DECISIONS OF ROMANIAN LAW COURTS IN CASES CONCERNING THE INTERPRETATION OF ARTICLE 3 (D) OF 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

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Abstract

The supplementary protection certificate is currently considered to represent an accessory of a national or European patent granted in order to extend the duration of the rights that said patent confers on its owner in respect of an active substance or a combination of active substances. Based on the above-mentioned patent and on the certificate, the owner shall have the exclusive right of manufacturing and commercializing the patented product, as well as the right to oppose to any form of counterfeiting of the patented product. The grant of this protection title for medicaments is regulated on the territory of the European Union by the 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 (Codified version). The conditions for obtaining the certificate are stipulated under Art. 3. The paper is intended to present the decisions made by the Romanian courts in the cases concerning the controversial interpretation of Art. 3 letter d) of the Regulation, which provides that the valid authorization to place the medicament on the market in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as the case may be, should be the first authorization to place the product on the market as a medicament. At the same time, the paper presents the differences in the approach and the judgment of such cases by OSIM (State Office for Inventions and Trademarks) and by the national courts. The paper aims at analyzing said decisions as compared to the European practice, with a view to identifying solutions for a uniform interpretation of Community legislation at the level of the Romanian courts.

Keywords*: patent right, supplementary protection certificate, medicinal products, EU Regulation, court decisions*

Introduction

The supplementary protection certificate is currently seen rather as a patent sub-domain, than as an independent industrial property title. It is an accessory of a previously granted national or European patent, intended to extend the duration of the rights that said patent confers on its owner in respect of an active substance or a combination of active substances. Based on the above-mentioned patent, the owner shall have the exclusive right of manufacturing and commercializing the patented product, as well as the right to oppose to any form of counterfeiting of the patented product.

In a field so dynamic as the field of medicaments and the industrial property rights of patent owners in medicaments within the EU, the Council Regulation (EEC) No. 1768/1992 on the creation of a supplementary protection certificate for medicaments[1], hereinafter referred to as Regulation, created the legal framework for the settlement of cases in which a pharmaceutical company that owns a patent for a medicament and is also authorized to place said medicament on the market, can enjoy the extension of duration of its exclusive rights by the grant of a *supplementary protection certificate*.

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[1] Council Regulation (EEC) of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, p.1, Special edition 13, volume 11, p.130)

The Regulation entered into force on 2 January 1993 and, in 2009, as a consequence of the evolution of exigencies in the pharmaceutical field, on the one hand, and of the changes occurred in the geopolitical area of the Community, on the other hand, the codified version thereof was adopted as the Regulation (EC) No 469/2009[2]. In the following pages, reference will be made especially to the Regulation of 1992 and, where appropriate, the Regulation of 2009 will be called by the phrase "*codified version"*.

Although the supplementary protection certificate was established in the Community almost 20 years ago, specialized literature in this field can scarcely be found in Europe, Romania not even having judicial practice.

The paper presents five decisions made by Romanian courts in disputes related to the controversial interpretation of Article 3 (d)[3] of the Regulation which provides that the valid authorization for placing a medicament on the market in accordance with the Directive 65/65/EEC should be the first authorization to place the product on the market as a medicinal product. The paper points out the different approaches and ruling of these five identically similar cases by the national protection granting authority - OSIM[4], and by the national courts. The paper aims at analyzing said decisions in the context of the European practice, with a view to identifying solutions for the uniform interpretation of Community legislation in Romanian courts.

Content

1. Case Insulin lispro (the medicament named "Humalog"). File No. 42590/3/2009, Law Court of Bucharest, Fifth Civil Section

The supplementary protection certificate application no. c2007-061 of the applicant Eli Lilly and Company, for the product having the chemical name Human insulin [Lys(B28), Pro(B29)] and the ICD Insulin lispro, was filed with OSIM on 20.06.2007, within the 6-month legal time limit of Romania's accession to the European Union, under the transitional provisions stipulated in Article 19a (l) of the Regulation[5].

With a view to granting the SPC applied for, the Examination Board of OSIM analyzed the compliance with the conditions stipulated under Article 3 of the Regulation, as follows:

The product named Insulin lispro is protected by the basic patent in force RO 2.192T, having the title *Insulin Analog Compound and Pharmaceutical Compositions Containing the Same,* as identified in Claims 1 and 2 and the examples in the description of the basic patent. The condition

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[2] Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version) (OJ L 152/1)

[3] Under the title *Conditions for obtaining a supplementary protection certificate,* (hereinafter referred to as SPC), Article 3 of the said Regulation provides as follows:

"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."

[4] State Office for Inventions and Trademarks, Romania, hereinafter OSIM.

[5] Article 19: "Additional provisions relating to the enlargement of the Community

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 authorisation 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;"

provided under letter a) of Article 3 is complied with. No SPC has been granted in Romania in respect of said product, the condition provided under letter c) of the same article being also met thereby. From the SPC application filed with OSIM, it results that the product Insulin lispro is retrieved as an active substance in the medicament named **Humalog**, authorized for the first time to be placed on the market in Romania as a medicinal product through the Registration Certificates no. 5256/96, 5257/96 and 6764/98 and reauthorized to be placed on the market through the authorization no. 3149/2003. Said later authorization obtained by the product as a medicament is an authorization granted in accordance with *Directive 65/65/EEC of the Council of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products*, so that the condition provided under letter b) of Article 3 is met, as well. For the cumulative compliance with the four conditions stipulated by Article 3 of the Regulation, the authorization no.3149/2003, granted in accordance with Directive 65/65/EEC, needs to be the first authorization for placing the product Insulin lispro on the market as a medicinal product (Article 3 (d)). It is worth mentioning that the first authorization for placing the product on the market, in the Community, was issued on 30.04.1996, as the applicant indicates in the SPC application.

The registration certificates for the medicament Humalog having Insulin Lispro as an active substance have been issued by the National Medicines Agency, based on Romanian Government Ordinance No. 31/1995 (Official Gazette No.201 of 30.08.1995) and the Order of the Minister of Health No.949/1991, which approved the Directives concerning the authorization, registration and monitoring of medicaments and other products for human use. These certificates were issued in the period of time when the above-mentioned national acts in force had provisions as to the harmonization with the Directive 65/65/EEC, with which they were already harmonized to a large extent. Based on said certificates, the medicament Humalog could be commercialized in Romania before the date of 01.01.2000. Taking into account the meaning of the date of 01.01.2000, i.e. in Romania, the first authorizations for placing the medicaments on the market were granted by virtue of procedures harmonized with the Directive 65/65 EEC, starting from this date, based on the Emergency Ordinance No.152/1999[6], OSIM interpreted the phrase *"the first authorization to place a product on the market as a medicinal product"*, in the Article 19 a (l), as referring to the first authorization for placing the product on the market in Romania, not in the Community. It results that the right to be granted an SPC in Romania is explicitly limited to those products that cumulatively comply with the provisions of Article 3 (b) and (d), and of Article 19 a (l) of the Regulation, in this case it being relevant that the product had not been placed on the market in Romania before 01.01.2000.

Consequently, as the conditions for the grant of the SPC for the product Insulin lispro were not cumulatively complied with, the application was refused by the Examination Board, through the Decision No.3/29 of 28.12.2008.

On 17.04.2009, the company Eli Lilly and Company, represented by SCA Turcu & Turcu, lodged an appeal against the decision of the Examination Board, with the OSIM Board of Appeal, asking for *"the annulment of the decision no. 3/29 of 28.12.2008 and, consequently, for the granting of a supplementary protection certificate for the medicinal product Humalog – Insulin lispro"*.

The grounds, as claimed in the appeal, related to the fact that Article 19 a (l) of the Regulation does not explicitly limit the right to be granted an SPC to the products commercialized on the Romanian market, for the first time after the date of 01.01.2000, *"but rather relates to the products whose first market authorization (as defined in the Regulation) was granted after 01.01 2000. With a view to obtaining an SPC in Romania, it is not relevant whether the product was placed on the*

[6] GEO No. 152/1999 of 14 October 1999 on medicinal products for human use, published in the O.G. No. 508 of 20 October 1999 and entered into force on 01.01.2000

market in Romania before the date of 01.01.2000, as long as those products were not authorized in Romania in accordance with a procedure similar to the procedure provided by the Council Directive 65/65/EEC". The appellant also showed that a contrary interpretation could lead to an erroneous conclusion, namely that, in Romania, an SPC can only be obtained for those products for which the first market authorization was obtained in a Community Member State, after the date of 01.01.2000, which would limit the purpose of application of the Regulation on the territory of our country. In the appellant's opinion, because Article 19 a (l) relates to Article 3 (b) and (d), the phrase "*first authorization*" used in Article 19 a (l) shall represent the first authorization in Romania. Invoking the uniform application of Community legislation, based on the fact that the same product has been granted an SPC in the majority of the other EU Member States, the appellant also points out that the product Humalog – Insulin Lys Pro obtained the first EMEA market authorization on 30.04.1996, which allows the granting of an SPC. The invoked legal grounds are Article 3, Article 17 and Article 19 a (l) of the Regulation, Article 7(1) of the Law No.93/1998 on the pipeline protection of patents[7], Article 51[8] of the Patent Law 64/1991, as republished.

Subsequently, the appellant also filed written conclusions to prove the unlawful character of the appealed against decision to refuse the application for the grant of an SPC. Essentially, the appellant considers that the decision appealed against was made as a consequence of the unlawful interpretation of the concept of "*first authorization to place the product on the market as a medicinal product."* With a view to explaining the meaning of the phrase "*first authorization to place the product on the market",* the appellant applied the reference decision of ECJ – Hässle vs Ratiopharm[9] to the case: "The first authorization for placing the product on the market in the Community", mentioned under Article 19 (l) in the Regulation No. 1768/92 must be, the same as "the first authorization for placing the product on the market " mentioned under Article 3 of the said Regulation, an authorization issued in accordance with the Directive 65/65/EEC."

The ruling of the OSIM Board of Appeal as to reject the appeal is pronounced with majority of votes through the Decision No. 64/16.07.2009. The Chairman of the Board formulated a separate opinion thereto, as to allow the appeal. The grounds of the Board judgment consisted in that the first authorizations for placing the product on the market as a medicament were issued as the Registration Certificates of 1996 and 1997, granted by the Ministry of Health, based on the Government Ordinance No.31/1995 (Official Gazette No. 201/30.08.1995) and the Order of the Minister of Health No.949/1991 approving the *Directives concerning the authorization, registration and monitoring of medicaments and other products for human use*. Said Certificates were granted by virtue of a procedure following to a great extent the structure and content of the Directive 65/65/EEC, still not being fully harmonized therewith, but based on a complete authorization file which contained a chemical-pharmaceutical and biological documentation, a pharmaco-toxicological documentation and a clinical documentation, as well, being elaborated in accordance with the European Communities good practice rules on pharmaceuticals. The said acts have permitted the circulation and use of the medicament Humalog (Insulin lispro) on the territory of Romania, since 1996. The legal grounds invoked are Article 18 of the Regulation (codified version) and Article 53 of the Patent Law 64/1991, as republished.

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[7] Law No. 93/1998 on the pipeline protection of patents of 13 May 1998, published in the O.G. No. 186 of 20 May 1998. By virtue thereof, the pipeline protection starts on the date of filing the patent application with OSIM and lasts until the date of expiry of the patent.

[8] Article 51 of the Patent Law 64/1991 republished in the Official Gazette of Romania, Part I, No.541 of 08.08.2007: *Any decision made by the Examination Board may be appealed against with OSIM within 3 months from communication."*

[9] C-127/00 – The court held with no doubt that there is no reason for different interpretation of the phrase „authorization for placing the product on the market", depending on the provision of the Regulation it is comprised in, and that the phrase cannot have different meanings when mentioned under Article 3 or under Article 19.

In his dissenting opinion, the Chairman of the Board argued that the allowability of the appeal was imposed by the reason that said Registration Certificates cannot represent first authorizations to place a medicament on the market, as they can be ignored in the meaning of Article 20 of the codified version of the Regulation.[10]

The above–mentioned Decision No. 64/16.07.2009 of the OSIM Board of Appeal was appealed against by the appellant Eli Lilly and Company, represented by SCA Turcu & Turcu, before the Law Court of Bucharest – Civil and Intellectual Property Section, on 28.10.2009, registered under the number 42590/3/2009.

In opposition with the respondent State Office for Inventions and Trademarks (OSIM), and pursuant to the provisions of Article 57 (1) of the Patent Law 64/1991 and Article 282 and the following of the Civil Procedure Code, the appellant asks for :

"the delivery of a decision as to allowing the appeal and consequently:

i) changing the decision appealed against in whole;

ii) accepting the application for the grant of a supplementary protection certificate for the medicament Humalog (Human Insulin Lys Pro);[...]"

In the statement of reasons of the attack, the appellant indicates the legal ground for its SPC application, i.e. Article 19 a (I) of the Regulation (EEC) 1768/92, and shows that *"the condition set out under this article is that the medicament had not been given a market authorization before the date of 1 January 2000."* And, despite the substantiation *in extenso* of the fact that the authorization referred to under Article 19 (I) is an authorization issued in accordance with the Directive 65/65/EEC and, consequently, the Certificates issued in 1996, allowing commercialization in Romania of the medicament Humalog, were not issued according to a procedure pursuant to the Directive, these essential arguments were not analyzed by OSIM and the Board of Appeal *"was content with assuming the examiner's opinion."* Thus, one of the pleas raised by the appellant in support of the appeal is the unsubstantiation: the attacked decision has not been substantiated.

Another plea in support of the appeal is the violation of the principle of equality of arms and fair trial[11], as OSIM gave the value of presumption *iuris et de iure* to a communication from the National Medicines Agency setting out that *"the certificates of registration issued before the date of 01.01.2000, although not fully harmonized with the Directive 65/65/EEC, are based on an extensive chemical-pharmaceutical, biological, pharmaco-toxic and clinical documentation"* thereby preventing the appellant from effectively appealing against its acts. This represented an obvious violation of the right to a fair trial.

Finally, the appellant also invokes the groundlessness of the judgment, as the respondent OSIM states that Romanian norms in 1996 were "*to a great extent"* in accordance with the Directive 65/65/EEC, even if the procedure was "*not fully harmonized";* however, *"to a great extent*" does not mean completely and *"not fully harmonized"* does not mean identical.

OSIM filed a statement of defence claiming that the Court should reject the appeal as unfounded and, subsidiarily, reject the head of claim concerning the payment of Court costs. In brief, the respondent OSIM shows that in Romania the right to obtain an SPC is limited to the products – active substances – which cumulatively satisfy the requirements of Article 3 (b) and (d) and Article 19 (l) of the Regulation, where it is relevant that the product was not placed on the market before the date of 01.01.2000, even if it had been already commercialized in the Community.

The Court ascertains that the decision appealed against was made based on a misinterpretation of the applicable legal provisions and allows the appeal. We quote from the statement of reasons of the Court:

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[10] Article 20 is the former Article 19 a (I) of the Regulation No.1768/92 – Additional provisions relating to the enlargement of the Community

[11] Principle of equality of arms and the fair trial is applicable in civil matters in the meaning of Art. 6 of ECHR

"The Court retained that the problem submitted for trial is to establish whether the Registration Certificates no. 5256/1996, 5257/96, 5258/96 and 6764/98, 5488/97, granted by the Ministry of Health, represent or not the first authorizations to place the product on the market, referred to under Article 3 (d) of the Regulation, as related to Article 3 (b) of the same Regulation and the harmonization of the Romanian legislation with the Directive 65/65/EEC.

These certificates cannot represent a valid authorization for placing the product on the market as a medicinal product, in accordance with the Directive 65/65/EEC, and do not comply with the requirements of Article 3 (b) and (d) of the Regulation. In support of this interpretation, the Court also considered the provisions of Article 8, (1) (b) of the Regulation, stipulating that: "The application for a certificate shall contain: […] a copy of the authorization to place the product on the market, as referred to in Article 3 (b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 4a of Directive 65/65/EEC". For the same purpose, the Court retains the case-law of the ECJ referring to the rulings in the case C-127/00 Hässle AB vs Ratiopharm. It also judges that a medicament that has not been authorized pursuant to the Community law cannot be introduced onto the market of a Member State. And there are no provisions in the Directive 65/65/EEC to stipulate the possibility of such derogations or to allow one to consider that the mere introduction onto the market, even during several years, of a medicament which was not the subject of a market authorization issued in accordance with the Community law, could replace such an authorization."[12]

In conclusion, the Court considered that the appellant's application for the grant of an SPC cumulatively satisfies the requirements of Article 3 of the Regulation, as follows:

a) The product is protected by a basic patent in force, i.e. patent RO 2192T, granted under the Law No.93/1998;

b) A valid authorization for placing the product on the market as a medicinal product was granted in accordance with the Directive 65/65/EEC – Market authorization no. 3149/2003/01 issued on 21.02.2003;

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

d) The authorization referred to under letter b) is the first authorization for placing the product on the market as a medicinal product.

Based on these reasons, ascertaining that the decision appealed against was given with the misinterpretation of the incidental legal provisions, through the Civil Matters Decision No. 593 pronounced in open session on 27.05.2009, the Court allowed the appeal lodged by the appellant Eli Lilly and Company against the Decision No. 64/16.05.2009 made by the respondent OSIM and ordered the same to grant the SPC for the product Humalog (Human Insulin Lys Pro). The decision remained final and irrevocable by lack of appeal.

Consequently, OSIM granted the Supplementary Protection Certificate for the product Humalog (Human Insulin Lys-Pro) valid from the date of 07.02.2010 until 30.04.2011.

