Experimental Use and Bolar Exemptions

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Chapter 19

Greece

Dr Nikolaos Lyberis

1. GENERAL

Greece is party to the EPC and PCT agreements on patents. The Greek Industrial Property Office (OBI) applies the so-called formal examination system in terms of limited substantive examination of national patent applications with respect to novelty, inventiveness and industrial applicability. Thus, review of fulfilment of said conditions lies within the competence of civil courts, who may declare a patent null and void *ab initio*.[1]

a. Terminology

There is no Greek case law to date dealing terminologically with the legal term exception v. exemption and the difference(s) between them. They have been approached instead in theory while commenting on the Greek Patent Law No. 1733/1987 ('Patent Law').

The term *exemption* is understood as indicating behaviour(s) of a third party that would constitute a defence against a patent infringement claim by the patent proprietor, and as such they are exempted from being characterized as illegal (Article 10(2) and (3) of the Patent Law).

The term exemption indicates the legislative limitation of the negative powers that would otherwise enable the patent holder to prohibit certain activities by a third party who makes use of the subject of an invention. Such exemptions are exhaustively enumerated by the Greek Patent Law and are the following:

1. Athens Multi-Member Court of First Instance (MMCFI), 729/2009, DEE 2009, 1194; Court of Appeal (CA) of Athens 3676/2010 DEE 2011, 39; Athanassiou in: Kallinikou/Athanassiou/Chrissanthis, *Intellectual Property Law in Greece*, 100-103 (Wolters Kluwer 2nd ed. 2019).

a. use of an invention for non-professional or for research purposes;
b. use of an invention incorporated in a vehicle, railway, vessel or airplane temporarily entering the Greek territory;
c. preparation of a medicinal product in a pharmacy to be delivered to a specific person upon a doctor's prescription, as well as the sale and application of such medicinal product;
d. continued prior use of an invention by a third person – other than the patentee – who, at the filing date respectively priority date, had used the invention in Greece or made necessary preparatory acts for the exploitation thereof;
e. exhaustion of patent rights when the patentee has put patented products on the market or has authorized third parties to do so for use, sale or importation of such products within the EU internal market (Articles 34 and 36 TFEU and relevant CJEU case-law); and
f. compulsory licensing (Articles 13, 14, and 14A of the Patent Law).

Furthermore, it is noteworthy that Article 5(8)(a) of the Patent Law introduces the general legal principles of *bonos mores* and *ordre publique* (Article 281 GCC) into Greek patent law, which may be applied not only as an exception to patentability but also as a limitation to the exempted activities by a third party experimenting on a patented product in a manner contravening said principles.[2] According to Marinos,[3] such research or experimental activity may not be considered per se as prohibited, it may rather be a reflection of the non-patentability or the abuse of a patented invention itself (environmental policy, use of a photocopying machine for reproduction of fake banknotes).

This contribution focuses on experimental use and Bolar-type exemptions only.

Accordingly, the term exemption would refer to the use of an invention by a third party that is not considered as infringing, although said use takes place *without* the patentee's consent.

Furthermore, the above exemptions, provided for in Article 10(2) and (3) of the Patent Law, are *jus cogens*. As such, limitation or even abolishment of the exempted cases by virtue of a contract is prohibited.

b. Legal Basis in Greece

Exemptions from patent infringement liability are provided for in the Patent Law 'about technology transfer, inventions and technological innovation'.

Specifically, regarding *Experimental Use exemptions* – among other types of exemptions – Article 10(2) of the Patent Law provides for the following:

> 2. The owner of the patent may not forbid, in the meaning of the preceding paragraph, the following activities:
>
> a. The use of the invention for non-professional or research purposes.
>
> …

2. K. Liberopoulos, *The Law of Inventions*, 2010 (in Greek) p. 151-152.
3. Marinos, *Patent Law*, 2013 (in Greek) p.102-104.

> c. The preparation of a pharmaceutical product in a pharmacy for a specific individual, following medical prescription as well as the dispensing and use of said pharmaceutical product under the reservation of Article 25 paragraph 3 of the present Law.

To date, no regulations or interpretational guidelines have been issued by the Greek Patent Office (OBI), nor could any case law be located specifying the criteria to be borne in mind when using such defence clauses before court.

