important public health emergencies and promote the access to medicines. This specific nature of compulsory license should remain under serious consideration even in an interdisciplinary field as the investment law for its assessment as indirect expropriation.

Of course, following the analysis above, we have already established that compulsory license is considered to be a taking of patent- based investment that reaches the level of indirect expropriation under some certain conditions. The consideration of the important nature of compulsory license as a regulatory tool for States, would be useful for the assessment of providing or not compensation for the indirect expropriation happening as a result of compulsory licensing. As you might remember, in the first subsection of chapter three we have underlined that one of the most difficult issues in assessing compulsory license in investment law, is the fact that assuming that compulsory license is an indirect expropriation, under investment law adequate compensation is required while under intellectual property regime there is no obligation for compensation. The assessment, given below, attempts to resolve this important conflict between the two regimes.

In the investment law, the importance of the issuing of compulsory license when it serves important regulatory purposes has been received great acknowledgement recently and almost all the modern models of BITs in the last decade have explicit provisions which exempt explicitly from indirect expropriation all these cases when a patent- based investment has been deprived due to the issuance of compulsory licensing [29]. However, in the majority of existing investment agreements there are no specific exemptions for deprivation of patent- based investments due to compulsory license. In this second case, the consideration of the regulatory purpose of the license should be considered as a reason for exemption from compensation for indirect expropriation. Nevertheless, the regulatory purpose in Article 31 of TRIPS is quite broad notion and there is no exhaustive list of reasons that could justify the issuance of compulsory license. As we have seen already, the determination of this purpose is up to the sovereign states and particularly, after the Doha Declaration, for public health emergencies, the State is possible to make use of compulsory license even in cases where there is no emergency need and issue this license for preventive policy making. In the assessment of compulsory license under investment law, we feel that the regulatory purpose should be more limited as a notion and compatible with the standards of protection of investment law, as they are embodied by the relevant BIT agreement.

It is important here to make a short reference on these standards of protection under investment law so as to formulate the exact framework of assessment of the regulatory purpose behind the issuance of a compulsory license. In investment law, there is no central treaty or central body that coordinates, regulates or provides a framework for the content of all the agreements [30].

However, in all the agreements there are some core protective standards of great importance for the treatment of foreign investors and their investments, which are the following : i) fair and equitable treatment for the investment, ii) national treatment and non-discrimination, meaning that every investment deserves treatment as favourable as that accorded to the country' s own citizens, while avoiding arbitrary or discriminatory measures, iii) most favourable nation treatment, meaning treatment as favourable as that accorded to other' s countries' citizens and iv) minimum standard of treatment in accordance with the international law. As we realize most these protective standards for investments rely upon the non- discriminatory treatment of a foreign investment in the host country. Thus, the purpose of issuance of a compulsory license for the deprivation of patent- based investment should not follow only the conditions set in Article 31 of TRIPS but first and foremost should respect the standard of non- discriminatory treatment so as to be assessed in the investment law regime. For example, assuming that there is a claim from a patent- based investor of indirect expropriation due to the issuance of a compulsory license on the grounds of cheap access to medicines. Assuming, as well, that the State is up to raise the defence of compulsory license justified under Article 31 of TRIPS. In order for this argument to be successfully assessed under investment law, the State should be in position to prove that the compulsory license is justified only for the breakdown of prices in medicines and applies to any pharmaceutical company in the country, not only to the foreign ones. On the contrary, a compulsory license issued for the enhancement of domestic production of pharmaceuticals is not in conformity with the protection standards of investment law and its issuance would definitely amount to indirect expropriation.

4.THE CLAIMS AGAINST COMPULSORY LICENSING BEFORE THE INVESTMENT TRIBUNAL

In the chapter three we considered a detailed framework for evaluating a claim of indirect expropriation due to the issuance of compulsory license under international investment law. In the current chapter we attempt to assess a potential claim of indirect expropriation due to compulsory licensing before the investment tribunal. It is quite understandable that we are not going to repeat whether and how the issuance of compulsory license might amount to indirect expropriation but we are going to address the research question whether or not an investment tribunal can apply or make reference to the TRIPS Agreement standards.

Scholars, such as Ermias Biadgleng of South Centre, have suggested that: *'except in circumstances where the provisions of investment agreements specifically refer to the provisions of the TRIPS Agreement, providing investors with the opportunity to challenge governments on the violation of the TRIPS or any other WTO agreement would be a radical departure from the self- contained system of negotiation, implementation and dispute settlement of WTO'*. The reasoning behind this argument is that the patent owners being able to bring successfully a claim before investment arbitration under TRIPS Agreement may be able to enjoy a higher level of protection than the one agreed in TRIPS Agreement. We, on the contrary believe, that in a self-contained regime such as investment law, where everything is about the protection of investor, even if this protection put obstacles in the policy making of a State, the consideration of arguments deriving from TRIPS Agreement might work as a sufficient defence against the abovementioned protectionism.

There are different considerations on how an argument based on the criteria of Article 31 of the TRIPS Agreement could be possible to get raised before the investment tribunal in a case of issuing of compulsory license. For us, there are two possible scenarios on how this argument could be raised: the first scenario is the use of the argument directly by the investor. The investor can claim that the issuance of compulsory license for his patent based investment did not follow

the conditions of Article 31 of TRIPS so as the government action can amount to indirect expropriation. The second scenario seems to be more realistic where a State can use the compliance with conditions of Article 31 of TRIPS Agreement as a defence against the claim of an investor that the issuance of compulsory license on the behalf of the State constitutes indirect expropriation of his patent- based investment.

In order to answer to our initial question whether or not an investment tribunal can apply or make reference to the TRIPS Agreement standards, we have to start our research from the language of the relevant investment agreement concerning the applicable law for the resolution of the investment dispute. As we have seen in chapter three there are investment agreement, such as the Model Agreement of U.S., where the consideration of TRIPS Agreement' s provisions before the investment arbitration is explicitly mentioned. The majority of existing investment agreements, though, does not contain any explicit reference to the use of TRIPS Agreement in international investment arbitration. Instead of this, there are general references for applicability of international law or the international customary law. Searching also in the provisions of ICSID Convention, as *lexspecialis* for the investment arbitration, there is also a reference in Article 42 for application of international law, unless the parties in the investment treaty have agreed upon the applicability of other national law. Despite the reference in international law, there is no explicit provision of what type of international law can be applied in the case. Thus, in the case of a compulsory license dispute before the investment arbitration, it is impossible to answer directly if the consideration of TRIPS Agreement is allowed or not.

Before we search for a possible answer outside the space of international investment law, we would like to try finding the answer to a regional investment agreement with great acceptance universally, meaning the NAFTA. Provisions on investments for the NAFTA members are placed in Chapter 11 of the Agreement. Article 1105 (1) states that: *'Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment'* [31]. This reference to international law has been interpreted by scholars and arbitral decisions in a quite conflicting way. While in several NAFTA chapter 11 cases, investors challenged violations by governmental regulatory measures, basing their arguments on violations of GATT and other trade agreements, which are equally applicable under the provision of Article 1105 (1) [32], the NAFTA Free Trade Commission has issued an interpretative guide for the Agreement, in which it is stressed out that the meaning of 'international law' in Article 1105 (1) is the applicability of international customary law only. This view of applicable international law under NAFTA is verified before the investment arbitrary tribunal in the case of *Mondev vs United States* [33]. Thus, we realize that there is no unified consensus on what type of international law can be applicable before the investment arbitration and consequently we cannot be sure that the international intellectual property regime can apply before the investment arbitration in cases of dispute due to the issuance of compulsory license.

Maybe one possible solution in order to answer our question is the use of a tool of the general international law such as the Vienna Convention on the Law of Treaties (hereinafter VCLT). Under Article 31(3)(c) VCLT, when interpreting a treaty, all the relevant rules of international law that are applicable in the case should be taken into account [34]. In other words, whenever an investment dispute involving a compulsory license is brought by an investor in international investment arbitration, according to the Article 31 (3) of VCLT, the standards of Article 31 of TRIPS Agreement as well as the relevant decisions of WTO Dispute Settlement Bodies could amount in a useful interpretative guide for the assessment of the case by the investment arbitration. Nevertheless, according to the abovementioned analysis, a separate argument based on TRIPS Agreement is not easy to stand as such before the investment arbitration. The fact that TRIPS Agreement can be useful in interpreting the framework of

investment law that we discussed in chapter three, does not mean that the agreement is applicable as such in relevant investment disputes. Thus, assuming that a dispute involving a compulsory license is brought by an investor in ICSID arbitration, the defensive argument of the State that compulsory license issued has been in conformity with the standards of Article 31 of TRIPS, might not be successful if the issuance of compulsory license does not meet first and foremost the requirements of investment law, discussed in the third chapter.

5. CONCLUDING REMARKS

From the interdisciplinary analysis of the compulsory license, in this study, we realized that compulsory license has a contested character both in intellectual property and investment law. Every government intended to authorize such a license should keep in mind that it might face a serious clash between significant opposing interests, meaning on the one hand the legitimate expectations of a patent-based investor founded by the International Investment Law for protection of exclusivity and on the other hand the public emergency situations, such as health crisis and outbreaks. The circumstances that may be associated with the compulsory licensing are providing the investor with a strong incentive so as to bring a dispute before the dispute settlements.

The patent based investor is entitled to have legitimate expectations with regard to the exclusivity of exploitation of his patent and a regulatory measure might amount to an indirect expropriation of his investments. On the side, it is a bit worrying that the State has to fulfil so many different standards set by both TRIPS Agreement and International Investment Law in order to be able to use the compulsory license for the purpose of lawful regulatory goals. A dispute involving compulsory license before the international investment arbitration, it is also problematic since there is no reference in the investment law regime on the application of other international legal regimes, so as the arbitral tribunal has to succeed always a balance between different interests on a case by case basis. This creates one more uncertainty for the States on the use of compulsory license as a regulatory measure.

By this study, we attempted to answer to two important questions, by placing compulsory license into the framework of international investment law. The first one was the status of compulsory license under international investment law, which has been addressed in part three and the second one was the application of TRIPS Agreement in investment arbitration, which has been addressed in part four. Since our scope was to examine the effect of compulsory license in the investment law regime and not to resolve a complex legal case, this studies gives a legal basis for a fruitful scientific dialogue regarding future litigation that will involve these two main legal fields related to pharmaceuticals, technology transfer and scientific progress.

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