National and EU case law in the field of supplementary protection certificates

Judge Ileana Ruxandra Tirică
Bucharest Court of Appeal – Fourth Civil Section
Bucharest, Palace of the Parliament

Supplementary Protection Certificate

- Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products
- Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products
- Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products

Supplementary Protection Certificate

- Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
- Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Art.2 of Regulation 1786/92/EEC
(similar to art.2 of Regulation 469/2009/EC)

The scope

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorization procedure as laid down in Council Directive 65/65/EEC (4) or Directive 81/851/EEC (5) may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

Art.3 of Regulation 1768/92/EEC
(similar to art.3 of Regulation 469/2009/EC)

Conditions for obtaining a certificate

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product.

Art.19 (l) - then (j) of Regulation 1768/92/EEC

(Art.20 (j) of Regulation 469/2009, transitional provisions)

Without prejudice to the other provisions of this Regulation, the following provisions shall apply:

j) any medicinal product protected by a valid basic patent and for which the first authorization to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Romania. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 January 2007;

National law

- **OUG no.152/1999** regarding the medicinal products for human use, approved by
- **Law no.336/2002** for approval of OUG no.152/2009
- This legislation was aimed to **harmonize** the national law with the Directive 65/65/EEC, therefore, all MAs granted before the 1st of January 2000 could not be considered as being in accordance with the Directive.

The first authorization to place the product on the market as a medicinal product granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC

- The Romanian NPO refused the grant of the SPC for the medicinal products that had been put on the market prior to the 1 of January 2000, considering that the first authorization to place the product on the market was not issued according to the said Directive and, therefore, the conditions in art.3 of the Regulation were not fulfilled.
- The Romanian courts (both the Bucharest Tribunal and the Bucharest Court of Appeal) repeatedly overturned the NPO's decisions and granted the SPCs, considering that, since the MAs were granted before the Directive 65/65/EEC, they cannot represent the first MA in the meaning of art.3 (b) and (d) of the Regulation.

The first authorization to place the product on the market as a medicinal product granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC

- The courts also consider as relevant the CJEU decision in *C-127/00 Hassle AB vs Ratiopharm GmbH*, where the court stated that "the first authorization to place ... on the market ... in the Community, mentioned in, among others, Article 19(1) of Regulation No 1768/92, must, like the authorization to place ... on the market mentioned in Article 3 of that regulation, be a marketing authorization issued in accordance with Directive 65/65."

The first authorization to place the product on the market as a medicinal product granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC

- decision no.593/27.05.2010, Bucharest Tribunal, 5th Section, no appeal was filed;
- decision no.875/07.07.2010, Bucharest Tribunal, 3rd Section, confirmed by decision no.84R/01.03.2011, Bucharest Court of Appeal, 9th Section (OLANZAPINE)
- decision no.523/13.05.2010, Bucharest Tribunal, 5th Section, confirmed by decision no. 169R/19.04.2011, Bucharest Court of Appeal, 9th Section (ANASTROZOL)
- decision no.593/27.05.2010, Bucharest Tribunal, 5th Section, no appeal was filed (HUMAN INSULIN LYS PRO)

The first authorization to place the product on the market as a medicinal product granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC

- The NPO continues to refuse the grant of SPCs for the medicinal products for which the first MA was not granted according to Directive 65/65/EEC and was prior to 1st of January 2000
- The Court of Appeal **shifts** and validates the NPO's reasoning, **dismissing the requests for SPC** under these circumstances
- decision no.577R/15.11.2011, Bucharest Court of Appeal, 9th Section (DONEZEPIL) - which overturns the first instance's decision no.1087/19.10.2010, Bucharest Tribunal, 5th Section
- decision no.1583R/26.06.2013, Bucharest Court of Appeal, 9th Section (SILDENAFIL) - which overturns the first instance's decision no.1638/01.07.2011, Bucharest Tribunal, 4th Section

The first authorization to place the product on the market as a medicinal product granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC

- The courts find the claimant's argument that conditions in art.3 and art.19 of the Regulation are fulfilled to be wrong
- They underline that, indeed, the MAs issued before the 1st of January 2000 were not granted according to the Directive 65/65/EEC
- Therefore, the next step is to determine whether the MA granted after the harmonized legislation has come into force (which are, of course, in accordance with the said Directive) **is the first MA in the meaning of art.3 (d) of the Regulation,** and **the answer is no**