The *Bolar-type exemption* is provided for in the Joint Ministerial Decision (JMD) DYG3a/G.P.32221/2013 which was codified and published in the Government's Official Gazette 1049/B/29.04.2013. Said JMD is entitled 'Harmonization of Greek legislation with the corresponding EU legislation on the production and circulation of medicinal products for human use, in compliance with Directive 2001/83/EC concerning the Community Code relating to medicinal products for human use (L311/28.11.2001), as amended by Directive 2011/62/EU relating to the prevention of the entry into the legal supply chain of falsified medicinal products'.

The Greek patent law provision transposing EU legislation into national law is contained in Article 11(6) of JMD and reads as follows:

> Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to rights protected by patents or supplementary protection certificates for medicinal products.

The Bolar-type exemption is herewith applicable for generic pharmaceuticals for which the grant of a Greek market authorization invoking a so-called reference medicinal product is pursued (see section 3. below).

c. Bodies that Are Authorized to Decide on the Legitimacy of Exemptions

Patent infringement cases are adjudicated before the civil courts of First and Second Instance (Court of Appeal), as well as the Supreme Civil Court (*Areios Pagos*) for revision only concerning legal faults of decisions issued by the aforementioned First and Second Instance Courts. Their judicial power covers both ordinary lawsuits and preliminary injunctions when urgent legal interest is invoked. Said courts are authorized to decide whether exemptions are legitimate or not.

2. THE EXPERIMENTAL USE EXEMPTION

a. History and Rationale of Adopting the Experimental Use Exemption

The legislative rationale for the introduction of the Experimental Use exemption was to strike a balance between legitimate patent protection (negative powers of the patentee) and activities of third parties not affecting the proprietary right of patent exploitation (positive powers of the patentee) (Article 30 of the TRIPS Agreement).

b. The Laws Applicable to the Experimental Use Exemption in Greece

With respect to exemptions from patent infringement liability, Article 10 of the Greek Patent Law makes a distinction between non-professional and research purposes of the use of an invention:

> 2. The owner of the patent may not forbid, in the meaning of the preceding paragraph, the following activities:
>
> a. The use of the invention for non-professional or research purposes.

Non-professional use of the invention refers to the private activities of the patentee. This is in compliance with the patentability requirement of industrial applicability. In other words, the invention is to be used as an active intervention in economic activities and not in private and family activities.[4] A private, non-professional use of the invention can be made in a family circle or in the frame of a close personal friendship or even in a broader circle, such as in a private party at home. Consequently, the use of an invention not connected to profit-oriented professional activities is not prohibited, according to Article 10(2) of the Patent Law.

The exemption of the use of the invention for research purposes constitutes an important rule of patent law aimed at the promotion of innovation, or the avoidance of hindering technological progress in the relevant technical field. This exemption is necessary for conducting basic research.[5] It also touches upon aspects of free and undistorted competition in the market. Consequently, the patentee is not allowed to impose cease and desist claims on third parties who use the invention solely for their research purposes.

c. Procedural Aspects of Invoking the Experimental Use Exemption

Substantial evidence must be presented to the competent civil court of First or Second Instance that will decide whether there is a legitimate exemption or not (see also section 1.c. above). Research protocols, laboratory reports, eyewitnesses and sworn statements are some of the crucial evidentiary elements for the defendant raising an exemption claim in a patent infringement case.

d. Scope of the Experimental Use Exemption in Greece

i. Fields of Technology

Almost any invention from every technological branch may, under the applicable legal provisions, be subject to experimental use exemption.

4. *Ibid.*, p. 162.
5. *Ibid.*

ii. Purpose of Experiments/Infringing Activities

In this context, it should be clarified that this exemption is limited to the experimental use of the invention *per se* (e.g. reverse engineering). This is meant to refer to experimenting on alternative technical solutions to the same technical problem, or to develop improvements of the invention, or to put the invention to the test, or to examine whether there are additional unknown results of the inventive activity, e.g. side effects of medication.[6] However, using the invention as *a supporting research tool* to achieve other purposes going beyond the scope of protection of the patent itself would require the consent of the patent holder, in the absence of which no exemption would be available to the user.[7] It is irrelevant where and by whom such research is conducted.[8]

