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Supplementary protection Certificates - Circadin

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Agenda

- *Historia del Reglamento 469/2009*
- *Objetivo del reglamento: considerandos*
- *Disposiciones del Reglamento*
- *Problemas de interpretación. Decisiones ECJ*
- *El caso Circadin*
- *Problemáticas asociadas con los SPC's en España*

Historia del Reglamento 469/2009 (1768/92)

Medicamentos- Exclusividad de mercado

Obtención de exclusividad a través de:

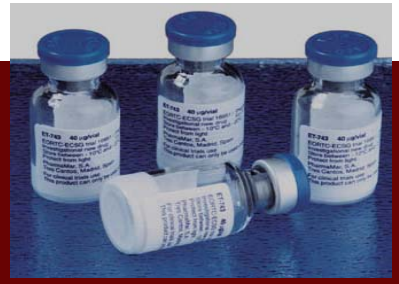
Propiedad Industrial

- Patentes (Ley de Patentes y Convenio Europeo de Patentes) **20 años**
- Certificado complementario de protección (Reglamento CEE 1768/92) máximo **5 años**
- Exclusividad pediátrica (EEUU, Europa Reg 1901/2006) **6 meses**
- Marcas (Marca vs. INN o nombre genérico)

- **Regulatorio**
- Protección de datos de productos medicinales (Directiva 65/65/EEC y 2001/83/EC y 2003/63/EC) **10 +1 años (8+2+1)**
- Status de medicamento huérfano (R 141/2000 CEE) **10 años**

Medicamentos- tiempo de desarrollo

abg patentes



- **Lanzamiento**
- **al mercado**
- **REGISTRO**

- **FASE III**
- Comparación con
- Tratamientos standard

- **5-7 años***

- **FASE II**
- Eficacia / Seguridad
- Selección indicación terapeutica

FASE I
- Dosis /régimen de administración
- Dosis máxima tolerada
- ADME/Toxicidad/farmacocinética/seguridad

- **3-4 años***

- **PRECLÍNICA**
- Toxicidad / farmacocinética
- Formulación / Estabilidad
- Estudios biológicos

- **2-4 años***

- **DISCOVERY**
- Patente
- Elucidación estructural/ Aislamiento / Purificación
- Screening primario/screening con targets

Historia del Reglamento 469/2009

- **EEUU**: en 1984 se promulga la *"Drug Price Competition and Patent Term Restoration Act*" ("The Hatch Waxman Act"), para aumentar la entrada de genéricos.
- Reduce los requisitos para su registro (ANDA), a cambio extiende el tiempo de protección a la industria innovadora.
- Introduce la exención "Bolar".
- De 1984 a 2001 el sector de genéricos aumenta su parte de mercado del 19% al 45% (IMS health, Facts and Figures)
- Iniciativas similares en otros paises:
- **Japón** en 1987
- **Italia y Francia:** con anterioridad al Reglamento europeo

Historia del Reglamento 469/2009

- Harmonización del derecho farmacéutico en la UE (Directiva 65/65)
- Propuesta para compensar el tiempo de protección de patente perdido hasta la autorización regulatoria para comercializar un medicamento.
- la Commisión Europea hizo una primera propuesta para un Certificado Complementario de Protección de medicamentos en 1990.
- Entrada en vigor (art. 23 reg.): 6 meses después de su publicación en el Diario Oficial de la UE: 2.7.1992-- **2.01.1993**
- **En España:** 5 años después (art. 21 reg.): **2.01.1998**, sin aplicación de disposición transitoria del art. 19.

Considerandos
del Reglamento 469/2009 (1768/92)

Considerandos del Reglamento CEE 469/2009

(2) **La investigación en el sector farmacéutico** contribuye decisivamente a mejorar constantemente la salud pública.

(3) Los **medicamentos**, y **en particular los obtenidos tras una investigación larga y costosa**, solo seguirán desarrollándose en la Comunidad y en Europa si están amparados por una normativa favorable que disponga una **protección suficiente** para fomentar tal investigación.

(4) Actualmente el período que transcurre entre la presentación de una solicitud de patente para un **nuevo medicamento** y la autorización de comercialización de dicho **medicamento** **reduce la protección efectiva que confiere la patente a un período insuficiente** para **amortizar las inversiones efectuadas en la investigación**.

(5) Tales circunstancias ocasionan **una insuficiencia de protección que perjudica a la investigación farmacéutica**.

