REPORT ON THE USEOF COMPULSORY LICENCES TO FACILITATE ACCESS TO ESSENTIAL MEDICINES IN GREECE

Legal analysis and recommendations

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Chloe Forette, Harm Reduction, HIV & HCV Advocacy Officer, Médecins du Monde

Yannis Natsis, Access to medicines Advisor, TransAtlantic Consumer Dialogue (TACD)

Hara Tziouvara, Medical Doctor, Member of Board, Doctors of the World Greece

Teresa Mimikou, Public Health programs officer, Doctors of the World - Greece

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Introduction

The agreements with the Troika (Memoranda of Understanding) have resulted in horizontal cuts in public health expenditure. The shrinkage of state expenditure, structures and services as well as the considerable understaffing of the public health system have created unprecedented obstacles to access to health services for many people living in Greece.

In this context access to essential medicines is rendered impossible for part of the population, while pharmaceutical expenditures cripple the public health budget.

Using generic medicines and encouraging competition to bring the prices down should be automatic for all unpatented medicines. But critical situations in terms of access concern medicines that are still covered by patents, for which there is a monopoly held by one company which is responsible for very high and unaffordable prices.

The present study was commissioned to explore the existing legal mechanisms in the Greek law on intellectual property which could allow the use of generic versions of key patented medicines which are currently extremely high- priced. This mechanism, commonly known as "compulsory licence", which exists in the international agreements on intellectual property of the World Trade Organization (WTO) and in other EU laws, makes it possible to authorize the use of a patent without the consent of the rightholder (s), but with the payment of a royalty.

As the legal analysis revealed that the Greek provisions on compulsory licensing on several accounts impose requirements and conditions that are more restrictive than the international standards (TRIPS Agreement of the WTO), the present study also developed recommendations for key amendments of the law.

HEALTH CONTEXT AND TARGETED MEDICINES

Access to medicines and in particular to life-saving treatments have been considerably hindered by the crisis and the austerity policies. This constitutes a harsh reality both for those who are not entitled to health insurance and have fallen out of social security due to chronic unemployment; and also for those who still maintain some sort of social coverage but have to cope with high co-payment rates. As a consequence, there is an alarming rise in patients who self-manage their condition based on the affordability of the treatments and not based on what is best for their health. Furthermore, drug shortages have been recorded over the past few years, while the pharmaceutical expenditure, and particularly the cost of some very recent and expensive drugs, is imposing a heavy burden on the public health budget and is unsustainable – public pharmaceuticals expenditure represented at least 23% of public health expenditure in 2012.

The cases of four costly cancer drugs as well as of three new drugs against hepatitis C were considered to explore alternative solutions that would guarantee patients' access to these much-needed medicinal products.

Cancer drugs

1. **Bevacizumab**, marketed under the trade name **Avastin®**, is approved for use for certain metastatic cancers, lung cancers, renal cancers, ovarian cancers, and for glioblastoma multiforme (GBM) of the brain. It is an angiogenesis inhibitor, a drug that slows the growth of new blood vessels. It is on the World Health Organization's Model List of Essential Medicines. Bevacizumab is also the first treatment in nearly a decade to extend the life of women with advanced cervical cancer. The patent of Bevacizumab is owned by the pharmaceutical company Roche. It is one of the most expensive drugs currently on the market. The hospital price of Avastin® (400mg/16ml) in Greece is 925,39 €[1] and its retail price is 1.145,52 €.[2] The cost of the

1 Source: http://www.galinos.gr/web/drugs/main/substances/bevacizumab#content

2 As from 29-1-2016, according to a Ministerial decision, these prices will be reduced; the hospital price will be 853,85 € and the retail price 1.062,02 €

active substance is 2.313 € per gram at the hospital price. A standard treatment is for instance 10 mg/kg of body weight given once every 3 weeks as an intravenous infusion. For a person weighing 75 kg the infusion then costs 1.734 € at the hospital price. A treatment may contain 6 cycles and can last up to 15 months. As Avastin® can treat many cancers it is very commonly used.

2. **Pertuzumab**, also called 2C4 and marketed under the name **Perjeta®**, is used in the treatment of HER2[3]-positive metastatic breast cancer. It is a monoclonal antibody used in combination with other drugs. It is well tolerated with very low toxicity levels and is commonly used in conjunction with Trastuzumab[4] due to the development of primary and acquired resistance in the majority of patients. In patients with HER2-positive metastatic breast cancer, the addition of Pertuzumab to Trastuzumab and Docetaxel significantly improved the survival of patients. Pertuzumab was developed by Genentech and is now marketed by Roche which acquired Genentech in 2009. It is expensive and unaffordable in Greece. The hospital price of Perjeta® (420mg/14mL) is 2.401,98 € for one vial and its retail price is 2.902,59 €[5]. As a matter of comparison, the per capita income in Greece in 2014 was estimated by the European Commission to be 17.000 €[6]. The recommended initial loading dose of Perjeta® is 840 mg administered as a 60 minute intravenous infusion, followed every 3 weeks thereafter by a maintenance dose of 420 mg administered over a period of 30 to 60 minutes. The initial loading dose amounts to 4.803,96 € at hospital price[7].