Exempted use of the invention for research purposes can be not only scientific, but also industrial. This is the case for pre-trials or clinical studies conducted by pharmaceutical companies, provided that such trials are carried out for the above permissible purposes. The difference of the Bolar-type exemption is that experimental use does not serve academic purposes but rather the interest of generic manufacturers to accelerate their entry to the relevant market immediately after the patent or supplementary protection certificate (SPC) expiration.[9]

Research purpose also exists in the framework of academic teaching for the benefit of students and researchers. Such purpose would not be eligible for an exemption claim if a specific university is also conducting research on behalf of a company, even less so if said research were conducted on the premises of an industrial enterprise. In the latter two cases it is obvious that only explicitly authorized use of the patent is permissible.

iii. Use of the Invention for the Preparation of a Medicinal Product in a Pharmacy

According to Article 10(2)(c) of the Patent Law:

> 2. The owner of the patent may not forbid, in the meaning of the preceding paragraph, the following activities:
>
> …
>
> c. The preparation of a pharmaceutical product in a pharmacy for a specific individual, following medical prescription as well as the dispensing and use of said pharmaceutical product under the reservation of Article 25 paragraph 3 of the present Law.

This exemption refers to the preparation of a medicinal product in the premises of a pharmacy for a specific person for whom an ad hoc medical prescription was given. Sales and delivery of such medicines are covered by the exemption. No exemption

6. K. Liberopoulos, *The Law of Inventions*, 2010 (in Greek) p. 150; Marinos, *Patent Law*, 2013 (in Greek) p. 163.
7. Marinos, *Patent Law*, 2013 (in Greek).
8. K. Liberopoulos, *The Law of Inventions*, 2010 (in Greek).
9. N. Rokas, *Industrial Property and Unfair Competition*, 4th ed., 2022, p. 64.

can be claimed or exempted activities can cease to be exempted if the medicinal product is delivered without prescription or is offered to more people beyond the one mentioned in the prescription.

e. Territoriality Issues

The question as to whether the exemption would apply if the results of the experiment(s) are used for infringing upon a corresponding patent in another jurisdiction has not been subject of Greek case law, nor has it been discussed in theory. Extra-territorial applicability of patent law would in principle contravene the rule of territoriality governing the intellectual property laws in Greece. Private international law aspects would also have to be considered in such cases. The problem is due to the low degree of harmonization of patent law in many jurisdictions. One could argue, however, that no exemption could be claimed under said circumstances in view of the purported patent infringement in another jurisdiction. In other words, the patentee would otherwise be exposed to unlimited possibilities of cross-border infringements through ordering experiments by the infringer extra-territorially with respect to the protected territory of the patent, provided that said experiments are indispensable and their results are destined for and are used by the infringer in the country of patent protection.

Specifically, with respect to clinical trial contracts the law of the country where the trials are conducted is usually applicable, although it may also be agreed that any relevant conflict is to be taken to arbitration. The Greek contract template for clinical trials provides for Greek applicable law and Greek jurisdiction.[10]

f. Burden of Proof and Onus

It is the defendant against a lawsuit for patent infringement who bears the burden of proof for substantiating the Experimental Use exemption applicable to the otherwise infringing activities (Marinos, supra, p. 250-251).

This must be done in that phase of the First Instance civil procedure in which the defendant submits written arguments in defence of the lawsuit. Any such claim raised at a later stage of proceedings is not expected to affect the outcome of the case.

g. Applicability during Patent Term Extension or Supplementary Protection Certificate

The Experimental Use exemption applies during the protection term of an SPC or an SPC pediatric extension term. This because according to Greek law, the rules governing the rights of the patentee during the twenty-year protection of a patent are applied, *mutatis mutandis*, on SPCs and pediatric extensions to SPCs.

10. Joint Ministerial Decision 36809/2019; A. Skouteli, *Clinical trials for pharmaceuticals* (in Greek), 2021, p. 125 and 455 f.

3. THE BOLAR-TYPE EXEMPTION

a. History and Rationale of Adopting the Bolar-Type Exemption

The rationale for Greece adopting the Bolar-type exemption was for the generic manufacturers to be ready to enter the market immediately after the lapse of the patent protection term. This could be achieved by saving time not being obligated to repeat clinical studies and trials before launching their generic products.

