

SUPPLEMENTARY PROTECTION CERTIFICATES IN EU LAW: A COMPENSATION MECHANISM AND TURKEY'S POSITION

AVRUPA BİRLİĞİ'NDE İLAÇ PATENTLERİNİN TAMAMLAYICI KORUMA BELGELERİ; BİR TELAFİ MEKANİZMASI VE TÜRKİYE'NİN POZİSYONU

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Özet: Patent koruması yasal olarak 20 yıl süreyle geçerli olmakla birlikte, ilaç sektöründe ürünlerin patentlenmesi söz konusu olduğunda, bu süre tam anlamıyla kullanılamamaktadır. Avrupa Birliği'nin yetkili organları, 1768/92 ve 1610/96 Sayılı Tüzüklerle tamamlayıcı koruma sistemi kurmuştur. Patent başvurusunun kabulü süreci, idari zorunluluklarla ürün geliştirme sürecinin uzaması ve özellikle pazara giriş izni gerekmesi gibi sebepler, verimli patent koruma süresini etkilemektedir. İlaç ve tarım kimyasalları sektöründe, yeni ilaç veya böcek ve bitki öldürücü, tarım kimyasalının verimli ve güvenli olup olmadığı uzun testler sonucu anlaşılabildiğinden verimli patent süresi kısalmaktadır.

Keywords: supplementary protection certificate, active ingredients, patent protection

I. INTRODUCTION

The exclusive right granted by a patent is not indefinite and, although it is restricted to a statutory period of twenty years, it is very difficult, indeed virtually impossible, in certain areas of industry for protection to be made to commence at the same time as the commercialisation of the patented product - however much the patent holder may wish for this.

Most countries envisage a statutory trial period for pharmaceuticals before they are placed on the market. Factors such as the patent application acceptance process, administrative requirements, extensions to the product development process and, especially, the need for authorisation to put products on the market impact on the effective patent protection period. In the pharmaceutical and agricultural chemicals sector, the requirement for lengthy testing in order to determine whether new pharmaceuticals or pesticides and herbicides are effective and safe reduces the effective patent protection period. This lengthy testing and registration process may last as long as eight years.

In the pharmaceutical sector, the cost of bringing a new product to the market may be as high as 800 million dollars, a substantial amount of which is spent on clinical testing².

The European Commission has adopted directives in the area of human and veterinary medicaments. Certain delays frequently occur before products are brought to the market. When a pharmaceutical is under patent, the patent protection period is reduced and the benefit that may be made of it is frustrated.

The Supplementary Protection remedy affords supplementary protection that may be granted in the case of patents obtained particularly in the fields of human pharmaceuticals, plant

¹ Judge, IPR Civil Law Court, İzmir.

² **KATZKA, Catherine;** "Interpretation Of The Term "Product" in EU Council Regulations 1768/92 and 1610 /96 on Supplementary Protection Certificates", Journal of IP Law, 2008, Vol. 3 No: 10, p. 250.

protection products and veterinary medicaments. A Supplementary Protection Certificate is a *sui generis* industrial property right. The aim of such certification is to enable the pharmaceutical industry to obtain effective patent protection. It facilitates the conducting of clinical studies and testing, and the obtaining of authorisation to put products on the market³.

Supplementary Protection starts on expiry of the relevant patent protection period. This type of right may be obtained for various biological active substances in human or veterinary medicaments and plant protection products, as well as derivatives. It extends the monopoly rights period for compositions with one or more of active substances or active substances that are patented protected.

There is a general debate on product definitions in Supplementary Protection Certificates, and on the subject of patent protection and supplementary protection certificates. Supplementary protection certificates may be obtained for national and European Patents.

II. RELEVANT EU LEGISLATION

SPCs sit on the boundary **between** of patent law and administrative-regulatory law- law, but knowledge of patent law principles and the local regulatory law is also required. SPCs were created and are governed by following EU regulations:

- EU Council Regulation No 1768/92 concerning Medicinal Products and EU Parliament and Council Regulation No 469/2009 of 6.05.2009 concerning the Supplementary Protection Certificate for Medicinal Products.
- EU Council Regulation No 1610/96 concerning Plant Protection Products
- EU Council Regulation No 1901/2006 concerning Medicinal Products for Paediatric Use⁴

III. PURPOSE OF THE SYSTEM

The basic aim of adopting these certificates is to encourage innovative efforts such as patents. Most countries provide for a regulatory framework for the testing of pharmaceuticals prior to them being placed on the market. That is why the European Union introduced the above mentioned regulations. Often, there will be substantial delays prior to the product coming on the market. Clearly where a pharmaceutical is the subject of a patent, this reduces the effective term of protection and often would make its exploitation uneconomic⁵. The normal twenty-year duration of patents undergoes a *de facto* reduction in the pharmaceutical sector. Depending on the type of patent, the *de facto* protection period may vary from thirteen years under molecule patents, to between fourteen and sixteen years under other patents. Justice thus demands an extension of this nature if the patent holder is to derive effective benefit from protection.