The first authorization to place the product on the market as a medicinal product granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC

- The Courts also take into consideration the CJEU decisions in *C-127/00 Hassle AB vs Ratiopharm GmbH, Case C-195/09, Synthon BV vs Merz Pharma GmbH & Co. KGaA* and *C-427/09, Generics (UK) Ltd vs Synaptech Inc.*
- In *C-427/09, Generics (UK) Ltd vs Synaptech Inc.,* the CJEU stated that "a product (…) which was placed on the market in the Community as a medicinal product for human use before obtaining a marketing authorization in accordance with Directive 65/65, and, in particular, without undergoing safety and efficacy testing, is not within the scope of Regulation No 1768/92, as defined in Article 2 of that regulation, and may not be the subject of an SPC."

The first authorization to place the product on the market as a medicinal product granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC

In other words, in C-195/09 and C-427/09 the CJEU held that there is no possibility for a MA granted prior to the one issued according to the Directive to be the first MA in the meaning of art.3 (d), because in this case the product itself (being on the market already when the MA according to the Directive was obtained) does not fit in the scope of the Regulation, as it is defined by art.2.

The first authorization to place the product on the market as a medicinal product granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC

- Such a conclusion is in complete accordance with the purpose of the Regulation as it is stated in its 3th (4th in the case of Regulation 469/2009/EC) recital: “At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.”

The grant of the SPC for the combination of two active ingredients

- The NPO refused to grant the SPC for a combination of two or more active ingredients, considering that the product (the active substance or the combination of active substances) protected by the basic patent in force did not cover all the active substances for which the SPC was sought.

The grant of the SPC for the combination of two active ingredients

- The Court of Appeal overturned the NPO's decision, considering that the active substances for which the SPC was requested were included in the scope of protection of the basic patent, even though they were not expressly mentioned in the claims – decision no.982R/23.04.2013, Bucharest Court of Appeal, 9th Section (ATRIPLA)
- The court held that by mentioning in the description of the patent claims that efavirenz will be combined with one or more HIV inhibitors, the protection of the basic patent will cover also the combination between efavirenz, emtricitabine and tenofovir disoproxil fumarate, the last two being just that: inhibitors of a viral enzyme known as reverse transcriptase.

The grant of the SPC for the combination of two active ingredients

The court relied for this decision also on decisions from the EUCJ in *C-322/10 Medeva BV vs Comptroller General of Patents, Designs and Trade Marks* and *C-422/10 Georgetown University, University of Rochester, Loyola University of Chicago vs Comptroller General of Patents, Designs and Trade Marks.*

The grant of the SPC for the combination of two active ingredients

Later on, the holder requested the NPO a limitation of this SPC only to the first two active ingredients, efavirenz and emtricitabine, but the NPO and the national courts refused this request – decision no.81A/10.02.2014, Bucharest Court of Appeal, 4th Section, definitive.

This decision states that, since the holder previously chose to ask the grant of the SPC for the combination of the 3 active ingredients, claiming on that occasion that this combination was covered by the basic patent, a revocation or a limitation of the protection conferred by the SPC is not possible, especially that the basic patent was no longer in force.

The grant of the SPC for the combination of two active ingredients

More than that, the court held that this request for limitation does not have the purpose of actually reducing the protection, but of extending it, because after the basic patent was no longer in force, all the possible combinations of the three active ingredients could freely be produced and marketed, except for the particular combination for which the SPC was granted.

Therefore, the exclusion of one of these active ingredients from the SPC would have the effect of a larger protection than the one resulted from the granted certificate.

The grant of the SPC for the combination of two active ingredients

C-322/10 Medeva BV vs Comptroller General of Patents, Designs and Trade Marks

"Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the SPC application"

"Article 3(b) of Regulation No 469/2009 must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a SPC for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the MA is submitted in support of the SPC application contains not only that combination of the two active ingredients but also other active ingredients."

The grant of the SPC for the combination of two active ingredients

Case C-121/17 Teva UK Ltd e.a. vs Gilead Sciences Inc.

"Article 3(a) of Regulation No 469/2009 of the European Parliament and of the Council of 6 May 2009, concerning the supplementary protection certificate for medicinal products, must be interpreted as meaning that a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, [if] those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

– the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

– each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent."