Intellectual Property Office

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29 July 2014

COUNCIL REGULATION (EC) 469/2009
CONCERNING THE CREATION OF A
SUPPLEMENTARY PROTECTION CERTIFICATE
FOR MEDICINAL PRODUCTS

APPLICANT	Leibniz-Institut für Neue Materialien Gemeinnützige GmbH
ISSUE	Whether application SPC/GB/10/051 for a supplementary protection certificate meets the requirements of Article 2 and Article 3(b) of the Regulation
HEARING OFFICER	Dr L Cullen

DECISION

Introduction

1 This decision relates to supplementary protection certificate (SPC) application SPC/GB/10/051 which was filed by Gill, Jennings & Every LLP (the "agent") on 14 December 2010 on behalf of Leibniz-Institut für Neue Materialien Gemeinnützige GmbH (the "applicant") to protect a product that is described as "*Aqueous dispersion of iron oxide nanoparticles*" (see section 6 of Form SP1 filed along with this application).

Background

2 The basic patent upon which this SPC application is based is EP(UK) 0636111 B1 entitled "*Method of Manufacturing Surface-modified Ceramic Powers with Particles in the Nanometre Size*", which was filed on 8 April 1993, with a priority date of 15 April 1992 and was granted by the European Patent Office (EPO) on 22 July 1998. The expiry date of this patent was 7 April 2013.

3 This patent describes a method of manufacturing surface-modified ceramic powders in the nanometre (nm) particle size range having an average size of not more than 100nm. The unmodified powder is dispersed, in water and/or an organic solvent, in the presence of at least one low-molecular weight organic compound (of molecular weight not more than 500) having at least one functional group which can react and/or interact with functional groups present on the surface of the powder particles. The dispersant may subsequently be wholly or partly removed. The patent refers to metal oxides as being suitable ceramic powders and organo-alkoxy-silanes as being suitable low-molecular weight organic compounds.

4 The document identified by the applicant as a Marketing Authorisation and supplied in support of the SPC application (see section 8 of Form SP1) was EC Design Examination Certificate No. 11870GB411100614, dated 14 June 2010. This EC Design Examination Certificate was issued by MedCert Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH (hereafter "MEDCERT"), which identifies itself as the Notified Body[1], and confirms that the design of the medical device identified as "***NanoTherm A51 (112 mg/ml Fe) article-number: MFL AS MO1***" fulfils the requirements of Annex II, Section 4, of Directive 93/42/EEC concerning Medical Devices. The manufacturer of the medical device identified by this EC Design Certificate is MagForce Nanotechnologies AG (with a German address).

5 A Declaration of Conformity dated 30 June 2010 was also filed with the SPC application. In it the manufacturer, MagForce Nanotechnologies AG, declares that the product meets the requirements of Directive 93/42/EEC (in consideration of Directive 2007/47/EC). This declaration also:

(i) states that the product covered by the declaration of conformity is "*NanoTherm AS1 (112 mg/ml Fe)*";

(ii) provides a general description of the product as "*Aqueous dispersion of iron oxide nanoparticles (iron concentration: 112 mg/ml)*";

(iii) states that the classification of the product according to Directive 93/42/EEC Annex IX is "*Medical device class III – rule 8, indent 2*"; and

(iv) indicates that the conformity assessment procedure followed was that according to Directive 93/42/EEC, Annex II.

6 In the correspondence on file, the applicant provides an explanation of how, what they refer to as a 'product', NanoTherm, works (see agents letter dated 18 September 2012). I note also that the manufacturer's website provides an explanation of how the NanoTherm product works[2].

7 Aminosilane-coated iron oxide nanoparticles are magnetic particles used in the treatment of cancer. They are used for local treatment of solid tumours, in particular the treatment of brain tumours, prostate cancer, cervical carcinoma, ovarian cancer, oesophageal cancer and pancreatic cancer. These extremely small nano-sized particles are introduced directly into a tumour and then subjected to an alternating magnetic field (e.g. one that varies its polarity very rapidly, up to 100,000 times per second). This causes the particles to heat up and, depending on the temperature achieved and/or the duration of the exposure to the magnetic filed, the tumour cells are irreparably damaged or are sensitised for additional treatment, such as chemotherapy or radiotherapy. The Aminosilane coating means that the nanoparticles remain localised at the tumour site and, as a result, they can be used

[1] MEDCERT is one of the largest Notified Bodies in Germany – see website at http://www.med-cert.com/. They are a Notified Body for the purposes of Directive 93/42/EEC and Directive 90/358/EEC (see footnotes 7-9 below).

[2] See entries for **NanoTherm** and explanation of how **NanoTherm Therapy** works at http://www.magforce.de/en/produkte/nanothermr-therapie.html

repeatedly and/or as part of a multi-modal therapy plan. The nanoparticles do not locate within healthy tissue.

8 There has been an extensive correspondence between the applicant and examiner concerning this SPC application. It has involved detailed argument and analysis with reference to a significant number of supporting documents. In summary, the examiner considers that the SPC application is out of scope of Council Regulation (EEC) No 469/2009 concerning the creation of a supplementary protection certificate for medicinal products ("the SPC Regulation") as it does not relate to a medicinal product subject to an "*administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use*" as set out in Article 2 of the SPC Regulation. In addition, the examiner considers that the application does not comply with the conditions for obtaining an SPC in that the marketing authorisation filed in support of the application does not comply with Article 3(b) of the SPC Regulation. This article requires that the marketing authorisation is "***granted in accordance with Directive 2001/83/EC*** *or Directive 2001/82/EC as appropriate*" (my emphasis added in bold). On the other hand, the applicant considers that the authorisation procedure which leads to the issue of the EC Design Certificate and Declaration of Conformity for the medical device under the procedure laid down in Directive 93/42/EEC, and filed in support of this SPC application, **is** equivalent to an authorisation to place the product (for which the SPC has been applied for) on the market as a medicinal product granted under the administrative procedure laid down in Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Thus the applicant considers that the assessment carried out on a medical device to meet the requirements of Directive 93/42/EEC is equivalent to that carried out on a medicinal product to meet the requirements of Directive 2001/83/EC. Thus, it can be used as a means to show that the requirement under Article 3(b) of the SPC regulation is met.

9 The applicant, in their letter dated 6 May 2014, waived their previously expressed request for an oral hearing and requested that a decision be made based upon all the papers on file.

The Relevant Law and its interpretation

The SPC Regulation

10 When the SPC application in question was applied for, Council Regulation (EC) 469/2009 concerning the creation of a supplementary protection certificate for medicinal products, hereafter referred to as the SPC Regulation, was in force.

11 Recitals 2-5, 9 and 10 of the SPC Regulation state (emphasis added):

> *'(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.*

(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

(4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation 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.

(5) This situation leads to a lack of protection which penalises pharmaceutical research.

…

(9) 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 15 years of exclusivity ***from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community****.*

(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. ***The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product****.'*

12 Article 1 of the SPC Regulation provides the definition of 'product ' and 'medicinal product':

For the purposes of this Regulation, the following definitions shall apply:

*(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) ....

(d) ....

(e) ....

13 Article 2 of the SPC Regulation defines the scope of the regulation (emphasis added) and reads:

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 of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use *or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products* ***may, under the terms and conditions provided for in this Regulation, be the subject of a certificate****.*

14 Article 3 of the SPC Regulation which defines the conditions for obtaining a certificate (emphasis added) reads 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 if that application****:*
>
> *(a) the product is protected by a basic patent in force;*
>
> ***(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;***
>
> *(c) the product has not already been the subject of a certificate;*
>
> *(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product*

The Medicinal Products Directive – Directive 2001/83/EC[3,4]

15 The Medicinal Products Directive has undergone a number of amendments since it came into force[5]. The references to Articles and other parts of the Directive below are to the version of the Directive that was in force when the SPC application in question in this case was made in December 2010[6].

16 Directive 2001/83/EC, as amended, relating to medicinal products, in its preamble and recitals states that (my emphasis added in bold):

> *(2)* ***The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health****.*

It then goes on in the recitals to provide the following explanation about the purpose of the authorisation procedure (my emphasis added in bold):

> *(7) The concepts of* ***harmfulness*** *and* ***therapeutic efficacy*** *can only be examined in relation to each other and have only a relative significance depending on the progress of scientific knowledge and the use for which the medicinal product is intended.* ***The particulars and documents which must accompany an application for marketing authorization for a medicinal***

[3] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Also referred to as MPD or MedProdDir or Dir 2001/83/EC.

[4] Directive 2001/83/EC updates and replaces original Council Directive 65/65/EEC of 26 January 1965 which was the first directive to deal with such medicinal products and is also the directive referred to in Council Regulation EEC/1768/92 which has been codified and superseded by Council Regulation EC/469/2009.