Lifting said obstacles for generic manufacturers was in principle successful except for massive production and stockpiling of their products during the patent protection term of the reference medicinal product, the latter being possible only outside the EU and if good manufacturing practices were applied. Thus, to counter this inefficiency, the SPC Waiver was introduced.[11]

b. The Laws Applicable to the Bolar-Type Exemption in Greece

The Bolar-type exemption is provided for in the JMD DYG3a/G.P.32221/2013, which was codified and published in the Government's Official Gazette 1049/B/29.04.2013. Said JMD is entitled 'Harmonization of Greek legislation with the corresponding EU legislation on the production and circulation of medicinal products for human use, in compliance with Directive 2001/83/EC concerning the Community Code relating to medicinal products for human use (L311/28.11.2001), as amended by Directive 2011/62/EU relating to the prevention of the entry into the legal supply chain of falsified medicinal products'.

Article 11(6) of JMD reads as follows:

> Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to rights protected by patents or supplementary protection certificates for medicinal products.

For reasons of clarity, it should be mentioned that paragraphs 1, 2, 3 and 4 of Article 11 of JMD contain provisions relating to the legal and formality requirements for generic pharmaceuticals and the necessary petition for them to obtain market authorization (para. 1). They also contain provisions relating to definitions of the terms 'reference of medicinal product' and 'generic medicinal product' (para. 2), and the necessity to present to the market authorization authority the results of appropriate pre-clinical tests or clinical trials, where the medicinal product does not fall within the definition of a generic medicinal product, or where the bioequivalence cannot be demonstrated through bioavailability studies, or in case of changes in the active substance(s) therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product (para. 3). In para. 4 the requirements for biological medicinal products similar to a reference biological product but not fulfilling the definition of generic medicinal products are regulated.

11. EU Regulation 2019/933 amending Article 4 EU Regulation 469/2009; D. Lempesi, *The sale of pharmaceuticals*, 2024, p. 206-207; see also section 3.i. below.

c. Procedural Aspects of Invoking the Bolar-Type Exemption

The alleged infringer of a patent or SPC may invoke the Bolar-type exemption before the civil courts, in the framework of a patent infringement civil action, to have said action dismissed. The District Courts will decide whether the circumstances of the case would allow, or not, an early working exemption such as the Bolar-type exemption for a specific generic pharmaceutical.

The Greek authorities responsible for the grant of a market authorization (EOF – National Organization for Medicines) and for pricing regulation [Pricing Department of EOF according to Ministerial Decision D3(α) 6295/9-2-2024 (Government's Official Gazette B1100/15.02.2024) about pricing rules and procedure for both compensated and non-compensated pharmaceuticals] do not consider themselves as mainly competent for protecting intellectual property rights, such as patents and SPCs. Thus, the EOF may issue a marketing authorization for a generic product during a patent term, and a pricing decision may also be granted; however, should this product be launched, or even shortly before its imminent market launch, a patent infringement action can be brought.

d. Scope of the Bolar-Type Exemption in Greece

i. Fields of Technology

The Bolar-type exemption concerns generic medicines, bioequivalents and biosimilars all for human use, and processes connected thereto.[12]

ii. Purpose of Experiments/Infringing Activities

The causal link between the experiments, studies and clinical trials undertaken by the third party, on the one hand, and their aiming at obtaining market authorization for a generic medicinal product, on the other hand, is usually the key for considering the admissibility of a Bolar-type exemption claim. Mentioning the name and full data of the reference medicinal product in the request for issuance of a market authorization for a generic pharmaceutical is an interesting indication which, however, must be accompanied by further substantial evidence as to whether the legal and procedural requirements and the regulatory scheme for such requests were properly observed by the third party.

iii. Exempted and Prohibited Activities

A Bolar-type exemption covers by law the preparation of studies and conducting clinical trials for medicinal products. Specifying the exempted and prohibited activities

12. Maucher Jenkins (website publication), *Comparison of Bolar Exemptions Across Europe*, 13 February 2015, as updated on 17 October 2017; https://www.maucherjenkins.com/commentary/update-on-bolar-exemptions-in-europe (2017); https://www.maucherjenkins.com/commentary/comparison-of-bolar-exemptions-across-europe (2015).