3. **T-DM1**, also known as **Trastuzumab emtansine**, is a combination of two drugs to treat patients with HER2-positive, metastatic breast cancer who previously received Trastuzumab and Taxane, separately or in combination. Trastuzumab emtansine is

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http://www.galinos.gr/web/drugs/main/substances/bevacizumab#content

3 Human Epidermal growth factor Receptor 2 (HER2), which promotes the growth of cancer cells

4 a monoclonal antibody that targets the sub domain IV of HER2

5 Source: http://www.galinos.gr/web/drugs/main/packages/21971#content
http://www.galinos.gr/web/drugs/main/drugs/perjeta

6 Source:
http://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&pcode=tsdec100&plugin=1

7 As from 29-1-2016, according to a Ministerial decision, these prices will be reduced; the hospital price will be 2.343,78 € and the retail price 2.832,32 €
http://www.galinos.gr/web/drugs/main/packages/21971#content
http://www.galinos.gr/web/drugs/main/drugs/perjeta

sold by Roche under the trade name **Kadcyla®**. The hospital price (one vial of 100mg) is 1.536,18 €[8], while the retail price is 1.708,59 €[9] .Although this is extremely expensive and unaffordable to the Greek budget, this medicine represents the only option of survival for many patients in Greece with HER2-positive metastatic breast cancer.

4. **Ipilimumab**, is marke**ted under the name Yervoy®** and used in the treatment of melanoma, a highly malignant skin cancer. It is a monoclonal antibody that activates the immune system by inhibiting CTLA-4, a protein receptor that regulates the immune system. Ipilimumab is approved to treat patients with late-stage melanoma that has spread or cannot be removed by surgery. The research on this type of tr**e**atment was conducted at the Cancer Research Laboratory at the University of California, Berkeley. Clinical development was initiated by Medarex, which was later bought by Bristol-Myers Squibb. Yervoy is expensive and unaffordable in Greece. The hospital price[10] of Yervoy® (200 mg/40 ml) is 12.776,40 € and its retail price 15.363,85 €[**11**]. The cost of the active substance is 63.882 € per gram at the hospital price. The recommended induction regimen of Yervoy is 3 mg/kg a dose administered intravenously over a 90-minute period every 3 weeks for a total of 4 doses. A person of 75 kg needs 225 mg every 3 weeks which amounts to 14.373,45 € at hospital price. The total treatment of 4 doses is 57.493,8 € at hospital price.

Drugs against Hepatitis C

For the past fifteen years, the leading treatment regimen combined the injection of pegylated interferon and ribavirin. This long and arduous treatment (with serious side effects) achieves cure rates ranging from 50% to 70%.

8 http://www.galinos.gr/web/drugs/main/packages/23699#content

9 As from 29-1-2016, according to a Ministerial decision, these prices will be reduced; the hospital price will be 1.414,44 € and the retail price 1.730,10 €
http://www.galinos.gr/web/drugs/main/packages/23699#content

10 Source: http://www.galinos.gr/web/drugs/main/packages/20596#content

11 As from 29-1-2016, according to a Ministerial decision, these prices will be reduced; the hospital price will be 11.959,89 € and the retail price 14.382,29 €
http://www.galinos.gr/web/drugs/main/packages/20596#content

2011 marks a milestone in HCV treatment with the introduction of a new generation of drugs, which have been put on the market since the end of 2013: direct-acting antivirals (DAAs)[12]. These medicines lead to a huge improvement in the treatment and care of hepatitis C patients. Combined, sofosbuvir and daclatasvir or sofosbuvir and ledipasvir allow patients to be treated in a more efficient manner: for example, the drugs do not require injection and can be administered orally. These drugs are better tolerated by patients and the cure rate exceeds 90%. Therefore, they represent a great hope for people suffering from hepatitis C and provide an opportunity to eradicate the virus.

International guidelines[13] for the treatment of hepatitis C, recommend the combined administration of sofosbuvir with daclatasvir, as well as sofosbuvir with ledipasvir instead of sofosbuvir alone.

1. **Sofosbuvir**, known under the brand name **Sovaldi®**, is used for the treatment of chronic hepatitis C. It is a nucleotide analog used in combination with other drugs. It provides a higher cure rate with fewer and less severe side effects than previous treatments. It was recently added to the World Health Organization's Model List of Essential Medicines. Sofosbuvir was developed by Pharmasset which was then bought by the pharmaceutical company Gilead. The price in Greece is very expensive: one gram of sofosbuvir costs 1.136,637 €. The hospital price for a box of 28 pills of 400 mg of sofosbuvir is 12.730,34 €, while its retail price is 15.308,80 €[14]. Thus the three weeks course reaches 38.191.02 €[15] at a hospital price and 45.926,4 € if purchased from a pharmacy.

12 DAAs are molecules that target specific nonstructural proteins of the virus and result in disruption of viral replication and infection.
http://www.uptodate.com/contents/direct-acting-antivirals-for-the-treatment-of-hepatitis-c-virus-infection?source=search_result&search=direct+acting+antivirals+for+the+treatment+of+hepatitis+c+virus&selectedTitle=1~150

13 American Association for the Study of Liver Diseases (AASLD), European Society for the Study of Liver Disease (EASL), Infectious Diseases Society of America (IDSA)

14 Source: http://www.galinos.gr/web/drugs/main/packages/23851#content

15 As from 29-1-2016, according to a Ministerial decision, these prices will be reduced; the hospital price will be 12.100,97 € and the retail price 14.551,95 €
http://www.galinos.gr/web/drugs/main/packages/23851#content

2. Daclatasvir, known under the brand name **Daklinza®**, is used for the treatment of chronic hepatitis C. It is a NS5A inhibitor used in combination with other drugs. It provides a higher cure rate and with less severe side effects than previous treatments. It was recently added to the World Health Organization's Model List of Essential Medicines. Daclatasvir is developed by Bristol- Myers Squibb (BMS). The price in Greece is very expensive: 1 gram of daclatasvir active substance costs 10.864,0476 €[16]. The hospital price for a box of 28 pills of 30 mg of daclatasvir is 9.125,80 €, while its retail price is 10.974,18 €[17]. Thus the twelve weeks course reaches 27.377,4 € at a hospital price and 32.922,54€ if purchased from a pharmacy.

3. Ledipasvir, associated with sofosbuvir in one tablet is known under the brand name **Harvoni®**. This combination is used for the treatment of chronic hepatitis C. It is also a NS5A inhibitor; it provides a higher cure rate with less severe side effects than previous treatments, while the required dosage is only one tablet per day. In addition, if it is administered at the early stages of the disease, therapy can be achieved within 8 weeks instead of 12 if administered at a later stage. It was recently added to the World Health Organization's Model List of Essential Medicines. Ledipasvir, in combination with sofosbuvir is developed by Gilead Science International Ltd. This drug is not priced yet in Greece but it is provided by the National Organization for Health Care Services Provision (EOPYY) following the submission of a request to the competent Committee, but many decisions are negative. The price of **Harvoni®** for a box of 28 pills (400 mg Sofosbuvir/ 90 mg Ledipasvir) is 12.293€ and the 3 week therapy costs 36.879 €[18]**.**

In order to deal with the excessive prices of these drugs and the situation it is creating for the patients and for the sustainability of the national health budget, the government should make use of existing legal tools in the patent law to allow generic competition, which would lead to significant decreases in the prices and would make the drugs accessible.

16 http://www.galinos.gr/web/drugs/main/packages/23479#content

17 As from 29-1-2016, according to a Ministerial decision, these prices will be reduced; the hospital price will be 7.972,30 € and the retail price 9.587,04 €
http://www.galinos.gr/web/drugs/main/packages/23479#content

18 Information provided by the Liver Patient Association of Greece "Prometheus"

LEGAL ANALYSIS OF THE GREEK PROVISIONS ON COMPULSORY LICENCES AND OTHER RELEVANT TEXTS

The International Agreements that regulate patent rights (e.g. the TRIPS Agreement from World Trade Organization (WTO) and the Paris Convention) offer options and flexibilities to the contracting parties to resort to generic drugs when they face serious health issues. Compulsory licensing is a provision of the international intellectual property system that allows a state to authorize a third party or a state entity to use (for instance produce or import and market) patented products without the consent of the patent owner, but in exchange for the payment of royalties to him/her. This possibility exists in all national patent laws.

The TRIPS Agreement allows compulsory licensing as part of the agreement's overall attempt to strike a balance between private exclusive rights and public interests and needs, and to prevent an abuse of rights by the initial holder of the patent or a misuse of the patent. Article 31 of the TRIPS Agreement, titled "Other use without authorization of the right holder", sets the conditions under which compulsory licences can be granted while protecting the legitimate interests of the patent holder.

In November 2001, Members of the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health during the Ministerial Conference in Qatar. This declaration states that WTO Members should implement intellectual property laws in a manner that promotes access to medicines for all, using to their full extent the flexibilities allowed by TRIPS. While the TRIPS Agreement provides countries with a broad discretion to establish the conditions under which they may issue compulsory licences, the Doha Declaration reiterates that countries have "the freedom to determine the grounds upon which such licences are granted".

In the Greek law, compulsory licensing is governed by Art. 13 and 14, of Law 1733/1987 (Government Gazette 171 A/22.09.1987) "Technology transfer, inventions, and technological innovation" as amended by Art. 18, of Law No. 1739/1987 (Government Gazette 201, A' of 20.11.1987), which is the main piece of legislation governing patents in Greece. It is referred to as "non-contractual licence"

in Article 13 (in patent laws in other countries it may be referred to as "non–voluntary licence") or “Licence for Public Sector” in Article 14 (this form of compulsory licence is called “Government use” or “Crown use” or "licence d' office" in patent laws of other countries).

These two Articles establish two different forms of compulsory licences[19].