[5] See full entry for Directive 2001/83/EC on EurLex European legislation website at http://eur-lex.europa.eu/Result.do?T1=V1&T2=2001&T3=83&RechType=RECH_naturel&Submit=Search

[6] See consolidated version of Directive 2001/83/EC on EurLex European legislation website at http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02001L0083-20091005&qid=1404139679811&from=EN

product demonstrate that potential risks are outweighed by the therapeutic efficacy of the product*.*

17 Article 1 of Title I of this Directive provides the following definitions (my emphasis added in bold):

> 2. Medicinal product*:*
>
> *(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or*
>
> ***(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.***
>
> 3. Substance*:*
>
> *Any matter irrespective of origin which may be:*
>
> *— human, e.g.*
>
> *human blood and human blood products;*
>
> *— animal, e.g.*
>
> *micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;*
>
> *— vegetable, e.g.*
>
> *micro-organisms, plants, parts of plants, vegetable secretions, extracts;*
>
> *— chemical, e.g.*
>
> *elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.*
>
> **3a. Active substance**:
> ***Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions*** *or to make a medical diagnosis.*

18 Title III of this Directive concerns placing medicinal products on the market and includes Articles 6-39; Chapter 1 of this Title is entitled ‘Marketing Authorization’ and includes Articles 6-12. Article 6 reads (emphasis added in bold):

> ***No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive*** *or an authorisation has been granted in accordance with Regulation (EC) No 726/2004,.....*

19 Article 8 reads (emphasis added in bold):

> *1. In order to obtain an authorization to place a medicinal product on the market regardless of the procedure established by Regulation (EEC) No 2309/93,* ***an application shall be made to the competent authority of the Member State concerned****.*

2. A marketing authorization may only be granted to an applicant established in the Community.

3. The application shall be accompanied by the following particulars and documents, submitted in accordance with Annex I:

(a) Name or corporate name and permanent address of the applicant and, where applicable, of the manufacturer.

(b) Name of the medicinal product.

(c) Qualitative and quantitative particulars of all the constituents of the medicinal product, including the reference to its international non-proprietary name (INN) recommended by the WHO, where an INN for the medicinal product exists, or a reference to the relevant chemical name.

(ca) Evaluation of the potential environmental risks posed by the medicinal product. This impact shall be assessed and, on a case-by-case basis, specific arrangements to limit it shall be envisaged.

(d) Description of the manufacturing method.

(e) Therapeutic indications, contra-indications and adverse reactions.

(f) Posology, pharmaceutical form, method and route of administration and expected shelf life.

(g) Reasons for any precautionary and safety measures to be taken for the storage of the medicinal product, its administration to patients and for the disposal of waste products, together with an indication of potential risks presented by the medicinal product for the environment.

(h) Description of the control methods employed by the manufacturer.

(i) Results of:

- *— pharmaceutical (physico-chemical, biological or microbiological) tests,*
- *— pre-clinical (toxicological and pharmacological) tests,*
- *— clinical trials.*

(ia) A detailed description of the pharmacovigilance and, where appropriate, of the risk-management system which the applicant will introduce.

(ib) A statement to the effect that clinical trials carried out outside the European Union meet the ethical requirements of Directive 2001/20/EC.

(j) A summary, in accordance with Article 11, of the product characteristics, a mock-up of the outer packaging, containing the details provided for in Article 54, and of the immediate packaging of the medicinal product, containing the details provided for in Article 55, together with a package leaflet in accordance with Article 59.

(k) A document showing that the manufacturer is authorised in his own country to produce medicinal products.

(l) Copies of any authorisation obtained in another Member State or in a third country to place the medicinal product on the market, together with a list of those Member States in which an application for authorisation submitted in accordance with this Directive is under examination. Copies of the summary of the product characteristics proposed by the applicant in accordance with Article 11 or approved by the competent authorities of the Member State in accordance with Article 21. Copies of the package leaflet proposed in accordance with Article 59 or approved by the competent authorities of the Member State in accordance with Article 61. Details of any decision to refuse authorization, whether in the Community or in a third country, and the reasons for such a decision. This information shall be updated on a regular basis.

(m) A copy of any designation of the medicinal product as an orphan medicinal product under Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (..), accompanied by a copy of the relevant Agency opinion.

(n) Proof that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

The documents and information concerning the results of the pharmaceutical and pre-clinical tests and the clinical trials referred to in point (i) of the first subparagraph shall be accompanied by detailed summaries in accordance with Article 12.

The Medical Devices Directive - Directive 93/42/EEC[7]

Relevant Articles from Directive 93/42/EEC

20 The Medical Devices Directive has undergone a number of amendments since it first came into force[7]. The references below to Articles and other parts of the Medical Devices Directive are to the form of the Directive that was in force when the SPC application in question in this case was applied for in December 2010[8].

21 Directive 93/42/EEC, as amended relating to medicinal devices in general[9], in its preamble and recitals identifies its essential objective thus:

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[7] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices – see full entry for this directive on EurLex European legislation website at http://eur-lex.europa.eu/Notice.do?val=294514:cs&lang=en&list=335843:cs,329393:cs,329392:cs,317994:cs,294514:cs,293822:cs,&pos=5&page=1&nbl=6&pgs=10&hwords=). Also referred to as MDD or MedDevDir or Dir 93/42/EC.

[8] See consolidated version of Directive 93/42/EC on EurLex European legislation website at http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:01993L0042-20071011&qid=1404140170771&from=EN.

[9] There are three directives which concern themselves with Medical Devices and which are often referred to together in the various guidance and discussion documents regarding the borderline between the authorisation process for medicinal products and that for medical devices. In addition to

"Whereas medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive;"

22 The Medical Devices Directive then goes on to outline the relationship between it and the Medicinal Products Directive as follows (emphasis added in bold):

" *Whereas certain medical devices are intended to administer medicinal products within the meaning of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products;*

whereas, in such cases, the placing on the market of the medical device as a general rule is governed by the present Directive and the placing on the market of the medicinal product is governed by Directive 65/65/EEC;

whereas if, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral unit which is intended exclusively for use in the given combination and which is not reusable, that single-unit product shall be governed by Directive 65/65/EEC;

whereas a distinction must be drawn between the above mentioned devices and medical devices incorporating, inter alia, substances which, if used separately, may be considered to be a medicinal substance within the meaning of Directive 65/65/EEC;

whereas in such cases, if the substances incorporated in the medical devices are liable to act upon the body with action ancillary to that of the device, the placing of the devices on the market is governed by this Directive;

whereas, in this context, the safety, quality and usefulness of the substances must be verified by analogy with the appropriate methods specified in Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products*;"*

The references to Directive 65/65/EEC in the extract above should be read as references to Directive 2001/83/EC[10]. Similarly, the reference to Directive 75/318/EEC in this extract should also be read as a reference to Directive 2001/83/EC[10.] At the time when the SPC application in question was made, Directives 65/65/EEC and Directive 75/318/EEC had been replaced by Directive

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Council Directive 93/42/EEC (MDD) referred to in footnote 7 above, the other two medical devices directives are: (i) *Council Directive 90/385/EEC of 20 June 1990 relating to active implantable medical devices (AIMDD)* (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0385:20071011:EN:PDF); and (ii) *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices (IVDMDD)* (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20090807:EN:PDF).

[10] Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products, are among the ten directives which were codified into a single text in Directive 2001/83/EC (see also footnotes 3-6 above)

2001/83/EC. Thus, all references to these two older directives in the following paragraphs, including extracts from the relevant EU legislation should be read as a reference to Directive 2001/83/EC.

23 The recitals to Directive 93/42/EEC indicate that a clinical investigation may be necessary to establish compliance with the requirements of the directive (emphasis added in bold) by stating:

> *Whereas* ***the confirmation of compliance with the essential requirements may mean that clinical investigations have to be carried out under the responsibility of the manufacturer****; whereas, for the purpose of carrying out the clinical investigations, appropriate means have to be specified for the protection of public health and public order;*

24 In addition these recitals also make clear the basis on which medical devices should be classified:

> *Whereas it is necessary, essentially for the purpose of the conformity assessment procedures, to group the devices into four product classes;* ***whereas the classification rules are based on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices****; whereas the conformity assessment procedures for Class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products; whereas, for Class IIa devices, the intervention of a notified body should be compulsory at the production stage;* ***whereas, for devices falling within Classes IIb and III which constitute a high risk potential, inspection by a notified body is required with regard to the design and manufacture of the devices; whereas Class III is set aside for the most critical devices for which explicit prior authorization with regard to conformity is required for them to be placed on the market;***

25 Article 1(2)(a) and (k) of Directive 93/42/EEC define a 'medical device' and 'clinical data' in the following manner:

> *(a)* ***'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination****, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application,* ***intended by the manufacturer to be used for human beings for the purpose of****:*
>
> *—* ***diagnosis, prevention, monitoring, treatment or alleviation of disease****,*
> *— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
> *— investigation, replacement or modification of the anatomy or of a physiological process,*
> *— control of conception*
> ***and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means****;*

.....

(k) 'clinical data' means the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from:

— clinical investigation(s) of the device concerned, or
— clinical investigation(s) or other studies reported in the scientific literature,
of a similar device for which equivalence to the device in question can be demonstrated, or
— published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;
.....

26 Article 1, in parts 3, 4, 4a and 5(c), then goes on to define the scope of the Medical Devices Directive as follows (emphasis added in bold):

3. Where a device is intended to administer a medicinal product within the meaning of Article 1 of Directive 2001/83/EC that device shall be governed by this Directive, without prejudice to the provisions of Directive 2001/83/EC with regard to the medicinal product. If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by Directive 2001/83/EC. The relevant essential requirements of Annex I to this Directive shall apply as far as safety and performance-related device features are concerned.

4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, that device shall be assessed and authorized in accordance with this Directive.

4a. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of Article 1 of Directive 2001/83/EC and which is liable to act upon the human body with action ancillary to that of the device, hereinafter referred to as a 'human blood derivative', that device shall be assessed and authorised in accordance with this Directive.

5. ***This Directive shall not apply to:***
(a) ...;
(b) ...;
(c) medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that Directive or this Directive, particular account shall be taken of the principal mode of action of the product;
(d) ...."

27 Article 3, entitled 'Essential Requirements,' states in the first sub-paragraph that (emphasis added in bold):

"*The devices must meet the essential requirements set out in Annex I which apply to them,* ***taking account of the intended purpose of the devices concerned."***

28 Article 9, entitled 'Classification', reads as follows (emphasis added in bold):

> *"****1. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX****.*
>
> *2. In the event of a dispute between the manufacturer and the notified body concerned, resulting from the application of the classification rules, the matter shall be referred for decision to the competent authority to which the notified body is subject.*
>
> *3. Where a Member State considers that the classification rules set out in Annex IX require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Article 10, it may submit a duly substantiated request to the Commission and ask it to take the necessary measures for adaptation of classification rules. The measures designed to amend non-essential elements of this Directive relating to adaptation of classification rules shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3)."*

29 Article 11, entitled 'Conformity Assessment Procedures', is also relevant for the purposes of this case. Article 11(1)(a), 11(1)(b), and 11(9) in particular state as follows (emphasis added in bold):

> ***"1. In the case of devices falling within Class III, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:***
>
> ***(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); or***
>
> *(b) follow the procedure relating to the EC type-examination set out in Annex III, coupled with:*
>
> *(i) the procedure relating to the EC verification set out in Annex IV;*
> *or*
> *(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance).*
>
> *.....*
>
> *9. Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorized representative established in the Community, may apply to a body of his choice within the framework of the tasks for which the body has been notified."*
>
> *.....*

30 Article 15, entitled 'Clinical Investigation', states that (emphasis added in bold):

> *1. In the case of devices intended for clinical investigations, the manufacturer or the authorised representative, established in the Community, shall follow the procedure referred to in Annex VIII and notify the competent authorities of the*

Member States in which the investigations are to be conducted by means of the statement mentioned in Section 2.2 of Annex VIII.

2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy.

Member States may however authorise manufacturers to commence the relevant clinical investigations before the expiry of the period of 60 days, insofar as the relevant ethics committee has issued a favourable opinion on the programme of investigation in question, including its review of the clinical investigation plan.

3. In the case of devices other than those referred to in paragraph 2, Member States may authorise manufacturers to commence clinical investigations immediately after the date of notification, provided that the ethics committee concerned has issued a favourable opinion on the programme of investigation in question including its review of the clinical investigation plan.

4. The authorization referred to in paragraph 2 second subparagraph and paragraph 3, may be made subject to authorization from the competent authority.

5. ***The clinical investigations must be conducted in accordance with the provisions of Annex X.*** *The measures designed to amend non-essential elements of this Directive, inter alia by supplementing it, relating to the provisions on clinical investigation in Annex X shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).*

6. The Member States shall, if necessary, take the appropriate steps to ensure public health and public policy. Where a clinical investigation is refused or halted by a Member State, that Member State shall communicate its decision and the grounds therefor to all Member States and the Commission. Where a Member State has called for a significant modification or temporary interruption of a clinical investigation, that Member State shall inform the Member States concerned about its actions and the grounds for the actions taken.

7. The manufacturer or his authorised representative shall notify the competent authorities of the Member States concerned of the end of the clinical investigation, with a justification in case of early termination. In the case of early termination of the clinical investigation on safety grounds this notification shall be communicated to all Member States and the Commission. The manufacturer or his authorised representative shall keep the report referred to in Section 2.3.7 of Annex X at the disposal of the competent authorities.

8. .....

31 Article 17, entitled ‘CE marking’, states that devices that meet the essential requirements under this directive must have the CE marking when they are placed on the market in the community (emphasis added in bold):

> ***1. Devices**, other than devices which are custom-made or intended for clinical investigations, **considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market.***
>
> ***2. The CE marking of conformity, as shown in Annex XII, must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use. Where applicable, the CE marking must also appear on the sales packaging.***
>
> ***It shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes II, IV, V and VI.***
>
> *3. It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking. Any other mark may be affixed to the device, to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not thereby reduced.*

32 This Directive also comprises a number of Annexes (12 in total) which provide greater detail on how the various procedures covered by the Medical Devices Directive work. Of these 12, five are relevant to the present case, Annexes I, II, III, IX and X.

Annex I of Directive 93/42/EEC

33 Annex I entitled “EC Declaration of Conformity (Full Quality Assurance)” describes in detail the essential requirements that devices must meet (see Article 3 of the Directive) in order to qualify for the CE marking and, as a result, for free movement within the Community.

34 Sections 1-6a of Annex I, under Part I, entitled ‘General Requirements', read as follows (emphasis added):

> *1. **The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.***
>
> *This shall include:*
>
> *— reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and*
>
> *— consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).*

2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- *— eliminate or reduce risks as far as possible (inherently safe design and construction),*
- *— where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,*
- *— inform users of the residual risks due to any shortcomings of the protection measures adopted.*

3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.

4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

***6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex** X.*

35 Section 7 of Annex I, entitled ‘Chemical, Physical and Biological properties’, in part II of this Annex under the title ‘Requirements regarding Design & Construction’ reads as follows (emphasis added in bold):

7.1. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the ‘General requirements’. Particular attention must be paid to:

- ***— the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,***
- ***— the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device,***
- ***— where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.***

7.2. The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.

7.3. The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; *if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.*

7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure

that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.

When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.

If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

Annex II of Directive 93/42/EEC

36 Annex II, entitled "EC Declaration of Conformity (Full Quality Assurance System)" describes the first of the EC Declaration of Conformity procedures which can be used to show that the device meets the requirements of Directive 93/42/EEC. The manufacturer needs to put in place a full quality assurance system to meet the requirements under this directive for a class III medical device (see Article 11(1)(a) above). Sections 1 and 2 of Annex II read as follows (emphasis added in bold):

*"**1. The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the products concerned, as specified in Section 3** and is subject to audit as laid down in Sections 3.3 and 4 and to Community surveillance as specified in Section 5.*

*2. **The EC declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and***

declares that the products concerned meet the provisions of this Directive which apply to them.

The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer."

37 Section 3 of Annex II is entitled 'Quality System' and, at section 3.1, it states that (emphasis added in bold):

"***The manufacturer must lodge an application for assessment of his quality system with a notified body***.

...."

and then goes on to list, in detail, all the elements that must be included in such an application and all documentation that the system needs to be able to collect and provide for subsequent inspection and verification.

38 Section 4 of Annex II is entitled 'Examination of the design of the product' and, at Sections 4.1-4.3, it states that (emphasis added in bold and underlined):

"4.1. In addition to the obligations imposed by Section 3, the manufacturer must lodge with the notified body an application for examination of the design dossier relating to the product which he plans to manufacture and which falls into the category referred to in Section 3.1.

4.2. The application must describe the design, manufacture and performances of the product in question. It must include the documents needed to assess whether the product conforms to the requirements of this Directive, as referred to in Section 3.2(c).

4.3. ***The notified body must examine the application and, if the product conforms to the relevant provisions of this Directive, issue the application with an EC design-examination certificate****. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of the Directive. The certificate must contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the product.*

In the case of devices referred to in Annex I, Section 7.4, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive.

Annex III of Directive 93/42/EEC

39 Annex III describes the EC Type-Examination procedure, which, as Part 1 of this Annex indicates, '*is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of this Directive*.' As noted, the procedure is carried out by Notified Bodies[11].

40 The EC Type-Examination procedure leads to the issue of an EC Design Examination Certificate (as referred to in Section 4.3 of Annex II (see above).

Annex IX of Directive 93/42/EEC

41 Annex IX, entitled 'Classification Criteria', outlines the rules to be used to decide what classification class your medical device falls into, i.e., class I, IIa, IIb, or III. The conformity assessment procedure that has to be followed by the manufacturer depends on which of these classes the device under consideration falls into.

42 Chapter I of this Annex is entitled 'Definitions' and sections 1.2 and 1.8 of this chapter defines 'Invasive Devices' and 'Central nervous system' as follows:

"1.2. Invasive devices

Invasive device*:*
A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

Body orifice*:*
Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

Surgically invasive device

[11] The conformity assessment procedure such as that described in Annex III is carried out by a **notified body** – as defined in Article 16 and Annex XI of Directive 93/42/EEC. Any organisation that meets the requirements laid down can be designated as a notified body by a Member State. The manufacturer can select which notified body they want to use based on the tasks relating to procedures under Article 11 of the Directive that the notified body has been designated for. The notified body carries out a technical assessment of the all the material submitted by the manufacturer to demonstrate that their device conforms to the requirements of this directive. If this technical assessment is favourable, the manufacturer can attach the CE mark to his device and place it on the market. In this instance, the notified body was MEDCERT from Germany.

An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.
For the purposes of this Directive devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

Implantable device:
Any device which is intended:
— to be totally introduced into the human body or,
— to replace an epithelial surface or the surface of the eye,
by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

.....

1.8. Central nervous system:
For the purposes of this Directive, 'central nervous system' means brain, meninges and spinal cord.

43 Chapter II of this Annex is entitled 'Implementing Rules' and Rules 2.1, 2.4 and 2.5 which are relevant to the present case, read as follows:

"2.1. Application of the classification rules shall be governed by the intended purpose of the devices.

2.2. .....
2.3. .....

2.4. If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.

2.5. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply."

44 Chapter III of this Annex is entitled 'Classification' and Section 2 of this chapter which includes Rules 5-8 deals with 'Invasive Devices'. Rule 8 reads as follows

*"**8. All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended**:*

— *to be placed in the teeth, in which case they are in Class IIa,*

— ***to be used in direct contact with the** heart, the central circulatory system or **the central nervous system, in which case they are in Class III**,*

— *to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III,*

— *or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III."*

Annex X of Directive 93/42/EEC

45 Annex X, entitled 'Clinical Evaluation', is concerned with how to decide if the characteristics and performances referred to in Sections 1 and 3 of Annex I are met (see above).

46 Section 1 of Annex X is entitled "General Provisions" and indicates the circumstances under which clinical evaluation of the device is necessary (emphasis added in bold and underlined):

1.1. ***As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I, under the normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 6 of Annex I, must be based on clinical data.*** *The evaluation of this data, hereinafter referred to as 'clinical evaluation', where appropriate taking account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on:*

1.1.1. Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where:

— *there is demonstration of equivalence of the device to the device to which the data relates, and*
— *the data adequately demonstrate compliance with the relevant essential requirements.*

1.1.2. ***Or a critical evaluation of the results of all clinical investigations made****.*

1.1.3. Or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2.

1.1a In the case of implantable devices and devices in Class III clinical investigations <u>shall</u> be performed unless it is duly justified to rely on existing clinical data.

1.1b The clinical evaluation and its outcome shall be documented. This documentation shall be included and/or fully referenced in the technical documentation of the device.

(.....)

47 Section 2 of Annex X entitled "Clinical Investigations" indicates that the overall purpose of clinical evaluation referred to in Section 1.1. Section 2.1 entitled "*Objectives"* reads as follows (emphasis added in bold):

> *The objectives of clinical investigation are:*
>
> — *to verify that, under normal conditions of use, the performance of the devices conform to those referred to in Section 3 of Annex I, and*
>
> — *to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.*

Relevant Case Law

Court of Justice of the European Union (CJEU)

48 In *C-195/09, Synthon BV v Merz Pharma GmbH & Co KGaA,* hereafter *Synthon*, the Court of Justice of the European Union (hereafter CJEU) were considering whether or not a product could get an SPC when it had been on the market prior to obtaining an authorisation under Directive 65/65/EEC (now Directive 2001/83/EC). The CJEU said (my emphasis added in bold):

> *"39 As regards the context of Article 2 of Regulation No 1768/92, it is true, as Merz argues, that the reference in that provision to the 'protect[ion] by a patent in the territory of a Member State' could imply that the market referred to by that provision is the national market of the Member State in respect of which the SPC is applied for. That interpretation would, moreover, be consistent with the concept of an SPC as a national right.*
>
> *40 However, as the Advocate General has observed at point 39 of his Opinion, such an interpretation would mean that the conditions laid down for obtaining an SPC, listed in Article 3(a) and (b) of Regulation No 1768/92 – namely, that a product is protected by a basic patent in the Member State in which the application for an SPC was submitted and has obtained marketing authorisation as a medicinal product in that Member State in accordance with Directive 65/65 – would already be provided for in Article 2 of that regulation. It follows that Article 2 would simply replicate the content of Article 3(a) and (b) of the regulation. Such an interpretation would therefore deprive Article 2 of any raison d'être.*
>
> *41 Indeed, as is apparent from the respective headings of Articles 2 and 3 of Regulation No 1768/92, namely, 'Scope' and 'Conditions for obtaining [an SPC]', first,* ***Article 2 of that regulation seeks to determine in a general manner which products may be the subject of an SPC and, then, Article 3 sets out the conditions under which those products may be granted an SPC.***
>
> *42. Those considerations therefore militate against interpreting the word 'market' in Article 2 of Regulation No 1768/92 as referring to the market of a Member State. On the contrary, they imply that the Community market is being referred to.*

43 As regards, second, the administrative authorisation procedure to which the product, as a medicinal product, must be subject, as laid down in Directive 65/65, it follows from Article 3(b) of Regulation No 1768/92 and from Article 3 of Directive 65/65 that that procedure is the one referred to in Chapter II of that directive, for obtaining a marketing authorisation. That procedure includes testing the safety and efficacy of the medicinal product, the results of which must accompany the application for marketing authorisation, in accordance with Article 4(2) of Directive 65/65.

44 It follows from this that Article 2 of Regulation No 1768/92 must be interpreted as meaning that only a product which is protected by a valid patent in the territory of the Member State concerned and which obtained a marketing authorisation after being subject ***, prior to being placed on the market in the Community as a medicinal product, to an administrative authorisation procedure as laid down in Directive 65/65, which included safety and efficacy testing, could be the subject of an SPC****."*

49 In *C-322/10, Medeva BV v Comptroller General of Patents, Designs and Trade Marks,* hereafter *Medeva,* the CJEU were considering SPCs for combination vaccines and stated as follows (my emphasis added in bold):

"30 First, ***it must be noted that the fundamental objective of Regulation No 469/2009 is to ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement in public health*** *(see Farmitalia, paragraph 19, and AHP Manufacturing, paragraph 30).*

31. The reason given for the adoption of that regulation is the fact that the period of effective protection under the patent is insufficient to cover the investment put into pharmaceutical research and the regulation thus seeks to make up for that insufficiency by creating a SPC for medicinal products (see Case C-181/95 Biogen [1997] ECR I-357, paragraphs 26, and AHP Manufacturing, paragraph 30).

32. Moreover, as is apparent in particular from subparagraphs 4 and 5 of paragraph 28 of the explanatory memorandum, ***the protection conferred by a SPC is largely intended to cover the cost of research leading to the discovery of new 'products'****, that term being used as a common denominator covering the three different types of patent which can confer entitlement to a SPC. Further, if the conditions laid down in Regulation No 469/2009 are met, even a patent protecting the process by which a 'product' within the meaning of the regulation is obtained may, in accordance with Article 2 of the regulation, enable a SPC to be granted and, in that case, in accordance with Article 5 of the regulation and as stated at paragraph 44 of the explanatory memorandum, the SPC confers the same rights as conferred by the basic patent as regards the process by which the product is obtained, and, if the law applicable to that patent so provides, the protection of the process by which the product is obtained will be extended to the product thus obtained."*

50 In *C-422/10, Georgetown University and Others v Comptroller General of Patents, Designs and Trade Marks,* hereafter *Georgetown I,* another case about vaccines, the CJEU reaffirmed its statement on the fundamental objective of the SPC regulation made in *Medeva* (my emphasis added in bold):

> *"24 First, **it must be noted that the fundamental objective of Regulation No 469/2009 is to ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement in public healt**h (see Case C-392/97 Farmitalia [1999] ECR I-5553, paragraph 19, and Case C-482/07 AHP Manufacturing [2009] ECR I-7295, paragraph 30).*
>
> *25. The reason given for the adoption of that Regulation is the fact that the period of effective protection under the patent is insufficient to cover the investment put into pharmaceutical research and the regulation thus seeks to make up for that insufficiency by creating a SPC for medicinal products (see Case C-181/95 Biogen [1997] ECR I-357, paragraphs 26, and AHP Manufacturing, paragraph 30).*
>
> *26. Moreover, as is apparent in particular from subparagraphs 4 and 5 of paragraph 28 of the explanatory memorandum to the proposal for Council Regulation (EEC) of 11 April 1990 concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final) ('the explanatory memorandum'**), the protection conferred by a SPC is largely intended to cover the cost of research leading to the discovery of new 'products', that term being used as a common denominator covering the three different types of patent which can confer entitlement to a SPC**. Further, if the conditions laid down in Regulation No 469/2009 are met, even a patent protecting the process by which a 'product' within the meaning of the regulation is obtained may, in accordance with Article 2 of the regulation, enable a SPC to be granted and, in that case, in accordance with Article 5 of the regulation and as stated at paragraph 44 of the explanatory memorandum, the SPC confers the same rights as conferred by the basic patent as regards the process by which the product is obtained, and, if the law applicable to that patent so provides, the protection of the process by which the product is obtained will be extended to the product thus obtained (Case C-322/10 Medeva [2011] ECR I-0000, paragraph 32)."*

51 In *C-130/11, Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents, Designs and Trade Marks,* hereafter *Neurim,* the CJEU were considering whether or not a product could get an SPC based upon a Marketing Authorisation under Directive 2001/83/EC which concerns authorisation of medicinal products for human use when it already had a marketing authorisation under Directive 2001/82/EC which concerns the authorisation of veterinary products for animal use[12]. The CJEU stated (my emphasis added in bold):

> *20. As is apparent from the respective headings of Articles 2 and 3 of the SPC Regulation, namely, 'Scope' and 'Conditions for obtaining [an SPC]', first, **Article 2 of that regulation seeks to determine in a general manner which products may be the subject of an SPC and, then, Article 3 sets out the conditions under which those products may be granted an SPC (see Case C-195/09 Synthon [2011] ECR I-7011, paragraph 41).***

[12] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, see entry for this directive on EurLex legislation website at http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1406546983378&uri=CELEX:02001L0082-20090807

21 The first three conditions set out in Article 3 of the SPC Regulation for the grant of an SPC concern the relevant 'product' and require it to be protected by a basic patent in force, to have obtained a valid MA as a medicinal product, and to have not already been the subject of a certificate.

