Experimental Use and Bolar Exemptions

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Chapter 11

Cyprus

Dr Nikolaos Lyberis

1. GENERAL

Cyprus is a common law country having been a British colony until 1960. The case law of the Supreme Court, as well as of the District Courts, often refers to relevant British judicial precedence which, however, is not binding but rather guides the Cypriot Courts in their decision-making procedure.[1]

Cyprus became a full EU Member State on 1 May 2004. Despite the open political question of the invasion of 1974, the international community, including the European Union (EU) and United Nations (UN), acknowledged the Republic of Cyprus as the only sovereign state entity of Public International Law. Consequently, as of the day of accession of Cyprus to the EU, the *acquis communautaire* was adopted by the new Member State and – at least theoretically – it is applicable on the entire territory of the island. This refers to all fields of EU legislation governing IP rights.

a. Patent Law in Cyprus

i. British Privilege (1960-1998)

As from 1960 (year of establishment of the Republic of Cyprus) until 1 April 1998, the date of enactment of the new Patent Law No. 16(I)/1998 ('Patent Law'), patent protection was granted in Cyprus based only on a corresponding UK patent registration (so called re-registration system). The privileges and rights conferred by a patent registered in Cyprus were in force if the British patent was valid, but without paying patent annuities at the Cypriot Registrar.

1. G. Pikis, *English Common Law, the Rules of Equity and their implementation in Cyprus*, Larnaca 1981, p.75 f., 82.

ii. Cypriot Patent Law – Accession of Cyprus to the European Patent Convention (EPC)

Patents are regulated by the Cypriot Patent Law, as amended and valid, in conjunction with the Patent Regulations of 1999, as amended to date.

The accession of the Republic of Cyprus to the EPC (December 1997) led to the incorporation in the above law of provisions enabling the validation of European patents in Cyprus.

The competent authority for the grant of patents is the Registrar of Patents, which is a department of the Direction of Intellectual Property as part of the Registrar's Office for Companies and Intellectual Property. The Registrar's Office is a State Service (Public Administration) of the Republic of Cyprus.

The Cypriot Patent Law provided for the grant of national patents, thereby rendering the registration of a patent in Cyprus independent from the registration of the corresponding patent in the UK, but subject to payment of annuities before the Registrar of Patents.

iii. Accession of Cyprus to the Patent Cooperation Treaty (PCT)

Cyprus became a Contracting State of the PCT (December 1997), which was an important change of patent law implemented on 1 April 1998. As of that date, nationals and residents of Cyprus are entitled to file international patent applications through the Cypriot Registrar, the European Patent Office or the International Bureau as Receiving Office.

Furthermore, from the same date it is possible for applicants from abroad to file international applications designating and electing Cyprus. Such designation indicates the interest of the applicant to obtain a European patent that will in due course offer protection in Cyprus under the EPC (Article 75 of the Patent Law). The direct national route on the basis of a PCT application is not possible. In other words, PCT applications can enter the national phase in Cyprus only after a European patent application (EURO-PCT) has been first filed and the patent has been granted.

b. Terminology

There is no Cypriot case law to date dealing terminologically with the legal term *exception* v. *exemption* and the difference(s) between them. They have been approached instead to a very limited extent in theory while commenting on the Cypriot 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 27(3) and (4) of 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 exempted acts are exhaustively enumerated by the Cypriot Patent Law and are the following:

a. an act concerning a product which has been put on the market by the patentee, or with his express consent, insofar as such an act is performed after that product has been put on the market in Cyprus;
b. an act done privately and on a non-commercial scale, provided that it does not significantly prejudice the economic interests of the patentee;
c. an act of making or using the product for purely experimental purposes or for scientific research;
d. extemporaneous preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;
e. supply or offer to supply a third person – other than the patentee – with means, relating to an element of that invention, exclusively for carrying out the invention, if such means are commercial products and the circumstances of the supply of such products do not constitute inducement to infringe the patent.

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.