is a matter of interpretation of the relevant legislation mentioned above. Importation, exportation, purchase, or possession of relevant goods with a view to sale or trade should, in principle, fall within the scope of patent or SPC infringing activities. Data obtained through the conducting of relevant experiments should be considered the property of the patentee or SPC holder and not be disclosed or exploited without an ad hoc consent. Stockpiling should not be permitted considering, among other factors, transparency obstacles and the difficulty of the patentee to locate and investigate storage facilities from where infringing products are put in circulation in the Greek market during the protection period of the patent or SPC. Similar situations are often faced because of the application of the SPC waiver.

e. Beneficiary Limitations

The Bolar-type exemption can be used by generic manufacturers only. They enjoy the exemption vis-à-vis the absolute and exclusive right of exploitation of a patent. Expanding the circle of the entities that may benefit from this exemption would run contrary to the timely limited legal monopoly of the patentee and would render its absolute and exclusive right to patent exploitation uncontrollably weak. IPRs being intangible assets are acknowledged and constitutionally protected as human rights.[13] Consequently, any interpretation broadening the persons or entities e.g. assisting the generic manufacturer would be unconstitutional and prohibited.

f. Territoriality Issues

There is no judicial precedence or discussion in theory concerning territoriality issues in Greece. It might be argued that the Bolar-type exemption could apply outside the country, provided that the purpose is a regulatory submission in another EU Member State, but not in a non-EU country. This by way of analogy with a view to a) the established mutual recognition of national market authorizations between EU Member States, b) the fundamental EU principle of freedom of transborder rendering of services within the European Internal Market and c) the European legal framework for clinical trials.[14] However, the Bolar-type exemption should not apply if the results of the experiment are used for infringing a corresponding patent in another jurisdiction (principles of *bonos mores* and *ordre publique*).

It is material that the person acting under the exemption is the applicant for regulatory approval or, in case of a group of companies, a member thereof, operating under the control of said applicant for applying the Bolar-type exemption. The same applies if the patented invention is used in the same jurisdiction of the relevant regulatory body, i.e. outside Greece, where the experiment was carried out.

13. Article 17(1) and (2) of the Greek Constitution; Article 1 of the First Additional Protocol to ECHR; Supreme Administrative Court (StE) 1116/2014, 4747/2014; Areopag (Supreme Civil Court) 1056/2020; European Court of Human Rights Decision of 21 July 2016, 91, in: *Mamatas et al v Greece*; N. Rokas, *Industrial Property and Unfair Competition*, 4th ed., 2022, p. 9-10; Tsironas, 'The protection of private property and assets', in: Sp. Vlachopoulos, *Fundamental Rights*, p.391 f., 409
14. Regulations 536/2014, 2017/556 and 2017/1569.

The question of data protection remains open with respect to information gained during or as a result of the experiment in Greece, when the regulatory submission takes place in another country. In this respect, the stance of national data protection authorities is crucial and may prove to be a hindering or at least delaying factor, unless there is explicit consent by the involved persons or entities for using said data in another EU jurisdiction.

g. Burden of Proof and Onus

It is the defendant in a lawsuit for patent infringement who bears the burden of proof for substantiating the Bolar-type exemption applicable to the otherwise infringing activities.

This must be done in that phase of the I. Instance civil procedure in which the defendant submits written arguments in defence of the lawsuit. Any such claim raised at a later stage of proceedings is not expected to affect the outcome of the case.

h. Applicability during Patent Term Extension or Supplementary Protection Certificate

The Bolar-type exemption applies during the protection term of an SPC or an SPC pediatric extension term. This is because, according to Greek law, the rules governing the rights of the patentee during the twenty-year protection of a patent are applied, *mutatis mutandis*, to SPCs and pediatric extensions to SPCs.

4. DIFFERENCES BETWEEN THE TWO EXEMPTIONS IN GREECE

A *prima facie* comparison of Experimental Use and Bolar-type exemptions may show differences from each other as to the purpose of the third party's acts. A closer consideration, however, may lead to the conclusion that there seems to exist a common denominator between them: the Experimental Use exemption is broader as far as applicable fields are concerned, whereas the Bolar-type exemption seems to be broader in types of activities.[15]

15. *See* a comparison between the European and the US approach in: Brian Coggio, 'Experimental use defence at the USPTO: too narrow or too wide?', *cipa journal* Oct. 2024, vol.53, no. 10, p. 9-13