22. That being so, ***it must also be noted that the fundamental objective of the SPC Regulation is to ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement in public health (see Case C-322/10 Medeva [2011] ECR I-12051, paragraph 30 and the case-law cited, and Case C-422/10 Georgetown University and Others [2011] ECR I-12157, paragraph 24).***

23. The reason given for the adoption of the SPC Regulation is the fact that the period of effective protection under the patent is insufficient to cover the investment put into pharmaceutical research and the regulation thus sought to make up for that insufficiency by creating an SPC for medicinal products (see Medeva, paragraph 31, and Georgetown University and Others, paragraph 25).

24. It is apparent from paragraph 29 of the explanatory memorandum to the proposal for a Council Regulation (EEC) of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final), that, like a patent protecting a 'product' or a patent protecting a process by which a 'product' is obtained, a patent protecting a new application of a new or known product, such as that at issue in the main proceedings, may, in accordance with Article 2 of the SPC Regulation, enable an SPC to be granted and, in that case, in accordance with Article 5 of the regulation, the SPC confers the same rights as conferred by the basic patent as regards the new use of that product, within the limits laid down by Article 4 of that regulation (see, by analogy, Medeva, paragraph 32, and order of 25 November 2011 in Case C-630/10 University of Queensland and CSL, ECR I-12231, paragraph 38).

25. Therefore, if a patent protects a therapeutic application of a known active ingredient which has already been marketed as a medicinal product, for veterinary or human use, for other therapeutic indications, whether or not protected by an earlier patent, the placement on the market of a new medicinal product commercially exploiting the new therapeutic application of the same active ingredient, as protected by the new patent, may enable its proprietor to obtain an SPC, the scope of which, in any event, could cover, not the active ingredient, but only the new use of that product.

26. In such a situation, only the MA of the first medicinal product, comprising the product and authorised for a therapeutic use corresponding to that protected by the patent relied upon for the purposes of the application for the SPC, may be considered to be the first MA of 'that product' as a medicinal product exploiting that new use within the meaning of Article 3(d) of the SPC Regulation.

27. In the light of all the above considerations, the answer to the first and third questions is that Articles 3 and 4 of the SPC Regulation are to be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier MA obtained for a veterinary medicinal product does not preclude the grant of an SPC for a different

application of the same product for which an MA has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC.

Intellectual Property Office (IPO)

52 The recent IPO decision *Cerus Corporation (BL O/141/14)*[13]*,* hereafter '*Cerus'*, issued by this hearing officer acting for the Comptroller-General of Patents, Designs and Trade Marks*,* concerned two SPC applications where, in each case, an EC Design Examination Certificate issued for a class III medical device under the Medical Devices Directive was provided to meet the requirements under Article 3(b) of the SPC regulation.

53 EC Design Examination Certificate No. G7 02 05 16178 063 was filed in support of SPC application SPC/GB/07/043 for "*Platelet preparation obtainable by addition, and subsequent photoactivation, of amotosalen or its salt, to a suspension of platelets in plasma"* and EC Design Examination Certificate No. G7 06 09 60562 004 was filed in support of SPC application SPC/GB/07/044 for "*Platelet preparation obtainable by addition to plasma, and photoactivation, of amotosalen or its salt"*. These certificates related to medical devices that met the criteria of Article 1(4) of Directive 93/42/EEC because they each related to a device that incorporated, "*as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device*". As a consequence of the fact that it was necessary to verify the safety, quality and usefulness of the substance, which acts upon the body with action ancillary to that of the device, by analogy with the methods laid down in Directive 2001/83/EC, as part of the assessment of the device overall, the applicant in *Cerus* argued that both of these EC Design Examination Certificates, as a result, do meet the requirements of Article 3(b) of the SPC regulation, i.e. they represented a valid authorization to place on the market as a medicinal product, the product for which an SPC has been applied for.

54 I discuss the relevance of the *Cerus* decision and quote from my decision in this case in my analysis below.

Issues to be decided

55 There are two issues to be decided: (a) was the product, for which an SPC has been applied for, subject to an administrative authorisation procedure as set out in Article 2 of the SPC Regulation; and, consequently, (b) whether a valid authorisation under Article 3(b) has been provided in support of the product for which an SPC has been applied for. I will consider each of these issues in turn below.

[13] For a full text of the decision see http://www.ipo.gov.uk/pro-types/pro-patent/pro-p-os/p-challenge-decision-results-bl?BL_Number=O/141/14.

56 I also note in this regard that if I find that the application is considered not to meet the requirement under Article 2 of the SPC regulation, as is clear from the decisions of the CJEU in the *Synthon* and *Generics*[14] cases, the application fails and I do not then need to go on and consider if it meets the requirement of Article 3(b). However, if I find that the application does meet the prerequisite of Article 2, I will then need to go on to consider if it meets the requirement of Article 3(b).

57 It is appropriate at this point also to observe [as did this Hearing Officer in the *Cerus* decision] that the role of the IPO as the body responsible for granting SPCs in the UK (see Article 9 of the SPC Regulation) is to determine if the applications for SPCs received meet the requirements of the SPC regulation, in particular, Article 3. If so, an SPC shall be granted (see Article 10 of the SPC Regulation). The SPC is granted for a period, calculated using the algorithm outlined in Article 13, for a product that is covered by a patent and is the active ingredient (or combination of active ingredients) in a medicinal product which has been authorised for human use under Directive 2001/83/EC. The SPC is designed to compensate the applicant for the loss of the term of their patent while they have sought the necessary regulatory approval to place the medicinal product comprising this product on the market. The IPO is **not** involved in the regulatory processes that lead to the grant of a marketing authorisation for a medicinal product. The latter is the responsibility of the Medicines and Healthcare Products Regulatory Agency (MHRA) at the national level in the UK[15] and of the European Medicines Agency (EMA) at the Community wide level[16].

58 The analysis presented below is based on my consideration and comparison of Directive 2001/83/EC and Directive 93/42/EEC, in the versions that were in force when the application was made, and my consideration of all the correspondence regarding this case on file at the IPO.

Views of the Applicant and the Examiner

59 I will first provide a summary of the main points made in arguments presented by the applicant and the examiner before presenting my analysis and conclusions regarding the issue to be decided.

The Applicant's View

60 The applicant is seeking the grant of an SPC for the aqueous dispersion of iron oxide nanoparticles using the assessment procedure carried out for a class III medical device under Directive 93/42/EEC instead of a marketing authorisation granted under Directive 2001/83/EC. The applicant considers that a conformity assessment procedure which involves evaluation of the medicinal device using clinical trials to

[14] See *C-427/09, Generics(UK) Ltd v Synaptech Inc., judgment of CJEU issued 28 July 2011,* which like the *Synthon* (C-195/09) case also considers the scope of Article 2.

[15] See MHRA website at http://www.mhra.gov.uk/index.htm#page=DynamicListMedicines

[16] See EMA website at http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/Home_Page.jsp&mid=

show that the device meets the requirements of Directive 93/42/EEC, is equivalent to the clinical assessment of a medical product and the active ingredient (or combination of active ingredients) which is also based on clinical trials to show that the medicinal product meets the requirements of Directive 2001/83/EC.