The accepted presumption is that the legislator did not aim at reducing, limiting or depriving the right holder (patentee) of his property's rights, unless there are specific and exceptional circumstances.[2] *Purposive construction* of the exemptions should, however, be available at the discretion of courts. For example, a case concerning the invention of an important pharmaceutical preparation might, under circumstances of the specific case, allow consideration of general interest in terms of public health.

Furthermore, the above exemptions provided for in Article 27(3) and (4) of the Patent Law are *jus cogens*. As such, limitation or even abolishment of the exempted cases by virtue of a contract is prohibited.

c. Legal Basis in Cyprus

Exemptions from patent infringement liability are provided for in the Patent Law.

Specifically, regarding Experimental Use exemptions – among other types of exemptions – Article 27(3) of the Patent Law reads:

> (3) Notwithstanding subsections (1) and (2) of this article, the owner of a patent shall have no right to prevent third parties from performing, without his authorization, the acts referred to in subsections (1) and (2) of this article in the following circumstances:
>
> (i) Where the act concerns a product which has been put on the market by the owner of the patent, or with his express consent, insofar as such an act is performed after that product has been put on the market in Cyprus.

2. P. Polyviou, *Interpretation of Cypriot law*, Nicosia 2023, p.79; Satlanis, Chr., *Methodology of Law for the Cypriot Legal Order*, Nicosia 2018, p.137

(ii) Where the act is done privately and on a non-commercial scale, provided that it does not significantly prejudice the economic interests of the proprietor of the patent.
(iii) Where the act consists of making or using for purely experimental purposes or for scientific research.
(iv) Where the act consists of the extemporaneous preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared.

To date no regulations or interpretational guidelines have been issued by the Registrar of Patents nor could any case law be located specifying the criteria to be borne in mind when using such defence clauses before court.

Reference to the *Bolar-type exemption* is made in Cypriot Law No. 75(I)/2006 entitled 'The Medicines for Human Use (Quality Control, Supply and Prices)' (transposing Directive 2004/27/EC into Cypriot law), as amended several times until issuance of Law No. 103(I)/2023. This law amends the 'Medicines for Human Use (Quality Control, Supply and Prices)' Law No. 70(I)/2001 (transposing Directive 2001/83/EC into Cypriot law). The provision harmonizing Cypriot law according to EU legislation with regard to the Bolar-type exemption is Article 10B(8) of Law No. 75(I)/2006 and reads as follows:

> Conducting the necessary studies and trials with a view to the application of the provisions of article 10A, subsections (1), (3), (4), (5) and (6) of this article and the consequential practical requirements shall not be regarded as contrary to the provisions of the Patent Law.

The Bolar-type exemption is herewith applicable for generic pharmaceuticals which pursue the grant of a Cypriot or EU marketing authorization invoking a so-called reference medicinal product.[3]

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

Patent infringement cases are adjudicated before the District Court of the respective district where there is: 1) the seat of defendant or 2) the place of infringement. There are six District Courts located in Nicosia, Famagusta, Kerynia, Larnaca, Limassol, and Paphos. Their judicial power covers both ordinary lawsuits and preliminary injunctions when urgent legal interest is invoked.

An appeal against a decision issued by a District Court is filed before the Supreme Court of Cyprus in its appellate jurisdiction.

The above courts are authorized to decide whether invoking the discussed exemptions is legitimate or not.

3. Maucher Jenkins (website publication), *Comparison of Bolar Exemptions Across Europe*, 13 February 2015, as updated on 17 October 2017; see also section 3. Below; https://www.maucherjenkins.com/commentary/update-on-bolar-exemptions-in-europe (2017); https://www.maucherjenkins.com/commentary/comparison-of-bolar-exemptions-across-europe (2015).

There are few cases of patent infringement which have already proceeded to full trial but none of them have so far dealt with exemptions from patent infringement.