Article 13 of Law 1733/87 reads as follows:

" *Non-contractual license*

1. The competent court mentioned in paragraph 10 of the present article may grant to a third party, without prior consent of the patentee, a license for exploitation of the patent in case that the following prerequisites concur accumulatively:

a. A period of three years has elapsed since the grant of the patent or a period of four years has elapsed since the filing date of the patent application;

b. The relevant invention has not been exploited [~~productively]~~ [20] in Greece or, in case it has, the production of the products thereof is insufficient to cover local demand;

c. The third party is in a position to exploit productively the invention covered by the patent;

d. The third party notified the patentee, one month prior to the initiation of the judicial proceedings, regarding his intention to request a non-contractual license.

2. The non-contractual license shall not be granted in case the patentee justifies lack of exploitation or insufficient exploitation in the country. The importation of the product does not constitute an excuse for the invocation and application of this paragraph. The regulation of item 1 above shall not apply to products imported from Member States of the European Union and the Member States of the World Trade Organization [1].

3. The grant of a non-contractual may not exclude other contractual or non-contractual licenses. The non-contractual license may be assigned only along with the part of the enterprise which exploits the invention.

4. The owner of the patent may request from the competent court mentioned in paragraph 10 the grant of a non-contractual license on an earlier patent, provided that his invention relates to the invention of the earlier patent, the productive exploitation of said invention is not possible without offending the rights of the owners of the earlier patent and his invention constitutes a significant progress in comparison with the invention of the prior patent. When the aforementioned non-contractual license has been granted, the owner of the earlier patent may request the granting of a non-contractual license for the subsequent invention.

5. The non-contractual license shall be granted following petition of the interested party before the competent court mentioned in paragraph 10.

19 In UK the word licence is used as a noun while license as a verb. In USA the word license is used both as a noun and verb. In our text we followed the UK use, while in the quotation from the law we kept the original orthography

20 This word does not appear in the official English translation but it is present in the Greek version.

The petition is accompanied by the opinion of the Industrial Property Organisation regarding the existence of the prerequisites for granting the non-contractual license in accordance with the preceding paragraphs, the amount, the terms of the compensation to be given to the owner of the patent, and the exclusive or non exclusive character of the exploitation of the invention. The Industrial Property Organisation states its opinion following petition of the party interested in exploiting the patent. The opinion of OBI is granted within one month form the date the relevant petition is filed and is not binding for the competent court. Copy of the application for granting a non- contractual license along with the relevant opinion of OBI and the note fixing the day of the trial shall be notified to the owner of the patent and to the beneficiaries of other contractual or non-contractual licenses.

6. In case the petition is approved, the competent court grants a non- contractual license. The license pertains to the extent of the exploitation rights of the invention, the duration of its validity, the date of commencement of the productive exploitation of the invention in Greece and the amount and terms of compensation to be paid to the patentee by the beneficiary of the license. The amount and the terms of the compensation are determined in accordance with the extent of the industrial exploitation of the protected invention.

7. The decision of the court in accordance with paragraph 6 shall be recorded to the Patents Register of OBI, published in the Industrial Property Bulletin and notified to the persons mentioned in paragraph 5.

8. Following petition of the owner of the patent or the beneficiary of the non-contractual license, the competent court mentioned in paragraph 10 may amend the terms of granting of the license if new data justify the amendment or revoke the non- contractual license if its beneficiary does not respect the terms of the licence or if the prerequisites for its granting have ceased existing. If the immediate revocation brings about a significant damage to the beneficiary of the non-contractual licence, the court may allow the continuation of the exploitation for a reasonable period of time.

9. The non-contractual license does not grant the right for importation of the products covered by the invention.

10. The competent court for the grant, assignment, amendment or revocation of a non-contractual license is the three member court of first instance at the place of residence of the petitioner, which judges in accordance with the proceeding of article 741 to 781 of the Code of Civil Procedure Law.

[1] Item 3 of paragraph 2 of Article 13 is cited as replaced by Article 2 of Presidential Decree No. 54/1992 and Article 9 par. 4 of Law No. 2359/1995"

The granting of a non-contractual patent licence to a third party is the result of a court proceeding. Below are some salient aspects of this Article that need to be commented on:

• **Article 13.1** requires four conditions to be met **"accumulatively"** for the court to grant a licence to a third party:

1. A period of three years since the grant of the patent or a period of four years since the filing date of the patent application.
2. Absence of productive exploitation in Greece or, insufficient production of the products to meet local demand.
3. The third party is in a position to exploit productively the invention covered by the patent.
4. The third party notified the patentee of its intention to request a non-contractual licence one month before the initiation of judicial proceedings.

- **Article 13.1.a** is a condition set by the Paris Convention.

- **Article 13.1.b** refers to "productive exploitation" which implies that exploitation cannot be fulfilled by importation.

- **Article 13.1.c** requires the third party that will benefit from the licence to be able to produce the product covered by the patent which is a severe limitation for third parties, because it means they cannot rely on importation.

- **Article 13.1.d** is a procedural requirement.

• In accordance with the Paris Convention (Art 5. 1.4), **Article 13.2** provides the possibility for the patent holder to justify the lack of exploitation or insufficient exploitation and block the non-contractual licence. According to the second sentence of the paragraph, importation cannot be used as an excuse by the patent owner to justify lack of or insufficient local exploitation, which implies that importation is not considered to be exploitation. The first two sentences of Article 13.2 were added to the patent law of 1987 in 1992. Later on, in 1995, a third sentence was added to specify that the second sentence does not apply to products imported from EU Members and more generally WTO Members. This means that for these countries (161 members of the WTO, which include all EU members) importation can be

considered as exploitation, however this is not the case for the rest of the countries in the world. The addition from 1995 improves the text a little, but it does not totally mitigate the limitation introduced in 1992.

• **Article 13.3** establishes that the granting of one non-contractual licence for a given patent does not preclude the granting of more non-contractual licences for these patent or voluntary licences. It also provides that a non-contractual licence cannot be transferred or sold (unless the whole enterprise that holds the licence is acquired), which is consistent with the Paris Convention.

• **Article 13.6** provides that the licence shall be used for "productive exploitation" which excludes the possibility of importation. It also mentions that the terms of the compensation depend on the "extent of the industrial exploitation" which can be understood as meaning that the percentage of royalty can be reduced if the exploitation is important (see insert below about remuneration).

• **Article 13.9** clearly provides that the non-contractual licence cannot be used to import products, which is a major limitation when patent owners with headquarters in the EU or any country member of the WTO are allowed to exploit their invention(s) through importation (Article 13.2).

• **On a procedural level**, **Article 13** establishes that the compulsory licence is granted following a petition by the third party before the three-member first instance court located at the third party's place of residence. The Patent Office provides an opinion about the granting of the licence and suggests the level of compensation for the patentee. The court's decision must be recorded with the Patent Office and the terms of the licence may be amended only by a decision of the same court, following a petition of the patentee or the licensor and on condition that new evidence to justify such an amendment exists.

The article 14 of Law 1733/87 reads as follows:

" License to the Public Sector

1. For imperative reason of serving public health and national defense after justified decision of the Minister of Industry, Energy, and Technology and, according to the case, any competent Ministers, a license for exploitation of an invention can be granted to bodies of the public sector which may exploit the invention in Greece, provided that the relevant invention

has not been productively exploited in Greece or the production of the products thereof is insufficient to cover local needs.

2. Prior to the issue of the relevant decision, the patentee and anyone who is in position to give useful advice, are called upon to express their views.

3. By the same decision, following the opinion of OBI, the amount and the terms of the compensation to the owner or the patent are determined. The amount of the compensation is determined in accordance with the extent of the industrial exploitation of the invention. In case of disagreement of the patentee as regards the amount of the compensation, the compensation is determined by the relevant one-member court of first instance of the jurisdiction, in the injunction proceedings."

The patent licence to the Public Sector is an administrative decision dedicated to serve public health or national defence.

Article 14.1 establishes that the compulsory patent licence shall be granted by the *Minister of Industry, Energy, and Technology*. However, the Ministry that existed in 1987 has been restructured over time. Today, the former "Industry, Energy, and Technology Ministry" is divided into the following Ministries:

- **The Ministry of Economy, Development and Tourism** is in charge of industry issues. Under this ministry is the General Secretary of Industry.
- **The Ministry of Environment and Energy** is in charge of energy issues.
- **The Ministry of Education, Research and Religious Affairs** is in charge of Technology issues. Under this ministry is the General Secretary of Research and Technology.

• **The relevant authority to grant the compulsory licence** in place of the Minister of Industry, Energy, and Technology **is the present Ministry of Economy, Development and Tourism** which is responsible for industry issues and industrial property titles (i.e. patents).

• **The Minister of Health** can either take part in the decision or advise the Ministry of Economy, Development and Tourism. The licence is granted to a body or an institution belonging to the public sector to exploit the patent, for instance order the supply of generic medicines to the public system.

• However, here also, as in Article 13, the precondition for granting a compulsory licence is that the patent has not been productively exploited in Greece or that ongoing production is insufficient to cover local demand.

• As explained above in Article 13, also in Articles 14.2 and 14.3, before the relevant administrative decision is issued, the patentee is asked to express its views, while the Patent Office is asked to provide an opinion about the non-contractual licence. Article 14.3 also establishes that the Minister of Industry, Energy, and Technology (today the Minister of Economy Development and Tourism) is to set the amount and terms of the compensation by the same decision. As in Article 13 the compensation needs to take into account the "extent of the industrial exploitation of the invention".

The TRIPS Agreement

The TRIPS Agreement allows compulsory licensing as part of the Agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs.

" Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use (7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the 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. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

• Prior negotiation before issuing a compulsory licence:

Article 31.b of the TRIPS Agreement requires that before a compulsory licence is issued "the 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". Concretely this means that there needs to be an attempt to obtain a voluntary licence from the patent holder and that the latter either says no or does not respond within a period of time considered as reasonable. To request the authorization, it is sufficient to send a letter to the patent holder (specifying the timeframe within which a response is expected, for instance two months).

However, Article 31 also waives this requirement in certain situations, that is: "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use". This typically applies to compulsory licences issued for the public sector (as provided by Article 14 of the Greek law). In this case TRIPS requires that the patent holder only be "informed promptly" (within a month for instance).

• Remuneration for compulsory licence:

Upon issuance of a compulsory licence and according to Article 31.h, the owner(s) of the relevant patents are entitled to remuneration. Article 31.h of the TRIPS Agreement states that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.” However, the term “adequate remuneration” is not defined in the TRIPS Agreement. WTO Members are free to determine the appropriate method of implementing it, within their own legal system and practice, and to determine what they consider to be an “adequate” remuneration.

According to Article 14.3 of the Greek law the Minister who grants the licence also decides regarding the remuneration. Article 14.3 requires that "*The amount of the compensation is determined in accordance with the extent of the industrial exploitation of the invention."*

In recent years, a number of countries have issued compulsory licences on essential drugs (HIV/AIDS, cancer, etc.) in developing countries (Thailand, Brazil, India, Indonesia, Malaysia, Zambia, Mozambique, etc.); the royalty rate they set was between 0,5% and 4% of the price of the generic medicines. Royalty guidelines proposed by the Japanese Patent Office (1998) set normal royalties of 2% to 4% of the price of the generic product with a possible increase or decrease of as much as

2%. The 2001 UNDP Human Development Report (HDR) proposed a base royalty rate of 4% of the price of the generic product which can be increased or decreased by 2% depending on factors such as the degree of innovation of the medicine or the role of governments in paying for medical R&D. The 2005 Canadian royalty guidelines for the export of medicines to countries that lack manufacturing capacity set royalties at 0 to 4% of the generic price, depending on the level of development of the importing county. Finally, a Tiered Royalty Method (TDM) relies upon (1) a proxy for the therapeutic benefit of the products, and (2) a measure of affordability. It gives a global base royalty (for instance 4%) which is then adjusted for different countries according to measures of affordability.[21]

21 See "Remuneration guidelines for non-voluntary use of a patent on medical technologies", James Love, 2005, WHO/TCM/2005.1. Accessible at: http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf

RECOMMENDATIONS FOR AMENDMENTS OF THE GREEK LAW PROVISIONS ON COMPULSORY LICENCES

The Greek Law N. 1733/1987 governing inventions and patents has never been significantly amended since 1987. On several accounts it appears to be setting requirements and conditions for the use of compulsory licence which are more restrictive than the international standards (TRIPS Agreement) and that may considerably limit the ability of the Greek government to respond to the contemporary and pressing health challenges that the country is facing.

These unnecessary limitations as well as the current financial and social constraints, call for key modifications of the law in order to promote the general interest, in particular the current needs of Greek patients, while being consistent with the TRIPS Agreement.

In this context, we suggest the following amendments to:

I. Article 13

II. Article14

I. Article 13

It is suggested to:

i) delete the word "accumulatively" from article 13.1.

ii) delete the words "productively" and "production of the products" from article 13.1.b and the word "productively" from article 13.1.c as well as anywhere else these words exist in the text of the law (article 13.4, 13.6).

iii) replace the term "production of the products" in article 13.1.b. by the word "exploitation"

iv) delete paragraph 9

Justification of the recommended amendments

Article 13, paragraph 1, which sets conditions for the judicial grant of a compulsory licence, requires that four conditions are met cumulatively.

For its part, the TRIPS Agreement (Article 31) does not require that all these conditions are to be satisfied, and does not even mention some of them (this is also true of the patent laws in Belgium, Cyprus, Finland, France, Germany, Italy, Portugal, Spain, Sweden, the United Kingdom, etc.). The TRIPS Agreement left much room to its members to design their provisions on compulsory licences in their national law. They can add restrictions and give up on flexibilities but in doing so they limit their own options. The fact that under the Greek law the conditions must be met cumulatively significantly impedes the application of such provisions.

In its Article 4, the TRIPS Agreement establishes that all WTO Members have to comply with Articles 1 to 12 and 19 of the Paris Convention. The Paris Convention includes some relevant requirements, among others it examines the issuance of compulsory licences, on the ground of failure to work or insufficient working, after "a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent".[22]

The Greek law has integrated this element into its Article 13.1.a, but it also introduces, as a requirement in Art. 13.1.b, that the invention has not been or not been sufficiently exploited "productively" in Greece. This would seem to mean that in order to trigger the compulsory provision it is necessary that the product covered by the invention has not been produced in Greece or produced in enough quantity to cover local demand – which is neither required by the Paris Convention nor by the TRIPS Agreement.

In addition, Article 13.1.c states that the third party has to be "in a position to exploit productively the invention covered by the patent", which means to be able to produce the invention covered by the patent. This implies that the compulsory licence

22 Article 5. A. (4) "A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license."

cannot be used to import a product. It is certainly not required by TRIPS or the Paris Convention and is a particularly problematic limitation.