61 The applicant's reasons for this view can be summarised as follows:

In relation to Article 2 of the SPC Regulation

a. A literal interpretation of Article 2 should not be taken. It is well established that European law should be interpreted purposively or teleologically. A narrow, i.e. literal interpretation of Article 2 of the SPC Regulation would contravene the fundamental objective of the SPC Regulation which is to ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement of public health (as set out in CJEU decisions *C-130/11, Neurim; Case C-322/10, Medeva*; and *Case C-422/10 Georgetown I*). This SPC application concerns a product which allows a novel therapy for the treatment of recurrent brain tumours. The period of effective protection by the patent is insufficient to cover the investment into pharmaceutical research and the SPC would make this up. The CJEU decision in *C-195/09, Synthon* should not be applied to this application because that decision concerned a product being placed on the market **before** it obtained a marketing authorisation. *Synthon* sets out, in paragraph 47 and head note 1, that it is the nature of the safety and efficacy testing which is important and not the exact procedure used to obtain the authorisation. Even if *Synthon* is considered to set out such a literal interpretation of Article 2 of the SPC Regulation then it has been overruled by *Neurim* which, in paragraph 22, puts emphasis on the overriding objective of the SPC Regulation to compensate for regulatory delay. Therefore, the SPC Regulation should not be interpreted in a manner to exclude any authorisation procedures not literally mentioned in Article 2 of the SPC Regulation. This is particularly so given the number of referrals to the CJEU on the SPC Regulation which demonstrate the lack of clarity and conciseness of the SPC Regulation. In his decision *GlaxoSmithKline Biologicals S.A. v Comptroller-General of Patents, Designs and Trade Marks* [2013] EWHC 619, Arnold J complained about the poor drafting of the SPC Regulation. This means that a purposive approach must be taken.

b. Article 2 sets out that the SPC Regulation covers any product that, prior to being placed on the market as a "medicinal product", is subject to an administrative authorisation procedure under Directive 2001/83/EC. The definition of "medicinal product" in Article 1(2)(b) of Directive 2001/83/EC includes:

> "***Any substance or combination of substances*** *which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by* ***exerting a pharmacological, immunological or metabolic actio****n, or to making a medical diagnosis." (my emphasis added in bold)*

However, the definition of "medicinal product" in Article 1(a) of the SPC Regulation does not refer to "*exerting a pharmacological, immunological or metabolic action*". Therefore, the definition in the SPC Regulation includes

substances which treat diseases by physical means, such as products within medical devices. In the applicants view, the nanoparticles, which are the subject of this SPC application, are used to destroy tumour cells in human beings or animals with a view to restoring physiological functions. The product is thus a "*medicinal product*" within Article 1(a) of the SPC Regulation and therefore within Article 2 of this regulation also.

c. The European Commission's view of 26 September 2008 (as set out in the note of the Third Meeting of National Supplementary Protection Certificate Experts held on 26 September 2008 and quoted by the examiner in his official examination report dated 27 March 2012) states that products subject to authorisations granted according to Directive 93/42/EEC may not be subject to an SPC. The Medicines and Healthcare Products Regulatory Agency (MHRA) opinion provided by the Examiner is that such authorisations are not a "*full assessment of quality, safety and efficacy*". The views of the Commission and MHRA have no legal basis and the Commission's view may have changed since 2008.

d. The wording of Article 2 of the SPC Regulation does not exclude products authorised by a different procedure. The procedure for getting an EC Design Examination Certificate under Directive 93/42/EEC is at least as comprehensive as getting one for veterinary products under Directive 2001/82/EC and is analogous to the procedures in Directive 2001/83/EC in light of the trials and documentation necessary. The applicant filed a Statutory Declaration, dated 8 July 2013, by Dr Jordan setting out the scope of the pre-clinical and clinical trials carried out on NanoTherm and showing that the requirements for obtaining authorisation under Directive 93/42/EEC are at least as onerous and therefore analogous to obtaining an authorisation under Directive 2001/83/EC. The scope and the quality, safety and usefulness of the medical device have been verified. Thus, the EC Design Examination Certificate filed in support of this SPC application is a 'full assessment of quality, safety and efficacy of the medicinal product'.

e. The authorisation procedure in Germany for certification under Directive 93/42/EEC is an administrative authorisation procedure within the meaning of Article 2 of the SPC Regulation. Directive 93/42/EEC provides in Article 16 (entitled 'Notified Bodies') for Member States to notify the Commission and other Members States of the bodies who will carry out the procedures that will lead to the issue of EC Design Examination Certificates. The Commission publishes, in the Official Journal of the European Union, a list of all such "notified bodies" which can amend and suspend EC Design Examination Certificates. MEDCERT was accredited by the Central Authority of the Laender[17] for Health Protection in Germany and is mentioned in the Commission's list of notified bodies in the Official Journal of the European Union dated 12 December 2013. The significance of this is that MEDCERT is a public authority under German law because the German Administrative Procedure Act provides that a public authority is one which performs an act of public administration. Therefore, the certification procedure under Directive

[17] i.e., German Regions. Germany has a Federal structure where each region or *Lande* (plural + *Laender*) is responsible for matters in its own territory.

93/42/EEC is analogous to the administrative authorisation procedure as laid down in Directive 2001/83/EC and Directive 2001/82/EC, which is mentioned in Article 2 of the SPC Regulation.

f. SPCs have already been granted by several Member States, including Great Britain (SPC application SPC/GB96/013), Germany (decision 14 Q (pat) 12/07 dated 26 January 2010), the Netherlands (decision *Genzyme Biosurgery Corp v Industrial Property Office (Netherlands)* dated 3 June 2004), Italy (SPC C-UB2007CCP983) and France (Certificates Complémentaires de Protection Nº 96 C 00 12 du 02 mai 1996 and Nº 96 C 00 13 du 02 mai 1996) on the basis of an authorisation under Directive 93/42/EEC. These Member States, including UK, at least until recently (i.e., current case and *Cerus*), are treating an authorisation under Directive 93/42/EEC as equivalent to a marketing authorisation granted under Directive 65/65/EEC (i.e., now Directive 2001/83/EC).

In relation to Article 3 of the SPC Regulation

g. Article 3(b) of the SPC Regulation should be interpreted teleologically particularly in light of *Neurim*.

h. Article 3(b) of the SPC Regulation provides that there must be a valid authorisation "*in accordance with Directive 2001/83/EC*". Synonyms for "in accordance with" are "analogously" and "correspondingly". Therefore Article 3(b) should be a read as follows: "(b) a valid authorisation to place the product on the market as a medicinal product has been granted **by analogy** with Directive 2001/83/EC..." Authorisations granted under Directive 93/42/EEC are granted by analogy with methods specified in Annex I of Directive 2001/83/EC.

The Examiner's view

62 The examiner considers that the SPC application is out of scope of the SPC Regulation as it does not relate to medicinal products subject to an "***administrative authorisation procedure as laid down in Directive 2001/83/EC*** *of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use*" as set out in Article 2 of the SPC Regulation.

63 In addition, the examiner considers that the SPC application does not comply with the conditions for obtaining a certificate because the authorisation filed in support of the application does not comply with Article 3(b) of the Regulation, which requires that the authorisation is "***granted in accordance with Directive 2001/83/EC*** *or Directive 2001/82/EC as appropriate*" (my emphasis).

64 The reasons for the examiner's view can be summarised as follows:

a. The examiner considers that this SPC application cannot be distinguished and should not be decided differently from the recent IPO decision in the case of. *Cerus* concluded that the tests that form part of the assessment of a class III medical device (this SPC application also concerns a Class III medical device) under Directive 93/42/EEC are designed to meet the requirements of that Directive and **do not** meet the requirements for the assessment of a medicinal

product under Directive 2001/83/EC where the medicinal product exercises its principal intended consequence by pharmacological, immunological or metabolic means.

In relation to Article 2 of the SPC Regulation:

b. It is not contrary to a purposive interpretation of the SPC Regulation to find that an SPC should be not be granted based upon this SPC application. Not all products that suffer a regulatory delay are considered worthy of an SPC. It is arguable that the present SPC application does not relate to pharmaceutical research and therefore the cases of *Neurim, Medeva* and *Georgetown I* are not relevant. Even if they are relevant then *Neurim* concerns a narrow set of circumstances concerning a new therapeutic application of an already authorised product.

c. Article 1(a) of the SPC Regulation merely defines "medicinal product". It does not determine which products should be granted an SPC. Article 4 makes it clear that SPC protection covers the product and not the medicinal product. Therefore, it is the definition of "product" in Article 1(b) which determines what is granted an SPC. If any substance within Article 1(a) could be granted an SPC then this could cover even those substances not subject to regulatory delay which would be against the purpose of the SPC Regulation.

d. The *Synthon* decision by the CJEU (*C-195/09*) is relevant to the issue about the procedure for getting the product onto the market. The case clearly sets out that Article 2 of the SPC Regulation prohibits SPCs for products placed on the market without "*first being subject to an administrative procedure as laid down in Directive 65/65 [now 2001/83/EEC] and, in particular, to safety and efficacy testing".* This SPC Application has not been subject to an authorisation procedure under Directive 2001/83/EC or safety and efficacy testing. There is nothing in *Synthon* to suggest that authorisation under a different Directive would be sufficient to meet the requirements of Article 2. The examiner has made reference to the general view of the MHRA who consider that a device subject to authorisation under Directive 93/42/EEC cannot also be considered a medicinal product, as set out in Article 2(2) of Directive 2001/83/EC. Different criteria appear to apply - an authorisation under Directive 2001/83/EC requires an assessment of efficacy but a scientific opinion as required by Annex I, section 7.5 of Directive 93/42/EEC does not. The statutory declaration dated 8 July 2013, by Dr Jordan does not propose the criteria which the regulator has used to judge them and so the examiner considered that the authorisation did not meet the requirements of Article 2 of the SPC Regulation.

e. The Commission has said that authorisations granted under Directive 93/42/EC cannot be the subject of an SPC (see page 15, Section VI, of the "Record of the Third Meeting of National "Supplementary Protection Certificate" (SPC) experts held on 26 September 2008). There is nothing to suggest that they have changed their opinion.

f. The status of the body which grants the authorisation is not instructive, instead it is the criteria which they use to grant authorisation which is important. MEDCERT would not appear to have the power to grant a medicinal product authorisation.

g. Earlier cases granted by the UK and other jurisdictions are persuasive rather than binding on this SPC Application.