(6) Existe el riesgo de que los centros de investigación situados en los Estados miembros se desplacen a países que ofrezcan una mejor protección.

Considerandos del Reglamento CEE 469/2009

(7) Es conveniente prever una **solución uniforme a nivel comunitario** para prevenir una evolución heterogénea de las legislaciones nacionales que cree nuevas disparidades, las cuales podrían obstaculizar la libre circulación de **medicamentos** en la Comunidad y afectar, por ello, directamente al funcionamiento del mercado interior.

(8) Por lo tanto, es necesario establecer un certificado complementario de protección **para los medicamentos** cuya comercialización haya sido autorizada y que pueda ser obtenido **por el titular de una patente nacional o europea**, **en las mismas condiciones en cada Estado miembro**. Por tal motivo, el reglamento es el instrumento jurídico más apropiado.

(9) La duración de protección conferida por el certificado debe determinarse de tal manera que proporcione **al medicamento** una protección efectiva suficiente. A tal fin, el titular a la vez de una patente y de un certificado debe poder disfrutar, en total, de **15 años de exclusividad** como máximo a partir de la **primera autorización de comercialización** en la **Comunidad del medicamento en cuestión**.

Considerandos del Reglamento CEE 469/2009

abg patentes

- (10) No obstante, deben tenerse en cuenta todos los intereses en juego, incluidos los de la salud pública, en un sector tan complejo y sensible como es el sector farmacéutico. A tal fin, el certificado no podría expedirse por un período superior a **cinco años**. Además**, la protección que confiere el certificado debe limitarse estrictamente al producto amparado por la autorización de comercialización en su calidad de medicamento**.

- (11) Conviene establecer que se limite de manera adecuada la duración del certificado en el caso concreto de una patente que ya haya sido prorrogada en virtud de una legislación nacional específica.

➢Los considerandos mencionan siempre el **medicamento** ("medicinal product"; art 1a) y no el **principio activo** ("producto"; art 1 b).

Reglamento CEE 469/2009 (1762/92)

Reglamento con el fin de :

- Proteger la **INVESTIGACIÓN** en farmacia, restaurando protección efectiva perdida en el proceso de desarrollo y autorización.
- Aumentar la competitividad de estas industrias en Europa frente a USA y Japón que ya tenían legislación favorable.
- Armonizar legislativamente las regulaciones en la materia de los países de la UE para evitar una evolución heterogénea de las legislaciones nacionales.
- Contempla periodo de transición (1998 en España (Art. 21)) y permite obtener SPC's para productos autorizados con anterioridad, desde 1/1/85, con algunas excepciones (BE IT AT:1982; DE DK FI NO:1988) (Art. 19).

Principales normas del reglamento 469/2009

Reglamento CEE 469/2009 (1768/92)

Aspectos legales:

- El reglamento es de aplicación directa en los paises miembros de la UE, y además en Noruega, Islandia y Lichtenstein (EEE).
- Sin embargo, son las administraciones nacionales las encargadas de su tramitación y concesión (Art.9), y es un certificado de ámbito nacional.
- EL CCP es un título de propiedad industrial autónomo, no es una “patente extendida” (Art. 5).
- Recursos por vías nacionales (Art 17) y posibilidad de recurrir al Tribunal de Justicia Europeo para la interpretación del Reglamento.

Art. 1 Definitions

- (a) **'medicinal product'** means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
- (b) '**product**' means the active ingredient or combination of active ingredients of a medicinal product;
- (c) **'basic patent'** means a patent which protects a product as defined in (b) as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;
- (d) '**certificate**' means the supplementary protection certificate.

Art. 2 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 authorisation procedure as laid down in Directive 2001/83/EC …on the Community code relating to medicinal products for human use or Directive 2001/82/EC …on the Community code relating to veterinary medicinal products may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

- Question:
- - "protected by a patent”?

Art. 3 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 2001/83/EEC or Directive 2001/82/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. 4 Subject-matter of Protection

- Within **the limits of the protection** conferred by the basic patent, the protection conferred by a certificate shall extend **only** to the product covered by the authorization to place the corresponding medicinal product on the market and for any **use of the product as a medicinal product** that has been authorized before the expiry of the certificate.