2. <u>Case Anastrozole (the medicament named "Arimidex"). File No. 42583/3/2009, Law Court of Bucharest, Fifth Civil Section</u>

The supplementary protection certificate application no. c2007-080 of the applicant AstraZeneka UK Limited for the product of the ICD Anastrozole (active substance having the chemical name 2,2'-[5-(1H-1,2,4-triazole-1-methyl)-1,3-phenylene]di(2-methylproiononitrile),

[12] Decision No. 593 of the Law Court of Bucharest, Fifth Civil Section, pronounced in open session on 27.05.2010

possibly as a pharmaceutically acceptable addition salt, was filed with OSIM on 29.06.2007, within the 6-month legal time limit of Romania's accession to the European Union, under the transitional provisions stipulated in Article 19a (I) of the Regulation.

With a view to granting the SPC applied for, the Examination Board of OSIM analyzed the compliance with the conditions stipulated under Article 3 of the Regulation, as follows:

The product named Anastrozole, optionally as a pharmaceutically acceptable addition salt, is protected by the basic patent in force, RO 2.189T having the title "*Aralkyl-Substituted Heterocyclic Compounds and Pharmaceutical or Veterinary Composition Containing the Same",* as identified in Claims 1 and 7 (first compound) and first example in the description of the basic patent. The condition provided under letter a) of Article 3 is complied with. No SPC has been granted in Romania in respect of said product, the condition provided under letter c) of the same article being also met thereby. From the SPC application filed with OSIM it results that the product Anastrozole is retrieved as an active substance in the medicament Arimidex, authorized for the first time to be placed on the market in Romania as a medicinal product through the authorization (Registration Certificate) no. 92/1999/01 of 27.05.1999 and reauthorized to be placed on the market through the market authorization no. 6459/2006/01 of 31.05.2006. The first authorization for placing the product on the market in EEA is the authorization no. PL12619/0106 granted on 11.08.1995, in the United Kingdom. For the cumulative compliance with the four conditions stipulated by Article 3 of the Regulation, the market authorization no. 6459/2006/01 of 31.05.2006, granted in accordance with the Directive 65/65/EEC, needs to be the first authorization to place the product Anastrozole on the market, as a medicinal product (Article 3 d).

OSIM ascertained that, based on the authorization no. 92/1999/01 of 27.05.1999, the medicament Arimidex could be commercialized in Romania before the date of 01.01.2000.

In a similar way with the Humalog cas, as the conditions for the grant of the SPC for the product Anastrozole have not been cumulatively complied with, the application was refused by the Examination Board, through the Decision No. 3/20 of 30.10.2008[13].

On 26.02.2009, the applicant AstraZeneka UK Limited, represented by SC Rominvent SA, lodged an appeal against the decision of the Examination Board, with the OSIM Board of Appeal, asking for the annulment of the decision of the Examination Board and admission of the SPC application c2007-080. The legal ground invoked: Article 17 of the Regulation, Article 51 (1) of the Patent Law 64/1991, as republished.

As an argument in favour of granting the SPC, the appellant invokes Article 2 of the Regulation, mentioning that*: "Article 2 in the Regulation No.1768/1992 provides that the medicinal product in respect of which the SPC is applied for should be the subject of a valid authorization for placing the product on the market, issued in accordance with the Directive 65/65/EEC (applicable to medicinal products for human use) abrogated by Directive 2001/83/EC, or the Directive 81/851/EEC (in case of medicinal products for veterinary use) abrogated by Directive 2001/82/EC on the Community code relating to veterinary medicinal products".*[14]

[13] From the whole number of SPC applications filed with OSIM under Article 19 (I) of the Regulation, for products contained in medicaments commercialized on the territory of Romania before the date of 01.01.2000, based on certificates or authorizations which were not fully harmonized with the Directive 65/65/EEC, the first decision to refuse the application was made in respect of Anastrozole. The chronology of the decisions is only relevant in the light of the evolution of the grounds invoked by the representatives of patent owners upon attacking OSIM decisions.

[14] Text of Article 2 of the Regulation No. 1768/1992: *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… may, under the terms and conditions provided for in this Regulation, be the subject of a certificate."

It also relies on the above-mentioned case Hassle vs Ratiopharm in order to substantiate the identity between the authorization referred to under Article 3 and the authorization under Article 19 of the Regulation, which must be in accordance with the Directive 65/65/EEC.

The ruling of the OSIM Board of Appeal as to reject the appeal is pronounced with majority of votes through the Decision No. 67/25.05.2009. The Chairman of the Board expressed a separate opinion thereto, as to allow the appeal. The ground of the Board judgment is similar with the Humalog case. The legal grounds invoked in support thereof are Article 20 of the Regulation (EC) No.469/2009 concerning the SPC for medicaments and Article 53 of the Patent Law 64/1991, as republished.

In his dissenting opinion, the Chairman of the Board argued that the allowability of the appeal was imposed by the reason that said Registration Certificates cannot represent first authorizations to place a medicament on the market, as they can be ignored in the meaning of Article 20 of SPC Regulation No.469/2009 (EC). He also referred to the case no. HC 08 C 02210 Synthon B.V. vs Merz Pharma of 02.04.2009, where the judge Justice Floyd presented a judgment of Bundespatentgericht of 11.12.2007 (pages 7-8) and stated that old authorizations, granted in accordance with the unharmonized legislation, are not taken into account by the Federal Patent Court of Germany.

The above-mentioned Decision No. 67/25.05.2009 of the OSIM Board of Appeal was appealed against by the appellant AstraZeneka UK Limited, represented by SCA David and Baias, before the Law Court of Bucharest – Civil and Intellectual Property Section, on 28.10.2009, under the number 42583/3/2009. In opposition with the respondent OSIM and pursuant to the provisions of Article 57 (1) of the Patent Law No. 64/1991 and Article 282 and the following of the Civil Procedure Code, the appellant claims that the Court should:

i) invalidate the Decision appealed against in whole;

ii) order OSIM to issue an SPC for the product Arimidex, with the active substance Anastrozole; […].

In the statement of reasons of the attack, the appellant indicates first that, although the Decision of the OSIM Board of Appeal is related to the Regulation (EC) No. 469/2009, which is the codified version of the SPC Regulation No. 1768/1992, reference will be made to the consolidated text of the Regulation, prior to the codification of 2009. The appeal is based on the unlawfulness and groundlessness of the Decision made by the Board of Appeal, the appellant putting forward its arguments to prove that:

1.The first authorization for placing the product on the market, within the meaning of Article 3 (d) of the Regulation must be a market authorization harmonized with the Directive 65/65/EEC.

In order to support the uniform application, at the Community level, of the Regulation, and thus, of the national procedures for medicaments authorization, which must be in compliance with the Directive 65/65/EC, the appellant relies on the cases Hassle AB vs Ratiopharm GmbH and Pharmacia Italia SpA. Because almost 30 years elapsed from the adoption of the Directive, in 1965, to the issuance of the Regulation, in 1992, it *is "impossible to retain that Article 3 (d) would relate to a market authorization unharmonized with the Directive."*

2.The market authorization-1999 (in fact the Registration Certificate of 1999) was not issued by virtue of a procedure harmonized with the Directive 65/65/EEC.

Starting from the assertion of the respondent OSIM itself, that the Certificate of 1999 was not harmonized with the Directive, the appellant points out the meaning of the date of 01.01.2000, and states:

"Thus, from the viewpoint of the Regulation purpose, the market authorizations issued after the date of 01.01.2000, under the GEO No. 152/1999, comply with the Directive 65/65/EEC and can

give the right to the grant of an SPC, while the market authorizations issued prior to this date, under the GO 31/1995 do not comply with the Directive 65/65/EEC and, by consequence, cannot be relied upon for the grant of an SPC. In other words, the date of 01.01.2000 is mentioned by this text only because the grant of any authorization in accordance with the Directive would not have been possible prior to this date. Consequently, the conclusion of the OSIM "analysis" alleging that the presence of the product on the Romanian market before the date of 01.01.2000 would represent a reason of non-compliance with the Regulation requirements for the grant of an SPC is obviously erroneous and lacks any legal support."[15]

The statement of reasons of the Court findings is identical with the statement in the Humalog-Insulin lispro. It is found that the first authorization to place the product on the market is not the Registration Certificate No. 92/1991/01, but the market authorization no. 6459/2006/01 issued on 31.05.2006 under the GEO No. 152/1999 harmonizing the national legislation with the Directive 65/65/EEC, coming to the conclusion that the decision appealed against was given with the misinterpretation of the legal provisions. OSIM was ordered to grant the SPC for the product Arimidex.

The Decision No. 523/13.05.2010 of the Law Court of Bucharest was further appealed against by OSIM.

This further appeal was based on the consideration that, in ruling the appeal brought against the OSIM Board of Appeal, the Court misinterpreted the provisions of Article 3 and Article 19 a (I) of the Regulation. As, under Article 267 of the Treaty on the Functioning of the European Union (former Article 234 EC), the mission of ensuring application, interpretation and enforcement of Community law throughout the territory of the EU is incumbent on the European Court of Justice, OSIM found necessary that the following question should be referred to the ECJ for preliminary ruling[16]:

"Does an authorization granted in Romania, which is in accordance with the Council Directive 65/65/EEC, represent for a product "the first authorization for placing the product on the Romanian market as a medicinal product", provided that this authorization was obtained following to a request for reauthorization based on a prior authorization issued under certain normative acts harmonized "to a great extent" with the Directive 65/65/EEC?"

Through a statement of defence, AstraZeneka UK Limited, represented by SCA Baias and Baias, asks the Court of Appeal to reject the appeal entered by the respondent OSIM, as unfounded, invoking, on the one hand, that there is no need of a preliminary ruling of the ECJ concerning the interpretation of Article 3 of the Regulation, and, on the other hand, that the Law Court of Bucharest considered correctly that the market authorization of 2006 was the first authorization for placing the product Arimidex on the market, within the meaning of Article 3 (d) read in conjunction with Article 3 (b) of the Regulation. The preliminary ruling of ECJ is considered unnecessary for the following reason: *"the concept of "first authorization for placing a product on the market" was settled by the ECJ in the case C-127/00 Hassle vs Ratiopharm GmbH, the court being not obliged de plano to refer*

[15] Decision No. 523 of the Law Court of Bucharest, Fifth Civil Section, pronounced in open session on 13.05.2010, pages 13-14.

[16] In accordance with the provisions of Article 267 of the Treaty on the Functioning of the European Union (TFEU), Article 2 (1) of the Law 340/2009 on a declaration made by Romania under the provisions of Art 35 (2) of TFEU, as well as in accordance with the Information Note on references from national courts for a preliminary ruling, published in the JO No.297 of 5 December 2009 and Article 23 in the Statutes of the European Court of Justice, where an instance has doubts on the interpretation of an act issued by a European institution, it may refer the case to the ECJ for preliminary ruling.

the case to the ECJ considering that a question within the meaning of Article 267 TFEU was raised.[17]"

The company Teva Pharmaceuticals SRL, represented by SCA Nestor Nestor Diculescu Kingston Petersen, entered, based on Article 49 (1) and (3) read in conjunction with Article 51, 54, 55 and 56 of CCP, an application for intervention in the interest of OSIM and in opposition with AstraZeneka UK Limited, claiming, among other things, that the Court should allow the appeal entered by OSIM and change the decision made by the Law Court of Bucharest[18]. Teva Pharmaceuticals SRL justified its interest in the case Anastrozole by its being the owner of the authorization for placing on the Romanian market the generic medicament Anastrozole TEVA, having the anastrozole as an active principle. Because the patent RO 2189T has expired since 14.06.2008, the company which manufactures generic medicaments is interested in the commercialization, on the Romanian market, of the generic medicament containing the active substance/principle Anastrozole, for which it already obtained the market authorization. The extension of the SPC duration may thereby affect the rights of the company to commercialize its products, rights obtained upon issuance of the market authorization. The arguments brought by the intervener in order to support the lack of legal grounds of the decision made by the Law Court of Bucharest concerning Article 3 and Article 19 a (I) of the Regulation are the following:

A. Arguments based on the interpretation of legal texts

Article 19 a (l) is an amendment brought to Article 19 a as a consequence of the Act of Accession of Bulgaria and Romania to the EU[19]. This article originates in Article 32 of the Law No 581/2004 on the supplementary protection certificate for medicaments and plant-protection products"[20] which has the following content:

"a certificate may be granted for any product which, on the date of entering into force of this law, is protected by a basic patent in force or by a pipeline protection certificate in force and for which ***a first authorization to be placed on the Romanian market as a medicament or plant protection product was obtained starting from 1 January 2000,*** *provided that the application for the grant of the certificate is filed within a time limit of 6 months of the date of Romania's accession to the European Union."*

Hence, as regards Romania, an SPC cannot be granted if the first authorization for placing a medicament on the market was issued before the date of 1 January 2000.

B. Arguments based on the interpretation of similar legal texts by other Member States

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[17] Paul Craig, Greinee de Burca – Dreptul Uniunii Europene, Fourth Edition, Ed. Hamangiu, Bucharest 2009, p. 585

[18] From the Application for accessory intervention entered by NNDKP, only the aspects relating to the appeal lodged by OSIM shall be hereinafter referred to.

[19] The Act of Accession of Romania and Bulgaria to the EU was published in the Official Journal of the European Union No. L 157/11 of 21.06.2005. In Annex III to the Protocol setting the conditions and arrangements for accession, the chapter concerning the company law contains the Industrial Property Rights section with the sub-section Supplementary Protection Certificates.

[20] Law No.581/2004 on the supplementary protection certificate for medicaments and plant protection products was published in the Official Gazette of Romania No. 1233 of 21 December 2004. The law never produced effects and was expressly abrogated by the Law No. 107/2007, because, on the date of Romania's accession to the European Union, the Community Regulations became directly applicable and prevailing over the conflicting provisions of national legislation.

It is the case of Hungary and Poland. For the transitional (pipeline) protection in the two said Member States, there are applicable the provisions of Article 19 a (f) and (h), respectively. In this two Member States, the same as in Romania, the transitional provisions of Article 19 a do not expressly refer to a first market authorization obtained in the respective Member State, as is the case in Cyprus, Estonia, Latvia, Lithuania, Malta, Slovenia and Slovakia. In its position of additional negotiation in the view of its accession to the EU, the government of Hungary upheld the **applicability of the SPC regime only for those medicaments whose first authorization to be placed on the Community or Hungarian market (or the market of other countries in course of accession) was obtained after 1 January 2000**, position which was accepted by the EU.

The interpretation presented above is also applicable to Poland, where an SPC cannot be granted for a product whose market authorization was obtained before the date of 1 January 2000, in Poland or in any Member State, as mentioned in the specialized literature[21].

C. Arguments based on the interpretation of the European Court of Justice

In the case C-66/09: Kirin Amgen. Inc. vs Lietuvos Respublikos valstybinis patent biuras, the ECJ concludes: *"the objective pursued by Regulation No 1768/92 of according uniform protection for a medicinal product throughout the European Union does not preclude transitional provisions, resulting from the accession negotiations, which may mean that it is not possible to apply for an SPC for certain medicinal products in certain Member States. This outcome, which may impede, even if only temporarily, that objective and the functioning of the internal market, is justified by the legitimate objectives concerning health policies, including, as the case may be, the financial stability of the health systems of the Member States".*

D. Arguments based on an interpretation *per a contrario*

Having in view that from the transitional provisions concerning states as Malta or Slovenia, from the wording of sub-paragraphs (g) and (i), it explicitly results that the first authorization for placing a product on the market relates to Malta or Slovenia, respectively, while the wording of sub-paragraph (I) concerning Romania is comparable with the situation of Hungary and Poland, it obviously outcomes that the interpretation of the provisions of the Regulation cannot lead with certainty to the conclusion that, in Romania, an SPC may be granted for a product for which an authorization for placing it on the market was obtained before the date of 1 January 2000 in any Member State, as interpreted by the Romanian Law Court of Bucharest.

The intervener further invokes the provisions of Article 2 of the Regulation.

The two requirements of this article provide that the product should be protected by a basic patent and should be subjected to authorization, pursuant to the Directive, prior to its being placed on the market. The provisions of Article 2 differ from those of Article 3 (a) and (b) in that Article 2 excludes from its scope the products placed on the market in the absence of an authorization pursuant to the Directive 65/65. Moreover, if the grant of an SPC based on other authorizations than those pursuant to the Directive were possible, the period of exclusivity would exceed, in certain cases, the total limit of 15 years from the date of the first authorization in Community, mentioned within the eighth recital of the preamble of the Regulation.

Finally, the arguments relating to the logic of the Regulation could be summarized by the following deduction: if the authorizations legally obtained before the date of 1 January 2000 could not be deemed to be the first authorizations for placing a medicament on the market, for lack of

[21] Rafal Witek, The *First Yyear of SPC in Poland: A Tentative Summary,* http: www.wtspatent.pl/files/en5.pdf

compliance with the Directive, the reference date mentioned under Article 19 a (l) (i.e. 1 January 2000) would be completely useless, as all the products having market authorization received after this date would be automatically eligible for the grant of an SPC (no market authorization in compliance with the said Directive was obtained before this date).

The intervener claimed that six questions should be referred to the European Court of Justice for preliminary ruling. Of these questions, we will mention the following:

1. In the meaning of Article 20 (j) (former Article 19 a (l)), may an SPC be granted in Romania for a product whose first market authorization, pursuant to the Directive 65/65/EEC, was obtained before the date of 1 January 2000 in any Member State?

2. Should the answer in the first question be in the affirmative, is a product firstly authorized to be placed on the market in Romania, before the date of 1 January 2000, without the administrative procedure provided for by the Directive 65/65, eligible to be granted an SPC in accordance with the Regulation?

3. Within the meaning of Article 3 (d) of the Regulation, is an authorization issued in accordance with the legislation in force in Romania before the year 2000, and which was not in compliance with the Directive 65/65 but allowed the product to be legally placed on the market, deemed to be the first authorization for placing a product on the market as a medicinal product?

The application to intervene is dismissed by the Court of Appeal of Bucharest – Ninth Civil Section for cases concerning intellectual property, based on the grounds invoked in the Statement of defence filed by AstraZeneka UK Limited, represented by SCA David and Baias. There was invoked the objection of inadmissibility of the legal strategy proposed by the intervener, namely the fact that the product Anastrozole is not within the scope of the Regulation, i.e. Article 2. Firstly, a new legal argument was invoked, i.e. Article 2, despite the fact that OSIM did not invoke or contest this article in its decisions; secondly, by invoking Article 2, the principle of availability was violated. Thus, OSIM entered its further appeal relying on the ground referred to under Article 304 (9) of the CPC, i.e. "wrongful application of law", in relation with Article 3 and Article 19 a (I) of the Regulation, which are the only legal norms under assessment by the Examination Board, Board of Appeal and Law Court of Bucharest. Whereas Article 2 was not the subject of a dispute between the parties, the arguments brought in support of the appeal entered by OSIM cannot be allowed. Thirdly, the fact of invoking Article 2 violates the principle of double jurisdiction, since the intervener Teva may not invoke criticism on applicability and interpretation of legal texts which were not discussed before the Law Court of Bucharest, but are brought, for the first time, before the Court of Appeal.

Although, in the Written Conclusions sent to the Court of Appeal on 08.02.2011, OSIM reiterates the need to refer the questions on the interpretation of Article 19 a of the Regulation for preliminary ruling by the ECJ, provided that, in SPC matters, after Romania's accession to the EU there is no corresponding case-law, the Court of Appeal is a court whose decisions cannot be subject of internal attack, and *" the preliminary ruling system is a fundamental mechanism of European Union law aimed at enabling national courts to ensure uniform interpretation and application of that law in all the Member States"*[22], this request is rejected by the Court.

The Court of Appeal dismisses the appeal entered by OSIM before the Court of Appeal of Bucharest against the Decision No. 523/13.05.2010 of the Law Court of Bucharest as unfounded and,

[22] Information Note on references from national courts for a preliminary ruling, 12, OJ No. C 297/1 of 5 december 2009.

at the same time, it rejects as groundless the application to intervene filed by Teva Pharmaceuticals SRL in the interest of OSIM. The Decision of the Law Court of Bucharest is thereby irrevocable.

As a consequence, OSIM granted the Supplementary Protection Certificate for the product Anastrozole, possibly as a pharmaceutically-acceptable addition salt, valid from 15.06.2008 until 11.08.2010.

3.Case Olanzapine (the medicament named Zyprexa). File No. 42589/3/2009, Law Court of Bucharest, Fifth Civil Section

The supplementary protection certificate application no. c2007-058 of the applicant Eli Lilly and Company, for the product having the ICD Olanzapine (the active substance with the chemical name 2-methyl-10-(4-methyl-1-piperazinyl)-4H-thieno[2,3-b][1,5]benzodiazepine), was filed with OSIM on 14.06.2007, within the 6-month legal time limit of Romania's accession to the European Union, under the transitional provisions stipulated in Article 19a (l) of the Regulation.

With a view to granting the SPC applied for, the Examination Board of OSIM analyzed the compliance with the conditions stipulated under Article 3 of the Regulation, as follows:

The product named Olanzapine is protected by the basic patent in force, RO 2.168T having the title *Pharmaceutical Compounds and Pharmaceutical Compositions* as identified by Claims 1 and 7 of the basic patent. The condition provided under letter a) of Article 3 is complied with. No SPC has been granted in Romania in respect of said product, the condition provided under letter c) of the same article being also met thereby. From the SPC application filed with OSIM it results that the product Olanzapine is retrieved as an active substance in the medicament named Zyprexa, authorized for the first time to be placed on the market in Romania as a medicinal product through the Registration Certificates no. 5920/1997, 5970/1997 and 5931/1997 by the Ministry of Health, based on the Government Ordinance No 31/1995 and the Order of the Minister of Health No. 949/1991 mentioned above. The authorization for placing the product on the market on which the SPC application is based is the market authorization no. 1806/2001/01 of 23.03.2001. The first authorization for placing the product on the market in EEA is in fact a series of authorizations issued by EMEA on 27.09.1996. For the cumulative compliance with the four conditions stipulated by Article 3 of the Regulation, the market authorization of 2001, granted in accordance with the Directive 65/65/EEC, needs to be the first authorization to place the product Olanzapine on the market, as a medicinal product (Article 3 d).

The case is identically similar with the first two cases presented above, i.e. Insulin lispro and Anastrozole, hence we will not analyze it in detail. The SPC application was refused by the Examination Board through the Decision No.3/21 of 30.10.2008.

On 25.02.2009, the company Eli Lilly and Company, represented by SCA Turcu & Turcu, lodged an appeal against the decision of the Examination Board, with the OSIM Board of Appeal, asking for *"the appeal to be allowed, the Decision no. 3/21 of 30.10.2008 to be annulled and a supplementary protection certificate to be granted for the medicinal product Zyprexa (Olanzepine)"*.

The statement of reasons of the appeal is similar to the Insulin lispro case-file and, following to the analysis of the reasons and documents enclosed with the case-file, the OSIM Board of Appeal decided to reject the appeal by virtue of the same *de facto* and *de jure* considerations referred to in the Insulin lispro case-file.

The Decision No. 62/16.07.2009 of the OSIM Board of Appeal as to reject the appeal, was appealed against by the appellant Eli Lilly and Company, represented by SCA Turcu & Turcu, in opposition with the respondent State Office for Inventions and Trademarks (OSIM). It was ruled through the Civil Decision No. 875A pronounced in open session on 07.07.2010 by the Law Court of Bucharest, Fifth Civil Section. The grounds and arguments as to accept the application for the grant of an SPC for Olazepine are the same as those referred to in the previously presented case Humalog

(Insulin lis pro). Also, the statement of reasons of the Civil Decision No. 875A is identical with the Civil Decision No. 593 pronounced in open session on 27.05.2009 in respect of the Humalog case.

But this time, the Civil Decision No. 875A is further appealed against by OSIM which asks the Court of Appeal of Bucharest for preliminary ruling by the European Court of Justice. The procedural steps and arguments brought by the parties are further on carried out in a way similar with the Anastrozole file. Teva Pharmaceuticals Europe BV also applies for accessory intervention. In the session of 23.12.2010, the Court adjourns the case with the following ruling: it unanimously dismisses the Teva application for accessory intervention as inadmissible and ascertains, with majority, the admissibility of principle of the intervention application, with the dissenting opinion of judge Stanciu as to the inadmissibility of the intervention application.[23] Through the Civil Decision No. 84/01.03.2011 it dismisses the appeal as unfounded and dismisses the application to intervene. The Court Decision is irrevocable.

Consequently, OSIM grants the Supplementary Protection certificate for the product Olanzapine, valid from 25.04.2011 until 27.09.2011.

4. Case Candesartan Cilexetil (Atacand). File No. 35794/3/2011, Law Court of Bucharest

The supplementary protection certificate application no. c2007-079 was filed with OSIM by Takeda Pharmaceutical Company Limited (hereinafter Takeda), based on the pipeline protection patent RO 2005T, granted on 31.08.1999, protecting the active substance Candesartan cilexetil and having the expiry date on 19.04.2011. The first authorization for placing the product on the market in the European Economic Area (EEA) under the number PL 15661/0001/0002/0003/0004, obtained by Takeda in UK, on 29.04.1997, for the medicament Atacand containing the patented product, is mentioned in the application form.

On 23.09.1998, the Ministry of National Health authorized the medicament Atacand, having Candesartan cilexetil as an active substance, to be placed on the Romanian market by issuing the Registration Certificates no. 7480/23.09.1998, 7481/23.09.1998 and 7479/23.09.1998. On 02.04.2003, Takeda applied with the National Medicines Agency for the reauthorization of the medicament Atacand and obtained the market authorizations no. 6959/2006/01 and 6960/2006/01 of 17.12.2006, granted through a procedure in accordance with the provisions of the Directive 65/65/EEC. The SPC application mentioned the market authorization of 2006 as the first authorization for placing the medicament on the market, in Romania, and asked for the extension of protection for the product 1-(cyclohexyloxycarbonyloxy)ethyl- 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]benzimidazole-7-carboxylate - Candesartan cilexetil in the basic patent.

Following to the analysis of the application documents, the SPC application was refused through the Decision No. 3/16 of 30.10.2008 of the Examination Board of OSIM, on the ground of not cumulatively complying with the conditions for the grant of an SPC, stipulated under Article 3 (b) and (d), and Article 19a (I) of the Regulation. In fact, the Board considered that the market authorization of 2006 was not the first market authorization of the product, as said product had been commercialized in Romania since 23.09.1998, based on the Registration Certificates. Moreover, said market authorization represents a reauthorization. The Decision No. 3/16 of 30.10.2008 was attacked by appeal lodged with OSIM.

Through the Decision No. 66/25.09.2009, the OSIM Board of Appeal rejected the appeal entered by Takeda, maintaining the decision to refuse the application.