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 is to strike a balance between the legitimate interest of the patentee on the one hand, and that of third parties on the other (Article 30 of TRIPS Agreement). In the framework of this attempt the promotion of research and innovation for the benefit of society should be prioritized. As such, no remuneration can be claimed by the patentee for a third party being exempted from patent infringement liability due to experimental use.

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

With respect to exemptions from patent infringement liability, the Article 27(3)(iii) of the Cypriot Patent Law provides for the research purposes of the use of an invention:

> (3) Notwithstanding subsections (1) and (2) of this article, the owner of a patent shall have no right to prevent third parties from performing, without his authorization, the acts referred to in subsections (1) and (2) of this article in the following circumstances:
>
> …
>
> (iii) Where the act consists of making or using for purely experimental purposes or for scientific research.

According to Article 27(3)(iii), the patentee is deprived of his right to raise claims against a third party for patent infringement when the act of the latter consists of making or using the subject matter of the patent for purely experimental purposes or for reasons of scientific research.

The exemption of the *use of the invention for purely 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 of essence for conducting basic research. It also touches upon aspects of free and undistorted competition in the market. Consequently, the patentee is not allowed to raise cease and desist claims against third parties, who use the invention solely and exclusively for their research purposes.

c. Procedural Aspects of Invoking the Experimental Use Exemption

Substantial evidence must be presented by the defendant to the competent District Court, which will decide whether there is a legitimate exemption or not. Research protocols and/or laboratory reports, expert opinions, eyewitnesses and sworn statements are some of the crucial evidentiary elements for substantiating an exemption counterclaim in a patent infringement case in Cyprus.

d. Scope of the Experimental Use Exemption in Cyprus

i. Fields of Technology

Almost every invention from all technological branches may, under the applicable legal provisions, be subject to the Experimental Use exemption.

ii. Purpose of Experiments/Infringing Activities

With respect to the purpose of the exempted infringing activities, it should be clarified that this exemption is strictly limited to the experimental use of the invention itself (e.g., reverse engineering). This includes experiments aimed at exploring alternative technical solutions to the same problem, developing improvements to the invention, testing the invention, or investigating whether there are additional, previously unknown outcomes of the inventive activity (such as side effects of a medication). However, using the invention as a research tool to achieve purposes beyond the scope of the patent's protection would require the consent of the patent holder. In the absence of such consent, no exemption would apply, and the user would be held liable for patent infringement.

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 should these trials be carried out for the above-mentioned admissible purposes. The difference with the Bolar-type exemption is that the latter functions not for academic purposes but rather for the generic manufacturer to be ready to enter the market immediately after the lapse of the patent protection term (see section 3. below).

Research purpose exists also in the framework of academic teaching for the benefit of students and researchers. Such purpose could not be eligible for an exemption counterclaim by the defendant 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 only explicitly authorized use of the patent would seem permissible.

iii. Exhaustion of Patentee's Rights

According to Article 27(3)(i) of the Cypriot Patent Law,

> (3) Notwithstanding subsections (1) and (2) of this article, the owner of a patent shall have no right to prevent third parties from performing, without his authorization, the acts referred to in subsections (1) and (2) of this article in the following circumstances:
>
> (i) Where the act concerns a product which has been put on the market by the owner of the patent, or with his express consent, insofar as such an act is performed after that product has been put on the market in Cyprus.

This provision establishes the principle of national exhaustion of the patentee's rights, aligning with the territoriality principle of patent rights in the Republic of Cyprus. For

this provision to apply – preventing the patentee from claiming infringement against a third party – the product must have been placed on the market in Cyprus either by the patentee or with their explicit consent. Such consent is deemed to exist when an intermediary is involved in a transaction that reflects the patentee's intention to allow the free circulation of the product on the Cypriot market. Accordingly, any experiments conducted with products purchased from the patent holder, on the Cypriot market are exempted from infringement.

iv. Act Done Privately and on a Non-commercial Scale

According to Article 27(3)(ii) of the Cypriot Patent Law,

> (3) Notwithstanding subsections (1) and (2) of this article, the owner of a patent shall have no right to prevent third parties from performing, without his authorization, the acts referred to in subsections (1) and (2) of this article in the following circumstances:
> …
> (ii) Where the act is done privately and on a non-commercial scale, provided that it does not significantly prejudice the economic interests of the proprietor of the patent.