Regulation 1610/96 (SPC for fitosanitary products)

- *Recital 13- Whereas the certificate confers the same rights as those conferred by the basic patent; whereas, consequently, where the basic patent covers an active substance and* ***its various derivatives (salts and esters), the certificate confers the same protection;***
- *Whereas the detailed rules in recitals 12, 13 and 14 and in Articles 3 (2), 4, 8 (1) (c) and 17 (2) of this Regulation are also valid, mutatis mutandis, for the interpretation in particular of recital 9 and Articles 3, 4, 8 (1) (c) and 17 of Council Regulation (EEC) No 1768/92,*

Art. 5 Effects of the Certificate

- **Art. 5 Effects of the Certificate**:
- Subject to the provisions of Article 4, the certificate shall confer the **same rights as conferred by the basic patent** and shall be subject to the same limitations and the same obligations.

- Patent law applies, as if it was a patent.

- right to exclude
- infringement actions
- injunctions

Art. 6 Entitlement to the certificate

- The certificate shall be granted to the holder of the basic patent or his successor in title.

- *<u>Regulation 1610/96 (SPC for fitosanitary products)</u>*

  Art. 3(2) The holder of more than one patent for the same product shall not be granted more than one certificate for that product.

  However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.

Art. 7 Application for a Certificate

1. The application for a certificate shall be lodged **within six months** of the date on which the authorization referred to in Article 3 (b) to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

3. The application for an extension of the duration may be made… (extensión pediátrica)

Art. 8 Content of the Application

1. The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:

(i) the name and address of the applicant;

(ii) if he has appointed a representative, the name and address of the representative;

(iii) the number of the basic patent and the title of the invention;

(iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3 (b) and, if this authorization is not the first authorization for placing the product on the market in the Community, the number and date of that authorization;

…

Art. 8 Content of the Application (2)

(b) 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 or Article 5a of Directive 81/851/EEC;

(c) if the authorization referred to in (b) is not the first authorization for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication.

… (extensión pediátrica)

2. Member States may provide that a fee is to be payable upon application for a certificate.

Art. 9 Lodging of the Application

- The application for a certificate shall be lodged with the competent **industrial property office** of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorization referred to in Article 3 (b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.

Art. 18 Procedure

1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless that law lays down special procedural provisions for certificates.

2. Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.

Art. 19 Appeals

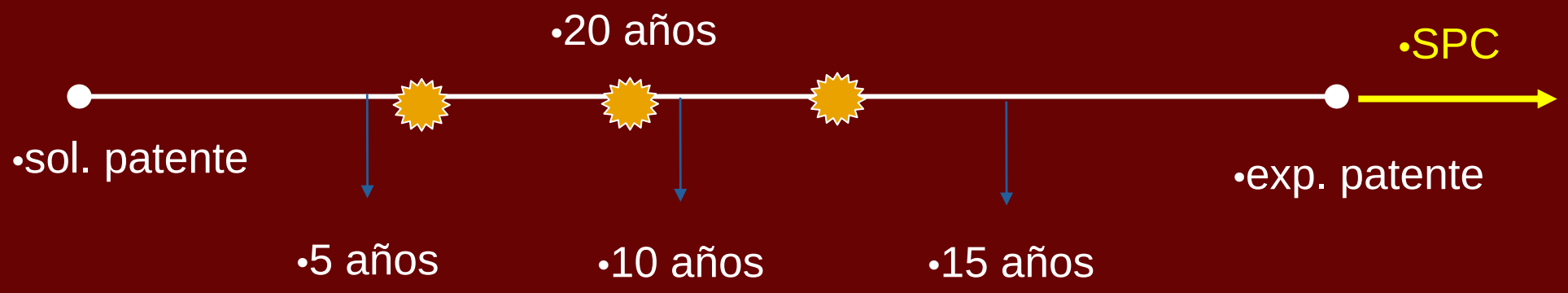
- The decisions of the authority referred to in Article 9 (1) or of the body referred to in Article 15 (2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

- *Art. 17(2) Regulation 1610/96 (SPC for fitosanitary products)*
- *17.2. The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorization to place the product on the market in the Community, contained in the application for a certificate as provided for in Article 8, is incorrect.*

Art. 13 Duration of the Certificate

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to
   - the period which elapsed between the date on which the application for a basic patent was lodged and
   - the date of the first authorization to place the product on the market in the Community
   - reduced by a period of five years.
2. Notwithstanding paragraph 1, the duration of the certificate **may not exceed five years** from the date on which it takes effect.

Art. 13 Cálculo de la duración:



•1ª autorización Medicamento

- •Caso 1: 6 años – 5 = 1año SPC
- •Caso 2: 9 años – 5 = 4 años SPC
- •Caso 3: 13 años –5 = 8 años > máximo 5 años SPC

Art. 15 Invalidity of the Certificate

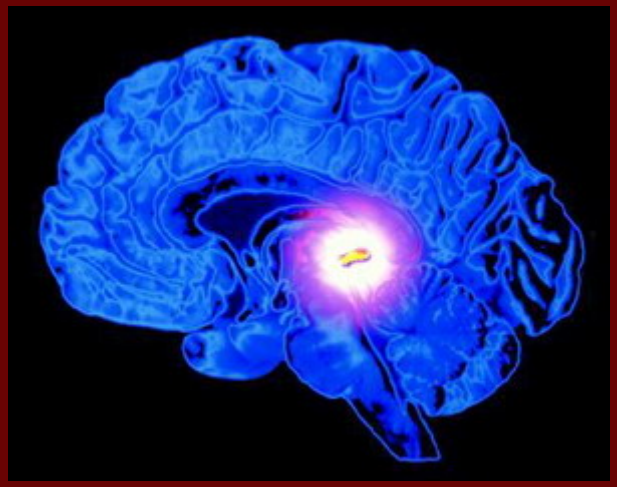
- The certificate shall be invalid if:
- (a) it was granted contrary to the provisions of Article 3;
- (b) the basic patent has lapsed before its lawful term expires;
- (c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

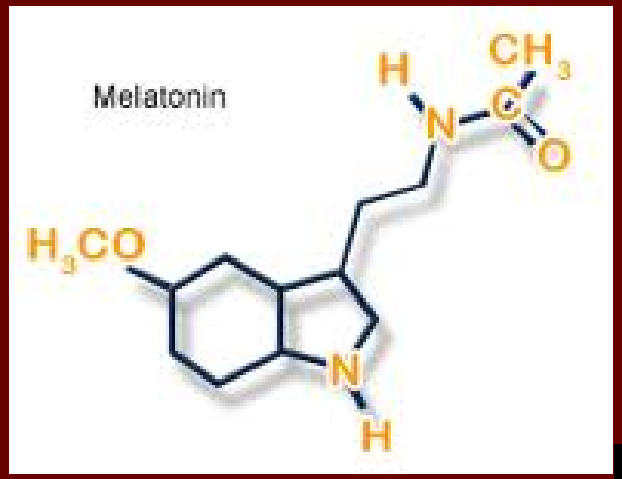
- 2. **Any person** may submit an application or bring an action for a declaration of invalidity of the certificate before the **body responsible under national law** for the renovation of the corresponding basic patent.

El caso de Circadin® -melatonina

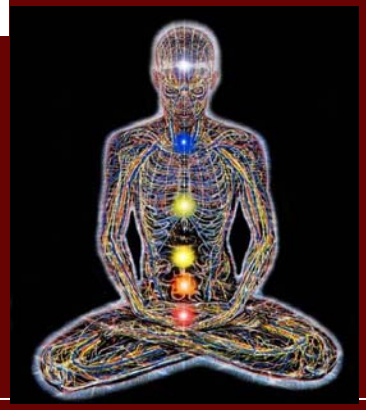
Melatonina

- Melatonina: una hormona natural aislada de la glándula pineal (Lerner et al *JACS* 80, 2587 (1958), donde se sintetiza a partir de serotonina cuando no hay luz.





Se relaciona a la glándula pineal con el “tercer ojo”



Funciones de la Melatonina

- Regulación del ritmo circadiano (ritmos de sueño, actividad diurna/nocturna de animales)
- Regulación de ritmos estacionales de reproducción en algunos mamíferos (por ejemplo ovejas)
- Regulación de la producción de pelaje y color del mismo (por ejemplo hamster siberiano, visones)
- Regulación la fisiología de la retina
- Antioxidante, ¿anti-envejecimiento?

Circadin® para el insomnio

- Prof. Zisapel, hypothesized that age-related sleep complaints are linked to the decay in production of melatonin.
- These findings initiated the creation of **Neurim Pharmaceuticals**, a company focused on age-related disorders, primarily in the central nervous system (CNS).
- Neurim developed a formulation that mimics the nocturnal release of melatonin and studied its effects on insomnia.
- Insomnia affects 1/3 of adult population, especially over 50 years of age.
- Previous treatment for insomnia:
  - benzodiazepines (hypnotics)
  - Alcohol (!)

Circadin® para el insomnio

- **Circadin®** is approved (EMA) for marketing in the EU as 2 mg prolonged-release melatonin formulation.
- **Indication**: monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep in patines who are aged 55 or over.
- It mimics the physiological secretion profile of melatonin.
- The **prolonged-release (PR) formulation** of melatonin (Circadin) circumvents the fast clearance of the hormone and provides a melatonin profile in the blood closely matched to the normal physiological release.

Circadin® para el insomnio

Development:

- **1991**: Neurim founded to develop project
- **04.1992**: filing of European patent application: (**EP 518 468**)
- **1994-2000**: 12 clinical studies performed with more than 1.000 subjects.
- **02.2000**: Submission of MA application at EMA
- **10.2000**: rejection because efficacy not been demonstrated in clinical studies. Questions regarding potential toxicity on the reproductive function and hormonal levels. EMA requested complete package of reproduction toxicity and additional clinical studies.
- **2002**: Following this Neurim withdrew application and requested scientific advice.

Circadin® para el insomnio

Development:

- **2003-2005**: Additional preclinical toxocity tests
- **2003-2005** :Additional phase III studies were performed, developing and validating a new methodology to evaluate sleep.1.880 patients in total received Circadin (Zisapel et al. *J Sleep Res* (2003) 12 291-298).
- **2005**: Neurim submitted application at EMA which gave "part B status" ("new active substance"-full application).
- **29.06.2007**:Circadin was authorised by decision of EC

23.04.1992 → **29.06.2007**

More than 15 years since patent application to develop and get authorization.

Circadin® para el insomnio

- Circadin licenciado en Europa a Nycomed y Lundbeck, TEVA en Israel.

Certificados Complementarios de Protección para Circadin

SPC applications for Circadin

- SPC applications based on MA 29.06.2007 and basic patents
- **Granted**:

  Austria, Belgium, Denmark, Spain, Greece, Italy, Luxembourg, Portugal, France, Sweden, Cyprus, Ireland, Lithuania, Latvia, Slovenia.

Rejected and under appeal:

- **UK**
- **NL**

¿Why?

SPC applications for Circadin - UK NL

- Patent Offices in UK and NL rejected patent applications on the basis of art 3(d):

  "*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:*

  (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;…*

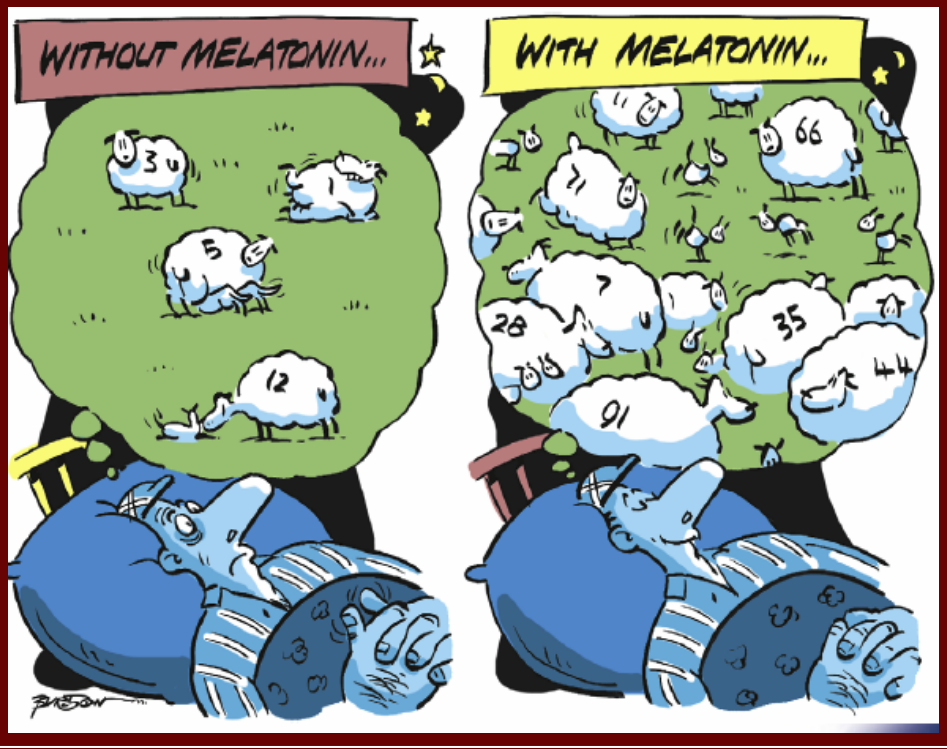
  (d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product*.*