The above-mentioned decision 66/25.09.2009 of the Board of Appeal was appealed against by the applicant Takeda, before the Law Court of Bucharest, the subject of the case-file no. 42584/3/2009. The reasons invoked were the same as in the previous cases and we will not insist

[23] http://noulportal.just.ro/InstantaDosar.aspx?idinstitutie

thereupon, as the cases are identical. The appeal brought by Takeda was allowed by the Law Court of Bucharest in an open session, on 11.05.2010, the Court changed the Decision 66/25.09.2009 of the Board of Appeal in whole and ordered OSIM to grant an SPC for the product Candesartan cilexetil. The Civil Decision No.626A/11.05.2010 remained final and irrevocable by lack of appeal and OSIM granted the SPC applied for, valid from 20.04.2011 to 29.04.2012.

The case differs from the other cases presented before in that a Romanian medicaments company, Teva Pharmaceuticals SRL, filed with OSIM, on 29.03.2011, a request for revocation of SPC Atacand, invoking the violation of the provisions of Article 2 and Article 19a (I) of the Regulation.

As regards Article2, Teva takes the view that: *"a product authorized to be placed on the market as a medicinal product for the first time in Romania, without being subjected to the administrative procedure provided for by the Directive 65/65/EEC (such as Candesartan cilexetil), should not be eligible for protection by SPC, in accordance with the provisions of the SPC Regulations and, consequently, does not enter within the scope of Article 2"*[24]. As regards the violation of the provisions of Article 19a (l) of the Regulation, within the same Request for revocation, Teva mentions that: *"the wording of Article 19a (l) is the direct result of negotiations carried out by Romania in the process of its accession to the European Union"* and from the historical interpretation of legal texts, it results that the said article *"sets out an exception from the general rule, currently applicable at the Community level, and this is why the said article should have, in its turn, a restrictive interpretation which must be supported by the case-law and the doctrine based on the interpretation of other identically similar legal texts adopted by other Member States of the European Union, as well as the interpretation of the European Court of Justice"*. The request for revocation does not expressly refer to the unlawfulness of application of Article 3 of the Regulation.

On 19.05.2011, Teva also brought before the Court an Action for Invalidation of SPC, in opposition with Takeda and with OSIM as issuing authority, based on Article 54 (1) of the Patent Law, as republished, read in conjunction with the provisions of Article 2, Article 3 (b) and (d), Article 15, Article 17, Article 18 and Article 19a (I) of the Regulation, read in conjunction with the provisions of Article 109 (1) and Article 112 of the Civil Procedure Code. The action is the subject of the case-file no.35794/3/2011 pending in the Law Court of Bucharest. In supporting the plea of violation of said Community provisions, Teva relied on the same arguments, as well as on an identical reasoning as in the Request for Revocation. Takeda, represented by D&B David and Baias SCA, filed with OSIM, based on Article 58 (5) and Article 59 (6) of the Implementing Regulations to the Patent Law No.64/1991, as republished, a request to suspend the proceedings concerning the Request for Revocation of SPC until a final and irrevocable decision is made in the case of the Action in Annulment pending before the Law Court of Bucharest.

We find that the request to suspend the proceedings, filed by Takeda with OSIM, is well founded, taking into account that the lawfulness of the SPC Atacand in relation with Article 2, Article 19a (I) and Article 3 are concomitantly assessed by OSIM, by means of the request to suspend the proceedings, and by the Law Court of Bucharest, by means of the Action in Annulment, in the case-file no. 35794/3/2011. The judgment to be given thereupon by the Law Court of Bucharest shall be enforceable judgment for OSIM, given its opposable and mandatory characteristics, hence, it shall play a decisive role as regards the ruling to be made by OSIM. In order to prevent contradictory rulings to be made with regard to the same case, with undesirable effects upon the stability of the legal relationship between the parties, it would be desirable that OSIM orders the proceedings concerning the Request for Revocation of SPC c2007-07912 to be suspended.

[24] Request for revocation filed with OSIM by Teva on 29.03.2011, page 6, point 5 (a).

At the same time, we assume the argument of Takeda according to which the grant of the SPC Atacand by OSIM does not represent the finality of a procedure carried out within OSIM, but *"the exclusive result of enforcing the Decision No 626A made by the Law Court of Bucharest on 11.05.2010, judgment by which the lawfulness and groundedness of the application for the grant of the SPC Atacand has been finally and irrevocably decided by the law courts […]. In this context, as OSIM is the administrative authority which observed the imperative provisions of a judicial decision, […] only the law courts could decide upon the lawfulness of the grant of the SPC Atacand, and not OSIM, to which the decisions of the law courts are mandatory and enforceable."* (page 7 of the Request to suspend the procedure filed with OSIM on 16.12.2011)

5. Case Donepezil and the Pharmaceutically Acceptable Salts Thereof (Aricept). File No.19925/3/2010 – Court of Appeal of Bucharest

The supplementary protection certificate application no. c2007-073 was filed with OSIM, on 27.06.2007, by the applicant Eisai Co. Ltd. of Japan (hereinafter Eisai), through the professional representative Cabinet Margareta Oproiu, based on the pipeline protection patent RO 2004T, protecting the active substance Donepezil hydrochloride. The first authorization for placing the product on the market in the European Economic Area (EEA), under the numbers 10555/0006 and 10555/0007, obtained by Eisai in UK, on 14.02.1997 for the medicament Aricept, containing the product Donepezil protected by the above-mentioned patent, is mentioned in the application form.

On 14.01.1998, the Ministry of National Health authorized the medicament Aricept, having Donepezil as an active substance, to be placed on the Romanian market by issuing the Registration Certificates no. 6662/1998 and 6663/1998. On 29.04.2005, Eisai applied with the National Medicines Agency for the reauthorization of the medicament Aricept and obtained the market authorizations no. 5307/2005/01 and 5308/2005/01, granted through an administrative procedure in accordance with the provisions of the Directive 65/65/EEC.

The SPC application mentioned the market authorization of 2005 as the first authorization for placing the medicament on the market, in Romania, and asked for the extension of protection for the product 2-[(1-Benzyl-4-piperidyl(methyl)]-5,6-dimethoxy-2,3-dihydroinden-1-one and the pharmaceutically acceptable salts thereof, according to Claims 1 – 3 and 5 and Example 4 of the basic patent.

Following to the analysis of the application documents, the SPC application was refused through the Decision No. 3/15 of 30.10.2008 of the Examination Board of OSIM, on the ground of not cumulatively complying with the conditions for the grant of an SPC, stipulated under Article 3 (b) and (d) and Article 19a (I) of the Regulation.

Through the Decision No. 12/25.02.2010, the OSIM Board of Appeal rejected the appeal entered by Eisai, maintaining the decision to refuse the application.

The said Decision 12/25.02.2010 of the Board of Appeal was appealed against by the applicant Eisai before the Law Court of Bucharest, said appeal being the subject of the case-file no. 19925/3/2010. The reasons invoked were the same as in the previous cases, and we will not insist thereupon, as the cases are identical. The matter pending before the Court was to establish whether the Registration Certificates of 1998 are or are not the first authorizations for placing the medicament Aricept on the Romanian market, referred to under Article 3 (d), as related to Article 3 (b) of the Regulation and the harmonization of Romanian legislation with the Directive 65/65/EEC.

The Law Court of Bucharest allowed, in the open session of 19.10.2010, the appeal brought by Eisai and decided to change the attacked decision in whole as to allow the request in the application c2007-073 for the grant of an SPC for Donepezil and the pharmaceutically acceptable salts thereof, particularly the hydrochloride.

The Civil Decision No. 1087A/19.10.2010, given by the Law Court of Bucharest in respect of the case-file no. 19925/3/2010, was further appealed against by OSIM before the Court of Appeal of

Bucharest. The appeal relies on the ground that the attacked Decision was given with wrong application and interpretation of the law, as provided under Article 304 (9) of the Code of Civil Procedure. Thus, in this Decision, it was found that the Registration Certificates of 1998 were not the first authorizations to place the medicament Aricept on the Romanian market, because it was found that the first market authorization obtained by virtue of a procedure harmonized with the Directive 65/65/EEC was the market authorization no. 5307/2005, finally coming to the obviously unlawful and groundless conclusion that this authorization is, at the same time, the first authorization for placing the product on the market, in Romania. However, the condition set forth by Article 3 (d) of the Regulation provides that the authorization obtained in accordance with the Directive should be the first authorization for placing the product on the market as a medicinal product, and said provisions cannot be interpreted within the meaning that the first authorization obtained in accordance with the Directive is implicitly the first authorization for placing the product on the market, taking into account that the product has been commercialized in Romania since 1998 and the authorization was renewed in 2005.

The Court of Appeal of Bucharest allowed the appeal entered by OSIM against the Civil Decision no. 1087/A/19.10.2010 given by the Law Court of Bucharest, changed the attacked decision in whole as to the rejection of the appeal brought before the Law Court of Bucharest as unfounded. It consequently maintained the Decision of the OSIM Board of Appeal No. 12/25.02.2010 to refuse the SPC application c2007-073. The decision is irrevocable. Up to now, said decision has not been drafted yet.