Indeed, in the majority of cases in most countries, there is no chance to produce domestically the necessary medicines to cover the domestic needs and the only possible exploitation of the patent is through importation. This is why provisions on compulsory licences usually only require third parties to be able to "exploit", "exploit commercially", "work the invention" the patent as it is the case of patent laws in Cyprus, Finland, France, Germany, Italy, Portugal, Spain, Sweden, the United Kingdom, among others.

Taking all the above into consideration, a simple and easy way to solve these problems is to:

1. **delete the word "productively" in Article 13.1.b**
2. **delete the words "productively" and "production of the products" from article 13.1.b and the word "productively" from article 13.1.c as well as anywhere else these words exist in the text of the law (article 13.4, 13.6).**
3. **replace the term "production of the products" in article 13.1.b. by the word "exploitation"**

Accordingly, the following wording is suggested:

Article 13, paragraph 1

1. The competent court mentioned in paragraph 10 of the present article may grant to a third party, without prior consent of the patentee, a licence for exploitation of the patent in case that the following prerequisites concur ~~accumulatively~~: ……..

Article 13, paragraph 1.b

*b. The relevant invention has not been [~~productively~~] exploited in Greece or, in case it has, the ~~production of the products thereof~~ **exploitation** is insufficient to cover local demand;*

Article 13, paragraph 1.c

c. The third party is in a position to exploit ~~productively~~ the invention covered by the patent;

Article 13, paragraph 4

*4. The owner of the patent may request from the competent court mentioned in paragraph 10 the grant of a non-contractual licence on an earlier patent, provided that his invention relates to the invention of the earlier patent, the ~~productive~~ **exploitation** of said invention is not possible without offending the rights of the owners of the earlier patent and his invention constitutes a significant progress in comparison with the invention of the prior patent. When the aforementioned non-contractual licence has been granted, the owner of the earlier patent may request the granting of a non-contractual licence for the subsequent invention.*

Article 13, paragraph 6

*6. In case the petition is approved, the competent court grants a non- contractual licence . The licence pertains to the extent of the exploitation rights of the invention, the duration of its validity, the date of commencement of the ~~productive~~ **exploitation** of the invention in Greece and the amount and terms of compensation to be paid to the patentee by the beneficiary of the licence. The amount and the terms of the compensation are determined in accordance with the extent of the industrial exploitation of the protected invention.*

Paragraph 9 of Article 13, explicitly states that the compulsory licence cannot be used to import products covered by the patent.

This provision significantly restricts the application of the compulsory licence, as the persons that benefit from a compulsory licence must exclusively produce the object covered by the patent and not import it. In the case of pharmaceutical products, it seriously limits the possibility to introduce generic competition. In Greece, as in most countries, the vast majority of pharmaceutical patents are exploited through importation and most drugs that are placed on the market are produced elsewhere and imported. Although there are capacities in Greece for local productions they may not be sufficient to ensure rapid supply of complex recent drugs, or to meet the needs in terms of volumes in some cases. The exclusion of the use of compulsory licensing for importation is certainly not required by the WTO and is not a feature of the vast majority of the patent laws across the world. For instance, in the EU such limitation does not exist in the patent law of the following, among other countries: Cyprus, France, Germany, Italy, Portugal, Spain, Sweden, Finland and United Kingdom.

In Greece, as elsewhere, those who apply for a compulsory licence must be permitted to import medicines from other countries. In this way, access to the medicines will be rendered easier and they will reach more patients who currently either cannot pay for, or due to insufficiency of supply have difficulty in obtaining, their medicines. This would not prevent local producers from benefiting from the

compulsory licence as they would have the opportunity to produce the drugs if they can.

Accordingly, it is suggested to delete paragraph 9 of Article 13:

Article 13, paragraph

~~*9. The non-contractual licence does not grant the right for importation of the products covered by the invention.*~~

II. Article 14

It is suggested to:

i) **delete the word "productively" from paragraph 1 and to replace the term "production of the products" by the term "exploitation" in the same article.**

ii) **Insert a third condition concerning the high prices of the medicines in paragraph 1.**

iii) **replace the word "called" by the wording "may be called" in paragraph 2**

Justification of the suggested amendments

A. As analyzed above in the justification of the suggested amendments of article 13, **the word "productive" should be also deleted from paragraph 1 of article 14.**

Accordingly, the following wording of paragraph 1 of article 14 is suggested:

Article 14, paragraph 1

"For imperative reason of serving public health and national defense after justified decision of the Minister of Industry, Energy, and Technology and, according to the case, any competent Ministers, a licence for exploitation of an invention can be granted to bodies of the public sector which may exploit the invention in Greece, provided that the relevant

*invention has not been ~~productively~~ exploited in Greece or the ~~production~~ **exploitation** of the products thereof is insufficient to cover local needs."*

B. In addition, taking the example of other European countries that have included interesting language (wording) in their patent law which is both consistent with the TRIPS Agreement and can facilitate access to medicines, Greece should introduce a third ground for compulsory licensing related to the price of medicines.

In France for instance, in the Intellectual Property Code of 1992, article L. 613-16 relating to compulsory licences reads as follows:"If the **interest of public health** so requires and in the absence of an amicable agreement with the patent owner, the Minister for Industrial Property may, at the request of the Minister for Public Health, subject, by decree, to the ex officio license regime, under the conditions specified in Article L613-17, any patent granted for: (a) a medicine, medical device, an in vitro medical diagnostic device, or a related therapeutic product; (b) the process for obtaining them, a product necessary for obtaining them or a process for manufacturing such a product; (c) an ex vivo diagnostic method. The patents for these products, processes or methods of diagnosis may be subject to **the ex officio license regime in the interest of public health** only when these products, or products resulting from these processes, or these methods are **made available to the public in an insufficient quantity or quality**, **or at abnormally high prices,** or when the patent is worked in conditions contrary to the interest of public health, or constituting anticompetitive practices following an administrative or court decision made final. Where the license aims to remedy a practice declared anti-competitive or in case of emergency, the Minister for Industrial Property shall not be obliged to seek an amicable agreement"[23]

In Cyprus, in the Patent Law of 1998, article 49.2 of part IX on Non-Voluntary Licenses and Government Use reads: "49.-(1) At any time after the expiration of four years, or of such other period licenses. as may be prescribed, from the date of the granting of a patent, any person may apply to the Registrar on one or more of the grounds specified in subsection (2) below:

(a) for a non-voluntary license under the patent,

(b) where the **applicant is a government department**, for the grant to any person specified in the application of a license under the patent.

23 Text available at:http://www.wipo.int/scp/en/exceptions/replies/france.html#Q1

(2) The grounds for the submission of an application for non-voluntary license are

(a) where the patented invention is capable of being commercially worked in Cyprus but it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable;

(b) where the patented invention is a product, **that a demand for the product in Cyprus**

(i) is not being met, or

(ii) **is not being met on reasonable terms**, or (…)"

In Portugal, in the industrial property code (2008), articles 107 and 108 read as follows:

"Article 107

COMPULSORY LICENCES

1. Compulsory licenses may be granted for a certain patent, in any of the following cases:

a) Lack or insufficient exploitation of a patented invention;

b) Dependency between patents;

c) **Reasons of public interest**.

(…)

Article 108

LICENSE DUE TO FAILURE TO EXPLOIT INVENTION

1.After the time limits referred to in Article 106(2) have expired, a patentee who, without good reason or legal basis, does not exploit an invention, directly or under license , or **does not do so in such a way as to meet national needs**, may be obliged to grant a license for its exploitation.

2. A patentee may also be obliged to grant an exploitation license for an invention if he ceases to exploit it for three consecutive years without a good reason or legal basis.

3. Objective technical or legal reasons beyond the patentee's control and irrespective of his situation making the **exploitation of the invention impossible or insufficient are considered good reason, but not economic or financial difficulties**.

4. For as long as a compulsory license remains in force, the patentee may not be obliged to grant another before the previous one is cancelled.

5. A compulsory license may be cancelled if the licensee does not exploit the invention in such a way as to meet national needs. (…)"

Such provisions are particularly useful in the case of very expensive medicines and in circumstances where it is not possible to obtain affordable prices from the patent owner.

Therefore, the suggested addition of a third condition concerning the high prices of the medicines in article 14 of the Greek Law could be as follows:

Article 14, paragraph 1

" For imperative reason of serving public health and national defense after justified decision of the Minister of Industry, Energy, and Technology and, according to the case, any competent Ministers, a license for exploitation of an invention can be granted to bodies of the public sector which may exploit the invention in Greece, provided that the relevant invention has not been ~~productively~~ exploited in Greece or the ~~production of the products thereof~~ **exploitation** is insufficient to cover local needs**, or the price of the relevant invention is abnormally high as compared to the health system financial capacity.**"

C. Article 14.2 states that before the decision to grant the compulsory licence is taken, the patent holder shall express his views.

This is not required by the TRIPS Agreement. Article 31.b of that Agreement only establishes that the patent holder need be "informed promptly" of the decision to grant a compulsory licence. A modification in order not to impose further preconditions than those required by international standards would be to change "are" into "may be"

Hence, the following wording of paragraph 2 of article 14 is suggested:

Article 14, paragraph 2

*''2. Prior to the issue of the relevant decision, the patentee and anyone who is in position to give useful advice, ~~are~~ **may be** called upon to express their views.''*

Additionally, the law needs to state that when a compulsory licence is granted by the competent Minister in order to prevent shortage or rationing of medicines, the Minister shall also give authorization to third parties using the patent under the compulsory licence to market the product covered by the patent in Greece. Evidence should be provided by the third party to ensure that the product is bioequivalent[24] (in the case of a generic) or biosimilar[25] (in the case of a biogeneric) to the product already marketed in Greece or the EU. A royalty should be paid to the owner of the product that was first registered in Greece or the EU.

24 A medicine which is identical to another , in terms of active ingredients, effects and results in the body

25 A biological medicine (derived from live organisms) that is similar to another biological medicine that has already been authorized for use