SPC applications for Circadin - UK

UK ---- Regulin® (Ceva Animal Health)

In UK prior authorisation (**1993**) of melatonin implant in sheep (ewes), to advance breeding ("lambing") season (approx 2 months).

EP 246 910 B1



SPC applications for Circadin - NL

NL --- PRIME-X

In NL prior authorisation of melatonin implant for accelerating "priming" (fur production) by 4-6 weeks in minks (*Mustela vison*).

Reasons for rejection

Literal interpretation of art. 3(d):

Regulin or Prime-X are first MA in the country (UK or NL) in accordance with Directive 81/851/EEC.

→ Condition of art. 3(d) not met

(d) the authorization referred to in (b) is the <u>first</u> authorization to place the <u>product</u> on the <u>market</u> as a medicinal product

Art. 1 (b) defines Product:

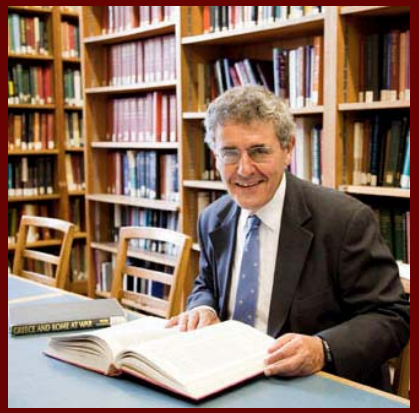
*(b) '**<u>product</u>**' means the active ingredient or combination of active ingredients of a medicinal product*

UK (fast) Proceedings

- 26 September 2007: Circadin SPC application filed
- 15 July 2008: Office Action
- 1 October 2009 Hearing
- 15 December 2009 Decision of UK IPO - Rejection of SPC app.
- 12 January 2010 Appeal Patents Court (Justice Arnold)
- 27 April 2010 Hearing
- 6 May 2010 Decision : rejection of SPC app.
- 3 June 2010 Appeal Court of Appeal (Justices Smith, Jacob, Patten)
- 3 February 2011 Hearing
- 8 March 2011 Judgment and reference to ECJ

UK Proceedings

- Notice of Appeal and short gorunds
- "Skeleton arguments" and reply
- Hearing at Court:
  - Barrister (Andrew Waught)
  - Patent Attorneys "instructing"
  - Justices



ECJ Cases referred during proceedings

SPC regulation has been interpreted a number of times by European Court of Justice.

- Cases cited in UK Proceedings for Circadin:
  - **C31/03: Pharmacia**
  - **C431/04 MIT**
  - **C202/05 Yissum**

C31/03 Pharmacia

Facts:

- 1st MA for Galastop (1987): cabergoline (active ingredient) to inhibit lactancy in animals (veterinary use)
- 2nd MA for Dostinex (1992): cabergoline to inhibit lactancy in women.

- Patent was the same in both cases (covers both products), the indication was the same, MoA was the same, and importantly, the **medicinal product** (medicament) was the same.

C31/03 Pharmacia

- **Question on interpretation of Art 19(1) SPC regulation**

  *'Is the grant of a supplementary protection certificate in a Member State of the Community on the basis of a **medicinal product** for human use authorised in that Member State precluded by a [marketing authorisation for **that product**] as a veterinary medicinal product granted in another Member State of the Community before the date specified in Article 19(1) of the Regulation No 1768/92, or is the sole determining factor the date on which the product was authorised in the Community as a medicinal product for human use?'*

Answer:

*In those circumstances, and in accordance with the observations submitted by the United Kingdom Government and the Commission, the answer to the question referred for a preliminary ruling must be that the grant of a certificate in a Member State of the Community on the basis of a **medicinal product** for human use authorised in that Member State is precluded by a marketing authorisation for **that product** as a veterinary medicinal product granted in another Member State of the Community before the date specified in Article 19(1) of the regulation.*

C431/04 MIT

Facts:

- MIT holder of patent on polifeprosan (polymer)
- Carmustine (active ingredient) was authorized for a long time for the treatment of brain tumors, intravenous
- New MA for a medicinal product Gliadel, an implant with Carmustine as active ingredient, with poliprofesan as excipient, for treatment of brain tumors.

C431/04 MIT

Question on interpretation of art 1(b):

1. *Does the concept of "combination of active ingredients of a medicinal product" within the meaning of Article 1(b) of Regulation [No 1768/92] mean that the components of the combination must all be active ingredients with a therapeutic effect?*
2. *Is there a "combination of active ingredients of a medicinal product" also where a combination of substances comprises two components of which one component is a known substance with a therapeutic effect for a specific indication and the other component renders possible a pharmaceutical form of the medicinal product that brings about a changed efficacy of the medicinal product for this indication (in vivo implantation with controlled release of the active ingredient to avoid toxic effects)?*

C431/04 MIT

Answer:

In those circumstances, the answer to the questions referred must be that Article 1(b) of Regulation No 1768/92 must be interpreted so as not to include in the concept of 'combination of active ingredients of a medicinal product' a combination of two substances, only one of which has therapeutic effects of its own for a specific indication, the other rendering possible a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first substance for that indication.

- In MIT despite investment in new medicament, no full dossier was necessary, since Active ingredient was authorized before.
- It is about interpretation of 1(b), not 3(d)

C 202/05

Facts:

- Calcitriol was authorized for many years, as IV solution for the treatment of hypocalcaemia
- Galderma: new MA for SILKIS ointment, for the treatment of psoriasis, via a new route of administration (topical)
- SPC application based on new MA and patent covering the topical cream.

C 202/05

Question relating to definition of product 1(b):

In a case in which the basic patent protects a second medical application of a therapeutic agent what is meant by “product” in Article 1(b) of the Regulation [No 1768/92] and in particular does the application of the therapeutic agent play any part in the definition of “product” for the purpose of the Regulation?

Answer:

Order referring to C31/03 and C431/04

Consequently, the answer to the question referred must be that Article 1(b) of Regulation No 1768/92 is to be interpreted as meaning that in a case where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product

Judgment and order in Circadin

Neurim arguments

- SPC regulation should be construed teleologically, taking into acocunt the purposes of the regulation. ECJ case law already applied this principle (C482/07 AHP, C229/09 Lovels vs Bayer).
- Cricadin patent does not cover Regulin or Prime-X, Regulin patent does not cover Circadin.
- Circadin was authorized with a full dossier, as a new active ingredient, and did not rely on Regulin or Prime-X prior authorizations.
- There are differences of fact with C31/03 (Pharmacia) C431/04 (MIT) and C202/05 (Yissum).
- These cases do not relate to interpretation of 3(d).

Judgment and order in Circadin

Judgment

We consider that Neurim's arguments are not only tenable: in our view they are right. Many kinds of valuable pharmaceutical research will not get the encouragement or reward they deserve if they are not. Pharmaceutical research is not confined to looking for new active compounds. New formulations of old active substances are often sought. Most are unpatentable but from time to time a real invention is made and patented.

Judgment and order in Circadin

Judgment

Moreover there is much endeavour to find new uses for known active ingredients. The European Patent Convention 2000 has indeed made the patenting of inventions in this area clearer. Its effect is that a patent for a known substance or composition for use in a method of treatment is not to be regarded as old (and hence unpatentable) unless use for that method is known. It would be most unfortunate if second medical use patents could not get the benefit of an SPC.

In short, ***if Neurim are wrong, then the Regulation will not have achieved its key objects for large areas of pharmaceutical research: it will not be fit for purpose****. Whether that is so or not is clearly a matter for the EU's highest court.*

Questions referred to ECJ (C130/11)

1. In interpreting Article 3 of Regulation EEC No. 1768/92 [now Regulation (EC) No. 469/2009] ("the SPC Regulation"), when a marketing authorisation (A) has been granted for a medicinal product comprising an active ingredient, is Article 3(d) to be construed as precluding the grant of an SPC based on a later marketing authorisation (B) which is for a different **medicinal product** comprising the same active ingredient where the limits of the protection conferred by the basic patent do not extend to placing the product the subject of the earlier MA on the market within the meaning of Article 4?