Conclusions (Author's opinion)

The cases presented above represent, in our opinion, five identically similar cases having as a subject-matter the application for the grant, in Romania, of SPCs in the transitional six month-period counting from the date of 1 January 2007, the date of Romania's accession to the European Union. The legal ground invoked therefore is represented by Article 3 and Article 19 a (I) of the Regulation. In each of said cases, the product (the active substance) is protected in Romania by a patent in force, it has not already been the subject of a certificate, and the medicament containing the respective active substance was granted, after the date of 1 January 2000, a valid market authorization in accordance with the Directive 65/65/EEC. However, each of said medicaments had been authorized to be placed on the market, in Romania, before the date of 1 January 2000, by registration certificates which, on the date of their issuance, represented the legal way to place a medicament on the market. All said medicaments had a first authorization to be placed on the Community market, which was therefore obtained in accordance with the administrative procedure provided for by the Directive 65/65/EEC, the date of which was earlier than the date on which the Registration Certificates were obtained in Romania.

A synoptic summary of the market authorizations for the five cases is shown below:

Medicament	Date of first authorization to place it on the market in the Community	Date of the first Registration Certificate in Romania	Date of the market authorization in Romania, in accordance with the Directive 65/65/EEC
Humalog (Insulin Lispro)	30.04.1996 (EMEA)	1996, 1997, 1998	2003
Arimidex (Anastrozole)	11.08.1995	27.05.1999	2006

Zyprexa (Olanzapine)	27.09.1996	1997	2001
Atacand (Candesartan cilexetil)	29.04.1997 (GB)	1998	2006
Aricept (Donepezil)	14.02.1997 (GB)	14.01.1998	2005

All said SPC applications were refused by the Examination Board of OSIM, as well as, following the applicant's appeal, by the Board of Appeal, on the ground that the market authorizations granted in Romania according to the administrative procedures provided for by the Directive 65/65/EEC were not the first authorizations to place the products on the market, relying on the legal ground of their failure to cumulatively comply with the provisions of Article 3 (b) and (d) and Article 19 a (I) of the Regulation, and Article 20 (j) of the codified version of the Regulation, respectively. In each of said cases, the Chairman of the OSIM Board of Appeal expressed a dissenting opinion, arguing *that "the phrase "first authorization to place a product on the market as a medicinal product" should be interpreted as the authorization granted in accordance with the Directive 65/65/EEC. In order to obtain the authorization, the patent owner had to comply with the entire procedure provided for by the Directive, in the case of a previously granted certificate the reauthorization being more than a simple renewal."*

All the decisions of the OSIM Board of Appeal, as to reject the appeal, were appealed against by the applicant, and the Law Court of Bucharest allowed the appeals, the statements of reasons in all said cases being very similar. In brief, the Court retains that the problem submitted for trial is to establish if the Registration Certificates granted by the Ministry of Health before the date of 1 January 2000, represent or not the first authorizations to place the product on the market, referred to under Article 3 (d) of the Regulation, as related to Article 3 (b) of the same Regulation and the harmonization of the Romanian legislation with the Directive 65/65/EEC. Because these certificates were not granted following a procedure pursuant to the Directive 65/65/EEC and do not comply with the conditions of Article 3 (b) and (d) of the Regulation, they cannot represent a valid authorization for placing the product on the market as a medicinal product and, thus, they are not deemed to be the first authorizations for placing the product on the market. The Court also finds that a medicament that has not been authorized pursuant to the Community law cannot be introduced onto the market of a Member State, and there are no provisions in the Directive 65/65/EEC to stipulate the possibility of such derogations to allow that the mere introduction onto the market, even during several years, of a medicament which was not the subject of a market authorization issued in accordance with the Community law, could replace such an authorization.

In conclusion, the Court finds that the decision appealed against was made with the misinterpretation of the legal provisions and OSIM is ordered to grant the SPC.

Whilst in the case Humalog, the decision of the Court remained final and irrevocable by lack of appeal, in the other cases the Civil Decisions of the Law Court of Bucharest were further appealed against by OSIM before the Court of Appeal of Bucharest.

The further appeal relied on the consideration that, in ruling the appeal brought against the OSIM Board of Appeal, the Court misinterpreted the provisions of Article 3 and Article 19 a (I) of the Regulation. Having in view that, under Article 267 of the Treaty on the Functioning of the European Union (former Article 234 EC), the mission of ensuring application, interpretation and enforcement of Community law throughout the EU is incumbent on the European Court of Justice, OSIM found necessary that reference should be made to the ECJ for preliminary ruling.

Although in two cases, i.e. Anastrozole and Olanzapine, there were applications for intervention in favour of the respondent OSIM, which claimed that the Court of Appeal should refer certain questions to the ECJ for preliminary ruling, the Court of Appeal did not find necessary to

suspend the trial and refer for preliminary ruling and dismissed the OSIM appeal as unfounded. The legal provisions discussed were Article 2, Article 3 and Article 19 (I) of the Regulation.

Court of Appeal and, consequently, the Decision No. 12/25.02.2010 of the Board of Appeal as to refuse the SPC application c2007-073 was maintained. This decision is irrevocable.

Before upholding our opinion concerning the five cases, it is worth mentioning that the wrongful application of Article 3 (b) and (d) and Article 19 a (l) represents the legal ground of the decision to refuse the applications, and of the appeals and further appeals, as well.

We will analyze in the first place the provisions of Article 3 of the Regulation: *Conditions for obtaining a supplementary protection certificate.*

In our opinion, the reasoning of the interpretation of this article, reasoning on which the arguments leading to the decisions to grant four SPC of the five presented cases are based, is wrong. In fact, it represents a "reversal of premise"; in other words, if an authorization for placing a medicament on the market does not comply with the Directive 65/65/EEC, it cannot be deemed to be the first market authorization referred to under Article 3 (d) of the Regulation. Consequently, in all the five cases, the arguments are based on evidence proving that the Registration Certificates issued before the year 2000 do not comply with the requirements imposed to the market authorizations issued in accordance with the Directive, hence, they cannot be considered to be first authorizations to place the medicaments on the market, in Romania. It cannot be denied that the Registration Certificates were not based on the entire procedure provided for by the Directive, however, they represented the legal acts authorizing the presence of medicaments on the market, under the legislation in force in Romania. In some cases, the argument invoked in order not to take into account the Registration Certificates was that, for being granted a market authorization after the date of 1 January 2000, i.e. in accordance with the Directive, the patent owner had to follow additional authorization procedures, not required on the date of the issuance of the Registration Certificates. This incurred important financial efforts for research, so that, if the Registration Certificates are deemed to be the first authorizations for placing the product on the market, the recital 4 of the preamble of the Regulation is not complied with. The recital 4 provides as follows: *"Whereas 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"*. In other words, the investment made with a view to obtaining authorization in accordance with the Directive 65/65/EEC is not covered and this is why the grant of the SPCs is justified. Obviously, all these arguments are worthless, and so is any piece of evidence brought before the Court for proving that the Registration Certificates were not in accordance with the Directive. The synoptic table presented above shows clearly that all these Registration Certificates were issued in Romania subsequently to the market authorizations obtained in the Community. Hence, on the date on which the Certificates were applied for in Romania, the patent owners had already passed the exigency tests imposed by the Directive, the research necessary for completing the authorization file was already done, so that no further investment and effort were necessary for obtaining the market authorizations after the year 2000. At the same time, one purpose of the Regulation was to compensate the time needed for making the tests imposed by the Directive, which diminishes the actual duration of the protection given by the patent. If all the tests required by the Directive had already been performed in order to obtain the first market authorizations in the Community, prior to the issuance of the Registration Certificates, is the compensation given through the SPC for having obtained the authorizations for placing the product on the market in Romania still justifiable? Of course not.

Moreover, in the majority of the presented cases, the market authorizations obtained after the year 2000 are in fact re-authorizations of the Registration Certificates. In a literal interpretation, the meaning of the word re-authorization leads to the idea of successive authorizations: an authorization existing at a certain moment is subsequently authorized again. In other words, the Registration Certificates may not be ignored. Moreover, they may not be ignored even when certain medicaments,

e.g. Zyprexa, existed on the market within the period 2000-2001, based on the Registration Certificates, without any obligation to withdraw the same. As a matter of fact, in the above mentioned period of time, the authorization regime based on Registration Certificates co-existed, in Romania, with the regime based on market authorizations in accordance with the Directive.

Our interpretation of Article 3 (b) and (d) of the Regulation is that the authorization obtained in accordance with the Directive 65/65/EEC should be understood as the first authorization having made possible for the product to be placed on the market as a medicinal product, and not that only the first authorization obtained in accordance with the Directive is the first authorization for placing the product on the market, as the applicants argued in all the presented cases. In other words, the concept of "market authorization" does not automatically include the conformity with the Directive, but, on the contrary, within the meaning of the Regulation, the conformity with the Directive is the condition that the first authorization must comply with for an SPC to be granted.