A private and non-professional purported use of the invention refers to the private life of the alleged infringer. This is in compliance with one of the patentability requirements i.e., industrial applicability. In other words, the invention is to be used as an active intervention in economic activities and not in private life. Consequently, the use of an invention not connected to professional activities is not prohibited, according to Article 27(3)(ii) of the Patent Law. A private, non-professional use of the invention can be made, for example, in a family circle or within a close personal friendship.

Any scientifically working person, such as a pharmacist, a medical practitioner, a chemical engineer or a businessman, may be meant under the notion of a professional.

v. Act for the Preparation of a Medicinal Product in a Pharmacy or by a Medical Doctor or Acts Concerning the Medicine so Prepared

According to Article 27(3)(iv) of the Patent Law:

> (3) Notwithstanding subsections (1) and (2) of this article, the owner of a patent shall have no right to prevent third parties from performing, without his authorization, the acts referred to in subsections (1) and (2) of this article in the following circumstances:
> …
> (iv) Where the act consists of the extemporaneous preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared.

This exemption is applicable provided that: a) it refers to the extemporaneous preparation of a medicinal product; b) said preparation is carried out on the premises of a pharmacy; c) for a specific person; and d) for whom an *ad hoc* medical prescription

was given. Sales and delivery of such medicines are covered by the exemption. No exemption 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.

vi. Commercial Products and Circumstances which Do Not Induce a Third Party to Infringe upon a Patent Right

According to Article 27(4) of the Patent Law:

> (4)(a) Subject to paragraph (b) of this subsection, a patent shall also confer on its owner the right to prevent third parties from supplying or offering to supply a person, other than a party entitled to exploit the patented invention, with means, relating to an element of that invention, exclusively for carrying out the invention, when the third party knows, or under the circumstances it is obvious, that those means are suitable and intended to be used for carrying out that invention.
>
> This provision shall not apply when the means are commercial products and the circumstances of the supply of such products do not constitute inducement to infringe the patent.
>
> (b) Persons performing the acts referred to in subsection (3), (ii), (iii) and (iv) of this article shall not be considered to be parties entitled to exploit the invention within the meaning of paragraph (a) of this subsection.

This subsection deals with the prohibition in favour of the patentee, from supplying or offering to supply a third person, who is not entitled to exploit the patented invention, with means being element(s) of the invention that are necessary for the implementation of the invention, if it is known or obvious to the third person that said means are appropriate and destined for execution of the invention.

On the contrary, the patentee cannot prohibit a third party from supplying or offering to supply an unauthorized person with said means, if these are commercial products and their supply does not induce to patent infringement.

Acts performed in the sense of Article 27(3), (ii), (iii) and (iv) are not meant to have been performed by persons entitled to exploit the invention according to Article 27(4)(a) of the Patent Law.

e. Territoriality Issues

The question as to whether the exemption would apply if the results of the experiment are used for infringing a corresponding patent in another jurisdiction has not been dealt with in Cypriot case law, nor has it been discussed in theory. Under any circumstances, extra-territorial applicability of patent law would in principle contravene the rule of territoriality governing the intellectual property laws in Cyprus. Private international law aspects, however, must be considered in such cases. One could argue that no exemption could be claimed under said circumstances in view of a purported patent infringement via another jurisdiction. In other words, the patentee would otherwise be irreparably exposed to unlimited possibilities of cross-border infringements through ordering experiments to be carried out 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 and used by the infringer in the country of patent protection. It is irrelevant if in the third country, where experiments are carried out, there is patent protection that would allow the patentee to sue the infringer for his acts there.

f. Burden of Proof and Onus

It is the defendant sued for patent infringement who bears the burden of proof for substantiating the Experimental Use exemption applicable to the otherwise infringing activities.

This must be done in that phase of the procedure before the District Courts in which the defendant submits written arguments in defence of the lawsuit. Any such claim raised at a later stage of proceedings will not affect the outcome of the case.

g. Applicability during Patent Term Extension or Supplementary Protection Certificate

The Experimental Use exemption also applies during the term of a supplementary protection certificate (SPC) and a pediatric extension of SPC. This is because, under Cypriot law, the rights of the patentee during the twenty-year patent protection period are applied, *mutatis mutandis*, to SPCs and pediatric extensions to SPCs.

3. THE BOLAR-TYPE EXEMPTION

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

The rationale for 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.[4]

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

The Bolar-type exemption is provided for in Cypriot Law No. 75(I)/2006 entitled 'The Medicines for Human Use (Quality Control, Supply and Prices)' (transposing Directive 2004/27/EC into Cypriot law), as amended several times until issuance of Law No. 103(I)/2023. This law amends the 'Medicines for Human Use (Quality Control, Supply

4. 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.

and Prices)' Law No. 70(I)/2001 (transposing Directive 2001/83/EC into Cypriot law). The provision harmonizing Cypriot law according to EU legislation with regard to the Bolar-type exemption is Article 10B(8) of Law No. 75(I)/2006 and reads as follows:

> Conducting the necessary studies and trials with a view to the application of the provisions of article 10A, subsections (1), (3), (4), (5) and (6) of this article and the consequential practical requirements shall not be regarded as contrary to the provisions of the Patent Law.

Cypriot Law No. 75(I)/2006 sets out acts necessary for obtaining regulatory approval, and a defendant who raises this defence needs to show that its acts did not exceed those set out in the law.

For example, in case where the generic medicinal product contains esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance as these are included in the meaning of 'active substance', then the applicant for issuance of a marketing authorization for a generic medicinal product shall be obliged to submit additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorized active substance.[5] Only actions performed for securing this purpose are exempt from patent infringement.

c. Procedural Aspects of Invoking the Bolar-Type Exemption

The Bolar-type exemption may be invoked with respect to a patent or SPC by the District Courts, in the framework of a patent infringement action, in case the defence is raised by the alleged infringer. The District Courts would decide whether an early working exemption, such as the Bolar-type exemption, for a specific generic pharmaceutical can be claimed by a third party.

The Cypriot authorities responsible for granting marketing authorizations (Pharmaceutical Services, Ministry of Health) and regulating pricing (Pricing Department of Pharmaceutical Services, Ministry of Health) do not consider themselves primarily responsible for protecting intellectual property rights, such as patents, SPCs and potential pediatric extensions to SPCs.

Thus, the Ministry of Health may issue a marketing authorization that would be in force during the patent term, and if a product is launched, a patent infringement action may be brought.

d. Scope of Bolar-Type Exemption in Cyprus

i. Fields of Technology

The Bolar-type exemption concerns generic medicines, bioequivalents and biosimilars all for human use, and processes connected thereto.[6]

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5. Article 10A(1) of the 'The Medicines for Human Use (Quality Control, Supply and Prices)' Law No. 75(I)/2006.
6. Maucher Jenkins (website publication), *Comparison of Bolar Exemptions Across Europe*, 13 February 2015, as updated on 17 October 2017; M. Stief, *The European Research and*

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 marketing 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 marketing 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. In this context, the purpose of activities should be clearly explained by the applicant for a marketing authorization for a generic product or at least be reasonably and objectively discernible. Thus, experiments by the applicant purporting to manufacturing a new drug going far beyond the patented composition or process of the reference medicinal product should not be accepted as falling within the Bolar-type exemption.