Questions referred to ECJ (C130/11)

2. If the grant of the SPC is not precluded, does it follow that in interpreting Article 13(1) of the SPC Regulation, “the first authorisation to place the product on the market in the Community” needs to be an authorisation to place a medicinal product on the market within the limits of the protection conferred by the basic patent within the meaning of Article 4?

3. Are the answers to the above questions different if the earlier marketing authorisation has been granted for a veterinary medicinal product for a particular indication and the later marketing authorisation has been granted for a medicinal product for human use for a different indication?

Questions referred to ECJ (C130/11)

4. Are the answers to the above questions different if the later marketing authorisation required a **full application for marketing approval** in accordance with Article 8(3) of Directive 2001/83/EC (formerly a full application under Article 4 of Directive 65/65/EEC)?

5. Are the answers to the above questions different if the product covered by authorisation (A) to place the corresponding medicinal product on the market is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant?

Cuestiones relativas a los CCPs en España

Práctica en España: CCPs

- Publicación de las solicitudes de Certificados Complementarios de protección

- Combinaciones de principios activos: STS Fosinopril

- En una solicitud de CCP para una combinación, ¿debe la patente básica reivindicar específicamente y explícitamente la combinación que es objeto de la autorización de comercialización?

STS 04.07.2007 Fosinopril

El dictamen pericial cuyo texto consta a los folios 318 y siguientes de los autos permitía deducir que la patente número ES 507.672 invocada como de base (que lo era de procedimiento y no de producto, hecho al que quizá no se ha prestado la suficiente atención), al referirse a los derivados de prolina, podía incluir el fosinopril sódico. Sin embargo lo que no figuraba entre sus reivindicaciones era, a juicio del perito que refrendará el tribunal de instancia, la asociación de dichos derivados de la prolina (entre ellos, el fosinopril) con la hidroclorotiazida, por más que hubiese una referencia genérica a que "los compuestos de la presente invención se pueden formular también en combinación con un diurético para el tratamiento de la hipertensión", diuréticos entre cuyos ejemplos se mencionaba, como uno más entre otros varios, la hidroclorotiazida.

La Sala sentenciadora bien pudo, pues, sin que su apreciación sea tachable de arbitraria o manifiestamente irrazonable (más bien al contrario) apreciar el dictamen pericial en el sentido en que lo hizo y concluir que un medicamento en el que confluían el fosinopril y la hidroclorotiazida no podía calificarse como "producto protegido por la patente de base número ES 507.672" pues excedía del ámbito de dicha patente (que se limitaba al procedimiento para preparar derivados de la prolina), todo ello a los efectos de obtener el CCPM para él solicitado.

C 6/11 Daiichi

1 Regulation 469/2009 (the Regulation) (1) recognises amongst the other purposes identified in the recitals, the need for the grant of an SPC by each of the Member States of the Community to holders of national or European patents to be under the same conditions, as indicated in recitals 7 and 8. In the absence of Community harmonisation of patent law, **what is meant in Article 3(a) of the Regulation by 'the product is protected by a basic patent in force' and what are the criteria for deciding this**?

C 6/11 Daiichi

3. In order for a combination of active ingredients cited in an authorisation for placing a medicinal product on the market to be the subject of an SPC, and having regard to the wording to Article 4 of the Regulation, is the condition that the product be ‘protected by a basic patent’ within the meaning of Articles 1 and 3 of the Regulation satisfied **if the product infringes the basic patent under national law**?

C 6/11 Daiichi

4. In order for a combination of active ingredients cited in an authorisation for placing a medicinal product on the market to be the subject of an SPC, and having regard to the wording to Article 4 of the Regulation, does satisfaction of the condition that the product be 'protected by a basic patent' within the meaning of Articles 1 and 3 of the Regulation depend upon **whether the basic patent contains one (or more) claims which specifically mention a combination** of (1) a class of compounds which includes one of the active ingredients in the said product and (2) a class of further active ingredients which may be unspecified but which includes the other active ingredient in the said product; or is it sufficient that the basic patent contains one (or more) claims which (1) claim a class of compounds which includes one of the active ingredients in the said product and (2) use specific language which as a matter of national law extends the scope of protection to include the presence of further other unspecified active ingredients including the other active ingredient in the said product?

See also **C630/10** Medeva (vaccines).

Documentación sobre SPC's en:

http://thespcblog.blogspot.com/

Gracias por su Atención

http://www.abgpatentes.com