As far as the case C-127/00 Hassle AB vs Ratiopharm GmbH, invoked by the SPC applicants, is concerned, we concur with the opinion expressed each time by OSIM on the erroneous decision of the Court as to admit said case-law. The subject of this case and the legal issue settled by the ECJ are different from the cases in Romania, because the problem raised by the case C-127/00 is whether an authorization concerning the price of a medicament can be considered to be a first authorization to place a product on the market within the meaning of the Regulation[25]. In support of our assertion, we further quote: "In this context, the Community Court admitted that the phrase "first authorization for placing a product on the market" refers to the "first authorization applied for in accordance with the provisions concerning the medicinal products, within the meaning of the Directive 65/65/EEC of 26 January 1965". In other words, it is the first authorization having the same nature as the authorization provided by the Directive 65/65/EEC, namely an authorization required, according to the legislation on medicinal products, for placing the product on the market (Note: The authorization provides for tests to be carried out with a view to completing pharmaceutical, pre-clinical pharmacological, pre-clinical toxicological and clinical files), which is different from other authorizations concerning pricing or price reimbursement in medicaments.[26]

Regarding Article 19 a (l), it is noticeable that the wording of this article referring to Romania is different in comparison with the provisions referring to the other Member States accessed after 2004, whereas the second sentence thereof refers to Article 7 (1) which, in its turn, refers to the market authorization obtained in accordance with the Directive 65/65/EEC. Consequently, the interpretation given invariably by the applicant for an SPC was that only the authorization obtained in Romania after 1 January 2000, as the only one granted in accordance with the Directive, represented in fact the first authorization for placing the product on the market, in Romania, as a medicinal product.

As regards the interpretation of Article 19 of the Regulation, we consider that, in both its letter and spirit, the Regulation does not aim to remove or annul the effects produced by the authorizations issued before the date of 1 January 2000 (referred to under Article 19 a (l) of the Regulation) or to deny the obvious fact that the medicaments have been placed on the market, even authorized in accordance with the national legislation in force on that date, which was not fully harmonized with the Directive. The purpose of the Regulation was to provide for uniform solutions at the Community

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[25] The relevant paragraph of the case C-127/00 reads as follows:

"*So far as concerns medicinal products for human use, the concept of 'first authorisation to place ... on the market ... in the Community' in Article 19(1) of Regulation No 1768/92 refers solely to the first authorisation required under provisions on medicinal products [...] granted in any of the*

Member States, and does not therefore refer to authorizations required under legislation on pricing of or reimbursement for medicinal products."

[26] Document drafted by the law firm Stoica & Asociații and filed with OSIM on 9 June 2011, in support of the further appeal lodged by OSIM against the Decision No. 1087A of 19.10.2010 of the Law Court of Bucharest in the case Donepezil, for SC Labormed Pharma SA, page 4.

level, in order to prevent the risk of displacement of the research centres in Member States offering better protection, and this has been related to Romania since 1 January 2000. If the authorizations legally granted in Romania prior to 1 January 2000 could not be considered to be the first authorizations to place certain products on the market, because they are not in accordance with the Directive, the reference date mentioned in Article 19 a (l) (i.e. 1 January 2000) would be completely useless, as all the products authorized to be placed on the market after this date would automatically be eligible for the grant of an SPC, provided that market authorizations in accordance with the Directive were only obtained after this date, and the provision would become redundant.

Special attention has been given throughout this paper to the case Anastrozole (medicament Arimidex) and the application for accessory intervention filed by Teva, because we completely agree with the arguments brought by the intervener in support of the opinion that a product authorized to be placed on the market for the first time in Romania before the date of 1 January 2000, without having previously been subject to the administrative procedure provided for by the Directive 65/65/EEC, is not eligible for the grant of an SPC under the provisions of the Regulation, as it does not comply with the scope of Article 2. It is only on the occasion of the applications for intervention that this article of great importance for the correct application of the Regulation is invoked for the first time. Unfortunately, OSIM has never had in view this article, its attention being exclusively focused on the legal ground invoked by the applicant in the applications for the grant of an SPC: Article3 and Article 19 a (I). And, as we have argued above, regarding the products eligible for the grant of an SPC, Article 2 sets out two conditions to be complied with: the product should be protected by a basic patent and subject to authorization procedure in accordance with the Directive before its being placed on the market. The difference between the provisions of Article 2 and of Article 3 (a) and (b) consists in that the scope of Article 2 excludes those products placed on the market without an authorization in accordance with the Directive 65/65/EEC. However, we cannot disagree with the fact that invoking Article 2 for the first time before the Court of Appeal contravenes the principle of double jurisdiction. Moreover, if the grant of SCP were possible for products placed on the market based on other authorizations than those granted in accordance with the Directive, in certain cases the exclusivity period would exceed the total limit of 15 years from the date of the first authorization in the Community, referred to in the eighth recital of the preamble of the Regulation (it is, for example, the case of the product Donepezil): *"The duration of the protection granted by the certificate should be such as to provide adequate effective protection; for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains authorization to be placed on the market in the Community"*

In support of this argument we also rely on the case C-195/09 Synthon BV vs Merz Pharma GmbH & Co KG in which the European Court of Justice ruled, on 28 July 2011[27], on the referrals concerning the interpretation of Article 2, 13 and 19 of the Regulation. The case is worth being briefly presented since, in our opinion, this case-law is also applicable to the previously presented cases and could lead, for the cases still pending before the Law Court of Bucharest and the Court of Appeal[28], to be ruled differently than the previous cases. Besides, it was also invoked in the case Anastrozole. It results from the case file that the active substance named memantine has been commercialized on the German market as the medicament Akatinol of the pharmaceutical company Merz before the date of 1 September 1976, based on a German regulation of 1961 which obviously did not comply with the provisions of the subsequent Directive 65/65/EEC. On 13 November 2002, the company filed in UK an application for the grant of an SPC for memantine, where an authorization granted in the UK in 2002 was mentioned as the first authorization for placing the

[27] http://eur-lex.europa.eu, OJ of 08.10.2011

[28] On the date of drafting this paper, the ruling of the Court of Appeal on the appeal entered by OSIM in the case Sildenafil is still pending pronouncement.

product on the market, without mentioning the market authorization obtained in Germany. The SPC was granted by the UK Patent Office. By the action brought before the High Court of Justice (Patent Court), the generic medicaments company Synthon claimed that the said SPC should be declared invalid or the duration of its protection should be fixed at zero. Having doubts relating to the scope of the Regulation and to the interpretation to be given to the concept of "first authorization to be placed on the market in the Community", the High Court of Justice specialized in the field of patents decided to suspend the judgment of the case to refer a series of question to the ECJ for preliminary ruling. The third of these questions is, in our opinion, relevant for the cases of Romania.

"Is a product which is authorised to be placed on the market for the first time in the EEC without going through the administrative procedure laid down in [Directive 65/65] within the scope of [Regulation No 1768/92] as defined by Article 2?"

The Court interpretation to the scope of the Regulation was that *" for the purposes of obtaining an SPC, the product concerned must be protected by a valid patent in the national territory and it must have been subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 65/65."*

This interpretation is confirmed by the purpose of the Regulation. As it is apparent from the first to fourth recitals in the preamble to Regulation No. 1768/92, in order to ensure sufficient protection to encourage pharmaceutical research, that regulation seeks, through the creation of an SPC for medicinal products that were granted marketing authorisation, to make up for the fact that the period of effective protection under the patent is insufficient to cover the investment put into the research, given the period that elapses between the filing of an application for a patent for a new medicinal product and the authorisation to place that product on the market. It would be contrary to that objective of offsetting the time taken to obtain a marketing authorisation – which requires long and demanding testing of the safety and efficacy of the medicinal product concerned – if an SPC, which amounts to an extension of exclusivity, could be granted for a product which has already been sold on the Community market as a medicinal product before being subject to an administrative authorisation procedure as laid down in Directive 65/65.

The conclusion of the Court was that such a medicinal product is not within the scope of Regulation No 1768/92 and may not, therefore, be the subject of an SPC.

We find that this case is similar with the previously presented cases and it must be noticed that a court having such a prodigious experience in the field of patents and SPC like the High Court of Justice (Patent Court) in the UK referred for preliminary ruling by the ECJ, in 2009, questions concerning the interpretation of the Regulation in force in the Community since 1992, in order for it to meet the essential condition for the Community legislative acts, namely to provide for uniform solutions at the Community level. That is why we cannot agree with the fact that, although in Romania there is no case-law in the SPC field and, for the discussed cases, various diverging interpretations were given to the Regulation, the Romanian courts refused the referral for preliminary ruling by the ECJ and contradictorily ruled in identically similar cases.

We hereby express our hope that this paper could contribute, to a certain extent, to create an overview of SPC cases which raised special problems of interpretation of a Community regulation, as well as to deliver judgments based, on the one hand, on the Community case-law, and, on the other hand, to ensure the observance of the constitutional principle of the free trade for those medicaments producers whose right to the free exploitation of the patented technical solution could be abusively restricted.

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