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 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 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 Cypriot market during the protection period of the patent or SPC. Similar situations are often faced because of the application of the SPC waiver (see below section 3.i.).

e. Beneficiary Limitations

The Bolar-type exemption can be used by generic companies only. Expanding the circle of the entities benefiting from this exemption would run contrary to the timely limited legal monopoly of the patentee and be against the principle of interpretation unduly narrowing further the scope of intellectual property rights. Intellectual property rights are intangible assets acknowledged and judicially protected human rights on property including, inter alia, patents and SPCs.[7]

Bolar Exemptions – Background, Status Quo and a Look at the Agreement on UPCA and the EU Commission's New Draft Directive for the Reform of Pharmaceutical Legislation, GRUR International, 73(9), 2024, 824-837

7. 'Movable incorporeal components', T.E. Synodinou, *Property and Trust Law in Cyprus*, Wolters Kluwer, 2020, par. 53 and 328.

According to Article 27(4) of the Patent Law:

> (a) Subject to paragraph (b) of this subsection, a patent shall also confer on its owner the right to prevent third parties from supplying or offering to supply a person other than a party entitled to exploit the patented invention, with means, relating to an element of that invention exclusively for carrying out the invention, when the third party knows or under the circumstances it is obvious that those means are suitable and intended to be used for carrying out that invention.
>
> This provision shall not apply when the means are commercial products and the circumstances of the supply of such products do not constitute inducement to infringe the patent.

f. Territoriality Issues

Although no judicial precedence on the Bolar-type exemption could be located, it should apply for otherwise infringing activities performed in Cyprus to fulfil regulatory requirements in other EU Member State(s), but not in non-EU countries.

EU Regulation (EU) 536/2014 on clinical trials on medicinal products for human use is noteworthy from the point of view of the European Internal Market. It established, inter alia, a Europe-wide central system for assessment and approval of clinical trials and a user-friendly EU Portal for all relevant information entries (Article 80 of this Regulation). It also secures transparency in the case of more sponsors. Moreover, if the sponsor – usually a pharmaceutical company or other organization – is seated outside the EU, then a central legal representative must be assigned (Article 74(1) of the Regulation) being responsible for the exchange of communications with the European and each of the involved national competent authorities in the name and on behalf of the sponsor.[8]

Using the results of the experiment infringing a corresponding patent in another jurisdiction should be a matter governed by the law of that other country considering its rules of private international law, unless it is a non-EU country, in which case a Bolar-type exemption should not be expected.

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 procedure before the District Courts (civil jurisdiction) in which the defendant and alleged infringer submits written arguments in defence of the lawsuit. Any such claim raised at a later stage of proceedings will not affect the outcome of the case.

8. On sponsors, CRO, researchers and other parties in a clinical trial contract see: A. Skouteli, *Clinical Trials for Pharmaceuticals*, 2021, p. 126-147.

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 Cypriot 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.

i. SPC Waiver

The Bolar-type exemption has not completely cured the exclusion of generic producers from the market for the duration of the patent, as it only allows research and the production of experimental products and not their mass production or mass storage. Consequently, generic manufacturers could create a generic version of an original drug with their own original studies, but they could not produce it on a large scale until the patent term of the reference medicinal product expired. As for the storage of finished products in large quantities, this could only be done in countries outside the EU as long as they follow European production standards (Good Manufacturing Practice). Given that the Bolar-type exemption was considered insufficient, Article 4 of EU Regulation No. 469/2009 was amended by EU Regulation No. 2019/933 excluding from the SPC protection products which are destined for export in third countries.

The SPC Manufacturing Waiver Regulation (EU) 2019/933 obtained direct effect in Cyprus in 2019. Said Waiver is subject to notification before the Cypriot Registrar and to the SPC owner so that the latter may inspect whether the SPC right(s) and connected formal and substantial requirements were observed by the third (notifying) party/parties. The notification form needs to be filed at the Registrar's Office for Intellectual Property by a local agent accompanied by the necessary authorization form.

4. DIFFERENCES BETWEEN THE TWO EXEMPTIONS IN CYPRUS

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.[9]

9. *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.