IV. CONDITIONS FOR OBTAINING A SUPPLEMENTARY PROTECTION CERTIFICATE

1. Criteria

³ BENTLY, Lionel-SHERMAN, Brad; Intellectual Property Law, 2002 Oxford New York, p. 551.

⁴ KUIPERS, Gertjan/DOUMA, Tjibbe/KOKKE, Margot; "European Union: Recent Developments Regarding Patent Extensions(SPCs And Pediatric Extensions), Bio-Science Law Review, Vol 12, Issue 4 BSLR

⁵ TRITTON, Guy; Intellectual Property in Europe, 2002 London, p. 177.

The protection provided by an SPC extends to the ‘product’ covered by the authorisation and any use of that product as a medicinal product that has been authorised before expiry of the SPC. The product is defined as the ‘active substance’ (in the case of plant protection) or ‘ingredient’ (in the case of medicinal products) for which approval has been gained.⁶ Supplementary Protection Certificates are intellectual property rights that are based on and similar in nature to patents. According to EU Parliament and Council Regulations 1768/92 and 469/2009:

- (i) The patent protecting the product must still be in force.
- (ii) The product must have a valid approval or authorisation to be placed on the market.
- (iii) The product must not yet have been the subject of a supplementary protection certificate.
- (iv) The authorisation to place the product on the market must have been granted for the first time.

The above-mentioned regulations apply in all EU Member states. However, Supplementary Protection Certificates are only valid on a country-by-country basis in the country where they have been obtained.

The basic patent may by itself be a patent for a process to obtain a product or products. It may protect a preparation, defined as being a solution or mixture consisting essentially of two or more substances, at least one of which is an active substance, for a plant protection product. The subject and scope of the supplementary protection is the same as that of the basic patent and is also subject to the same limitations and obligations. So it is important to define a few terms here. Basic patent means a patent protecting (i) a product as such, (ii) a process to obtain a product or (iii) an application of a product. Product means the active ingredient or combination of active ingredients of a medicinal product. And medicinal product means the substance presented for treating or preventing disease in humans⁷.

The term “active substance” or “active preparation” is construed to mean a substance for which authorisation to enter the market has been obtained and which is protected by patent, and generally its closest derivatives, particularly in the form of an ester or a salt. However, this is with the proviso that the active substance in question is not a new active substance. The Supplementary Protection Certificate covers one product/patent only. A separate Supplementary Protection Certificate must be additionally obtained for each individual product.

It has been suggested that the most appropriate interpretation of the definition of a product protected by a basic patent is that protection will be conferred on the active ingredient however formulated and for any therapeutic use covered by a marketing authorisation granted before expiry of the certificate⁸.

2. Entitlement

The owner of the basic patent and his successors are also entitled to obtain a Supplementary Protection Certificate. Even if this is not clearly stipulated in the Regulation, according to the

⁶ BENTLY, Lionel-SHERMAN, Brad; Intellectual Property Law, 2002 Oxford New York, p. 533.

⁷ KUIPERS, Gertjan/DOUMA, Tjibbe/KOKKE, Margot; “European Union: Recent Developments Regarding Patent Extensions (SPCs And Pediatric Extensions), Bio-Science Law Review, Vol 12, Issue 4 BSLR

⁸ TRITON, p. 179.

prevailing view, there is no absolute requirement for the applicant to be the holder of the authorisation to enter the market. However, if a licensee has obtained authorisation, application may be made on behalf of the patent holder for Supplementary Protection. Certain problems may arise if other persons have obtained process patents containing novelty and inventive steps for the same active substance. According to the Regulation, if a product is already the subject of a Supplementary Protection Certificate no additional SPC be issued. If a party holds a process patent and, after having obtained authorisation to market the product, acquires a supplementary protection certificate, the other patent holder may not obtain a Supplementary Protection Certificate even if he relies on an antecedent right.

Even though the Regulation has not made specific provision concerning the status of existing licences, as it is stated in Article 5 of the Regulation that the certificate is subject to the same limitations and the same obligations as the basic patent, it is accepted that licensees will also benefit from the period protected by the certificate⁹.

3. Lifetime of a Supplementary Protection Certificate

The additional and supplementary protection certificate has been devised to compensate for the time lost by virtue of regulatory procedures imposed on the manufacture and sale of such products. On the other hand, a supplementary protection certificate normally has a lifetime of five years, and this may be extended to at most five and a half years depending on the applicable approval process for the market entry of clinical data compiled where human medicinal products are concerned. The certificate takes effect at the end of the lawful term of the basic patent¹⁰.