Article 3 of the SPC Regulation

h. The MHRA said that an authorisation under Directive 93/42/EEC is not an authorisation under Directive 2001/83/EC and nor is it analogous because it is not based upon a "*full assessment of quality, safety and efficacy of the medicinal substance component or of the medicinal product in its entirety*". Therefore Article 3(b) is not met. MEDCERT has not had to refer to a competent authority for a scientific opinion as to the quality, safety and usefulness of the substance (Annex I, section 7.4 of Directive 93/42/EEC) and so the authorisation is not analogous.

Analysis

65 The issues raised in this case concern the interpretation of Article 2 and Article 3(b) of the SPC Regulation in the circumstance where an EC Design Examination Certificate pursuant to Directive 93/42/EEC has been filed in support of an SPC application.

66 On the face of it the answer to the question whether or not an approval gained for a medical device under Directive 93/42/EEC fulfils the necessary condition for the grant of an SPC has already been answered in the earlier IPO decision *Cerus* (*BL O/141/14*) as referred to above[13]. As the hearing officer in that case, I reviewed the SPC Regulation and the relevant parts of the Medical Devices Directive (Directive 93/42/EEC) and the Medicinal Products Directive (Directive 2001/83/EC) and took into account the purpose of each of these pieces of European Community legislation. I concluded that the assessment under Directive 93/42/EEC carried out in relation to a substance which acts upon the body with action ancillary to that of the device, is not the same as or equivalent to the process carried out to authorise a medicinal product for human use. Thus the assessment of the safety, quality and usefulness of this substance, when considered in light of the means by which the medical device delivers its action and considering the process by which a device is approved under the Medical Devices Directive, including the roles of notified bodies and competent bodies, means that the conformity assessment procedure for a class III medical device is not equivalent to the process carried out to authorise a medicinal product for human use under the Medicinal Products Directive.

67 The application before me now also concerns an EC Design Examination Certificate filed in support of an SPC application. However, I note that Directive 93/42/EEC was updated between the date when the SPC applications were filed in the *Cerus* case (9 August 2007) and the application was filed in this case (14 December 2010). The

latest amendments to the Medical Devices Directive took effect in October 2007[18]. The examiner sent the applicant a copy of the *Cerus* decision, along with the official examination report dated 2 April 2014, and explained that he did not "*find any substantive reasons why the present case should not be decided in accordance with the attached decision*", i.e. in accordance with the decision in *Cerus (BL O/141/14)*[13]. In response to that letter, the applicant did not address the examiner's views on the *Cerus* decision but merely requested a decision on the papers on file at the IPO in relation to this SPC application. In light of this request for a decision and their failure to provide a response to the question posed by the examiner, the applicant appears to be of the view that this SPC application (i.e., SPC application SPC/GB/10/051) should be treated differently from the two SPC applications discussed in the *Cerus* case. In light of this, I will consider whether or not there are substantive differences between this application and those before me in *Cerus*, and in doing so also consider if the amendments to Directive 93/42/EEC which have taken place in the interim make a difference. I will do so below as I consider the points which the applicant has raised in relation to Article 2 and Article 3(b) of the SPC regulation.

68 In relation to Article 2 and Article 3(b), the applicant has raised the general issue of the need for a teleological interpretation of the SPC Regulation. Such an interpretation is a well established principle of EU law and requires one to take into consideration the purpose and objectives of the relevant piece of EU legislation. However, as I have explained in some detail in the *Cerus* decision (see whole decision, but especially paras 61-63), to meet this requirement it is necessary to make an assessment of the purpose and objectives of the SPC Regulation and the relevant medical devices and medicinal products directives and then decide if the EC Design Examination Certificate can be deemed equivalent to a valid marketing authorisation under Directive 2001/83/EC. If, having done so, it is decided that it is not equivalent, then the SPC application will be outside the scope of the SPC Regulation under Article 2 which requires that, to qualify for an SPC, a product has to be the subject of an administrative authorisation procedure under Directive 2001/83/EC. The important factor in considering the EC Design Examination Certificates in *Cerus* was that they each related to a medical device that "*incorporates, as an integral part, **a substance which, if used separately, may be considered to be a medicinal product** within the meaning of Article 1 of Directive 65/65/EEC* [i.e., Directive 2001/83/EC] *and which is liable to act upon the body with action ancillary to that of the device, that device must be assessed and authorized in accordance with this Directive*" (my emphasis added). This is not the situation in the present case. Although the EC Design Certificate in this case is also a class III medical device, it does not incorporate, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Directive 2001/83/EC, in this case the medical device exerts its effect on the body by physical means (see discussion below).

69 The applicant has also referred to Arnold J's comments from his UK Patents Court decision in *GlaxoSmithKline Biologicals S.A. v Comptroller-General of Patents, Designs and Trade Marks* [2013] EWHC 619, where he observed:

[18] Directive 2007/47/EC of the European Parliament and the Council of 5 September 2007, amending Directive 93/42/EEC, took effect on 20th day after it was published in the Official Journal of the European Union on 21 September 2007, i.e. on 11 October 2007.

> *"Finally, I would observe that this is the third time in six months that I have had to refer questions of interpretation of the SPC Regulation to the CJEU. I do so with considerable regret. That this should be necessary demonstrates the dysfunctional state of the SPC system at present. This is primarily due to the poor drafting of the SPC Regulation and to the failure of the European Commission, Council and Parliament to revise it to address the problems which have emerged. Matters have not been assisted, however, by the fact that the Court of Justice's recent case law interpreting the SPC Regulation has not provided the level of clarity and consistency that is required."*

The applicant has suggested in the letter of 24 February 2014 that these comments of Arnold J mean that a *"literal interpretation of Articles 2 and 3(b) does not seem to be justifie*d". As I have already explained above, all EU law must be interpreted teleologically. Factors such as the number of referrals to the CJEU or concerns about the drafting of the SPC Regulation do not change this underlying principle. As a hearing officer dealing with this case, I have to apply the SPC Regulation in force at the date of the SPC application. I do not consider that Arnold J's comments dissuade me from a literal interpretation *per se*, but serve as a reminder that I should consider the text of the regulation and how it achieves the stated purpose(s) when deciding how to apply the regulation in a case such as this one.

70 I will consider the situation in relation to Article 2 first and then, if necessary, go on to consider the situation under Article 3(b).

Article 2 of the SPC Regulation

Teleological Approach

71 The applicants have suggested that the wording of Article 2 of the SPC Regulation does not mean that only products authorised by Directive 2001/83/EC and Directive 2001/82/EC can be subject to SPCs. As set out above, EU law must be interpreted teleologically and so I am unable to dismiss the applicant's suggestion on the basis of a literal interpretation of Article 2. I note that on this issue, the examiner and applicant discussed the relevance of the *Synthon* (*C-195/09)* case which related to a product that was sold in some member states without a marketing authorisation under Directive 2001/83/EC (or its predecessors), although it then went on to obtain such a marketing authorisation. This case turned on Article 2 of the SPC Regulation entitled "Scope" and whether or not an SPC application was in scope of this article even though the product in question had been on the market in the community before obtaining a marketing authorisation compliant with Directive 2001/83/EC. In its decision in *Synthon*, the CJEU stated "*Article 2 of that regulation seeks to determine in a general manner which products may be the subject of an SPC*" and also highlighted the need for "*safety and efficacy testing*" before an SPC can be granted.

72 However, I consider that in the *Synthon* case, different issues were being considered than those before me now. In the present case, there is no dispute that a marketing authorisation is needed. There is also no dispute that this case concerns a comparison of authorisation procedures under two different pieces of valid community legislation. The question is whether or not the EC Design Examination Certificate and the procedure for issuing it under Directive 93/42/EEC can come

within the scope of "*an administrative authorisation procedure as laid down in Directive 2001/83/EC*". The applicant has suggested that the subsequent decision in *Neurim* overrules that in *Synthon*. However, there is no indication that this is the view of the court in the *Neurim* judgment. The CJEU in paragraph 21 of *Neurim* even refers to the principles set out in the *Synthon* case. The CJEU in *Neurim,* taking a teleological approach, allowed for the grant of an SPC for the product melatonin based upon a marketing authorisation under Directive 2001/83/EC for a medicinal product which related to a completely different therapeutic use in the situation where melatonin had previously been authorised under Directive 2001/82/EC for veterinary use. Again, I think that this is a different issue from that before me now. I consider that the facts of this present case are, in fact, more similar to my previous decision on *Cerus.* As mentioned above, Directive 93/42/EEC was amended in October 2007 and thus the two SPC applications in *Cerus* were subject to different requirements than the SPC application which is the subject of this hearing. Therefore, I need to consider the relevance of Article 2 to the SPC application in this case in light of the amended version of Directive 93/42/EEC in force at the time that this SPC application was made and in light of the fact that the device product in this case is quite different to that in *Cerus,* albeit that the product in this application has been classified under the highest class (class III) of Directive 93/42/EEC (as was also the case for the two device products in *Cerus*).