4. Exploitation of a Supplementary Protection Certificate

The Supplementary Protection Certificate is accepted by all European Union Member states under the relevant Regulation. However, as it has no unified effect, application must be made for a certificate on a national basis. The rights granted under an SPC are subject to the same limitations and obligations as applied to the basic patent. An SPC will therefore be subject to licenses of right if the patent would have been subject to such a licence prior to its expiry¹¹.

There exist mechanisms with regard to Supplementary Protection Certificates in all European Union member states. However, separate application needs to be made in each country. A Supplementary Protection Certificate is valid only in the country in which it is obtained¹².

5. European Court of Justice's Decisions

European Court of Justice takes important decisions on the interpretation of Regulation No 469/2009. In practice there are problems in establishing what is meant by the terms “product, active ingredient and combination of active ingredient”. The European Court of Justice, in its interpretation of the term “product”, has consistently defined this as “active substance or active ingredient”.

⁹ EC Regulations, 469/2009, Art. 5.

¹⁰ Art. 13/1 EC Regulation No: 469/2009 of the European Parliament and the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (codified version)

¹¹ BENTLY-SHERMAN, p. 54.

¹² KATZKA, Catherine; “Interpretation Of The Term “Product” in EU Council Regulations 1768/92 and 1610 /96 on Supplementary Protection Certificates”, Journal of IP Law, 2008, Vol. 3 No: 10, p. 651.

Certain decisions assume importance for Supplementary Protection Certificate strategy: In the *Eli Lilly v. HGS* decision, it refrained from a broad interpretation in the matter of protection under a valid basic patent. A product may be defined specifically enough such that the claims are in functional terms. In *Actavis v. Sanofi* and *Georgetown II*, on the other hand, it was stated that it is possible for a separate Supplementary Protection Certificate to be obtained for each basic patent. The Court has also, in these decisions, made assessments regarding the duration of Supplementary Protection Certificates. The Court has established a new criterion for the issuing of Supplementary Protection Certificates: If the Supplementary Protection Certificate is inconsistent with the purpose of Regulation No 469/2009, it can be refused¹³.

V. Patent Exploitation and Supplementary Protection Remedy in Turkey

Within the pharmaceutical sector's competitive research environment, leaving aside the difficulty in obtaining a patent, the administrative problems in ensuring that a patent effectively serves to its holder make Supplementary Protection Certificates necessary. At the same time, according to the Competition Authority's latest reports, it takes an average of seven months for generic medicines to enter the market in Turkey once the patent protection period expires. This period can be as short as four months in the case of commercially successful medicines.

As Turkey is not yet a member of the European Union, it is not bound by EU legislation on Supplementary Protection Certificates. This means that there are no mechanisms in Turkey enabling applications for Supplementary Protection Certificates to be applied for and obtained.

However, according to the Competition Authority's reports, since it has been ascertained that the potential lost patent life incurred for administrative authorisation reasons by patent-holder pharmaceutical companies is fairly insignificant, there is no need for a supplementary protection period¹⁴. However, this matter falls within the realm of domestic political preferences.

VI. CONCLUSION

Supplementary protection is key to the pharmaceutical industry and has now been made more easily available by the CJEU¹⁵. It is very important for Industry because, up to 80 % of the total revenue for a major pharmaceutical product can be generated in the supplementary protection certificate system¹⁶.

However issues remain. Until 2012 there was uncertainty surrounding the application of SPCs to combination products. Two important decisions of the CJEU¹⁷ namely *Medeva*¹⁸ and *Novartis v. Actavis*¹⁹, have clarified these difficult issues and provide a reasonably workable solution to those who wish to obtain and enforce SPC protection for vaccines and other

¹³ KALDEN, Rian; "Latest Case Law Concerning SPC", 17. European Judges Symposium.

¹⁴ GÜLERGÜN C. Emin/KARAKOÇ H. Deniz/ HATİPOĞLU C. Atalay; 27.03.2013 Tarihli Rekabet Kurumu Sektör Araştırma Raporu, (Sector Research Report of Competition Board) p. 223. www.rekabet.gov.tr

¹⁵ KUIPERS, Gertjan/DOUMA, Tjibbe/KOKKE, Margot; "European Union: Recent Developments Regarding Patent Extensions (SPCs And Pediatric Extensions), Bio-Science Law Review, Vol 12, Issue 4 BSLR

¹⁶ KALDEN, Rian; "Latest Case Law Concerning SPC", 17. European Judges Symposium, p. 2.

¹⁷ Court of Justice of the European Union

¹⁸ C-322/10; www.curia.europa.eu

¹⁹ C-442/11; www.curia.europa.eu

combination products. From case law it can be inferred that the CJEU refrains from opening a path to evergreen patents and on the other hand attaches importance to the therapeutic effect of excipients in combination product. **Even if protected** by a basic patent, a product must fall within the scope of the claims either expressly or implicitly but then the claim must necessarily and specifically be understood to relate to the product.

From the comments made on the Eli Lilly case it is clear that CJEU needs to consider reform on the issue.

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