Definition of medicinal product

73 The applicant has suggested that the differences in definition of "medicinal product" in Article 1(b) of the SPC Regulation and in Article 1(2) of Directive 2001/83/EC mean that the SPC Regulation includes substances which treat diseases by physical means (such as the subject of this SPC application). Article 2 of Directive 2001/83/EC explicitly includes substances that exert a pharmacological, immunological or metabolic action but the SPC Regulation does not. This issue was considered in detail in my decision on *Cerus* and, although this decision is based upon the later version of Directive 93/42/EEC[16], the definitions in each of the Directives have not changed. I concluded in paragraph 67 of *Cerus* by saying "*The definition of 'medicinal product' in the Medicinal Products Directive, Directive 2001/83/EC, differs slightly from that in the SPC regulation. However, I consider that there is no material difference between these definitions and that, for our purposes, they relate to the same thing. As Article 2 of the SPC regulation makes clear, if a medicinal product has been approved under Directive 2001/83/EC, it is eligible for protection under the SPC regulation."* I consider that this conclusion is also valid in the present case.

74 I note that the examiner has pointed out that Article 4 of the SPC Regulation makes clear that SPCs confer protection on the product and not the medicinal product. It is therefore the definition of product in Article 1(b) of the SPC Regulation which is relevant for determining the subject of the SPC. I also considered the definition of product in my decision on *Cerus* and considered that the differences were not material. Article 2 of the SPC Regulation clearly states that a medicinal product which has been approved under Directive 2001/83/EC is eligible for protection under the SPC Regulation.

Authorisation Procedure as laid down in Directive 2001/83/EC

75 There are different procedures for authorisation of medicinal products under Directive 2001/83/EC and for authorisation of medical devices under Directive 93/42/EEC. Directive 93/42/EEC provides a list in Article 1(5) of devices and products to which Directive 93/42/EEC does **not** apply (see above). This includes in Article 1(5)(c) "*medicinal products covered by Directive 2001/83/EC*". The amendments made in September 2007 to Directive 93/42/EEC and set out in recital 13 provide greater clarity to what is the borderline between this directive and Directive 2001/83/EC. It attaches clear importance to being able to establish whether or not a product falls under the definition of a medical device and then adds further clarification as to the key question to be answered to decide when a product falls under Directive 93/42/EEC and when it falls under Directive 2001/83/EC by stating:

> "*In deciding whether a product falls under that Directive [2001/83/EC] or this Directive [93/42/EC], particular account shall be taken of the principal mode of action of the product*".

This is an issue which I, as the hearing officer, considered in paragraph 88 in *Cerus*:

> *"In deciding which approval process or directive applies to a product that lies on the border between medicinal products and medical devices, the regulator has to make a decision, taking account of the manufacturer's intended purpose for the product, the way it is presented, and the method by which the principal mode of action is achieved. In the case of a medical device, the principal mode of action is usually by physical means (such as mechanical action, physical barrier, replacement of, or support to, organs or body functions). Medical devices can be assisted in their function by pharmacological, immunological or metabolic means but not if this is their principal mode of action. Thus, where a product achieves its principal intended action by pharmacological, immunological or metabolic means, it is a medicinal product."*

In *Cerus*, I was using the previous version of the Directive which did not include the second part of Article 1(5)(c) (see above). However, as explained in the *Cerus* decision, European Commission guidance did refer to the "*principal mode of action*", and the Medical Devices Directive has now been amended to include this feature in its text. In this case, the manufacturer and notified body, by utilising the procedure under Directive 93/42/EEC have clearly decided that the product for which they are applying for an SPC is a medical device. As such, the inevitable conclusion from this is that the product is a medical device that achieves its principal mode of action by physical means. In their letter of 18 September 2012, the applicant states "*The treatment of tumours with the product is effected by physical means. Therefore, the product is a medical device product*." Thus, I consider that it is clear that the product for which an SPC application has been applied for in this case is not within the authorisation procedures set down in Directive 2001/83/EC.

76 Medical devices authorised under Directive 93/42/EEC are subject to a classification system – under Article 9 and Annex IX of Directive 93/42/EEC (see above). The recitals to Directive 93/42/EEC explain that this is based on determining "*the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices*". There are four classes of devices and the conformity assessment procedures for each class vary in significance and requirements based on the greater vulnerability of the human body

arising from the manufacture and use of these devices. In this case the medical device is within Class III which is the classification set for the most critical devices that constitute a high risk potential and for which explicit prior authorisation with regard to conformity to the essential requirements of the Medical Devices Directive is required in order for them to be placed on the market. The iron oxide nanoparticles which are at issue in this case meet the definition of an 'implantable device' (see above) and would, in the normal course of events, be required to meet the requirements for a Class IIb medical device. However, because they fall within the second indent of rule 8 of Annex IX i.e. they are "*to be used in direct contact with the central nervous system",* this means that this device needs to meet the requirements for the highest class of medical device - Class III.

77 The applicant referred to the CJEU decisions in both *Medeva* (C-322/10) and *Georgetown I* (C-422/10) which reiterate that the fundamental objective of the SPC Regulation "*is to ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement in public health*". However, in this case, as the applicant has said, the treatment is affected by physical means – and this is reflected in the fact it is only within Class III because of its contact with the heart or central circulatory/nervous system. So it could be argued that it is not a pharmaceutical product at all and therefore not within the fundamental objective of the SPC Regulation. Similarly, products which act through physical means are not within the objectives of either of Directive 2001/83/EC or Directive 2001/82/EC[19] which are both concerned with pharmaceutical products that treat humans and animals respectively by 'pharmacological, immunological or metabolic means'.

Time taken to get authorisation

78 The applicant has said that the procedure for obtaining an EC Design Examination Certificate is at least as onerous as obtaining an authorisation for a veterinary product under Directive 2001/82/EC and thus analogous to the procedures in Directive 2001/83/EC. In support of this the applicant has filed a statutory declaration, dated 8 July 2013, by Dr Jordan which sets out the pre-clinical and clinical trials which the device product which is the subject of this SPC application has undergone. Paragraph 7 of that statutory declaration observes that the trials involving the iron-oxide nanoparticles have gone on for more than 11 years; that the period for trials for veterinary products under Directive 2001/82/EEC generally only go on for three to six years and that those for medicinal products under Directive 2001/83/EC/EEC go on for eight to nine years.

79 I appreciate that it can be time consuming to get an EC Design Examination Certificate, particularly in relation to a Class III medical device as in this case and in the applications applied for in *Cerus.* The recitals to the SPC Regulation specifically refer to the time taken to obtain an authorisation. Recital 4 says:

> *"At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal*

[19] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code related to veterinary medicinal products

product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research."

However, the SPC Regulation does not merely provide for **all** products which have to have an authorisation to be placed on the market in the community as being worthy of having an SPC. If this were the case then all patented goods and processes which need such an authorisation would be entitled to SPCs; this clearly was not the intention of the legislators. The SPC Regulation specifically mentions authorisation under Directive 2001/83/EC or Directive 2001/82/EC and therefore I cannot merely consider the length of time it takes to get an authorisation under Directive 93/42/EEC when considering if such an authorisation is equivalent for the purposes of Article 2 and Article 3(b).

Assessment of usefulness v efficacy

80 As I have already set out above, this product device has been assessed as a Class III device under Directive 93/42/EEC which is the class of device which requires the greatest degree of investigation and prior approval before being put on the market. The statutory declaration dated 8 July 2013 by Dr Jordan, mentioned above, sets out that in order to obtain the EC Design Examination Certificate under Directive 93/42/EEC pre-clinical and clinical trials *"covered a period of more than eleven years."* The agent in their letter of 12 July 2013 indicate that this shows that *"the requirements for obtaining EC Design Examination Certificate of the MEDCERT, in particular the safety and efficacy testing, are as onerous and thus analogous to the requirements to obtain an authorisation according to Directive 2001/83/EC*." However, as I set out in the *Cerus* decision there is a fundamental difference in the assessment carried out under Directives 93/42/EEC and Directive 2001/83/EC and that is related to whether or not the test is about **usefulness** or **efficacy**. The *Cerus* decision states, at paragraphs 92 and 93 , that:

*"92. I consider that the assessment of the safety, quality and usefulness of a device is NOT the same as the assessment of quality, safety and efficacy on a medicinal product. I consider that determining the usefulness of a device is not equivalent to determining the efficacy of a medicinal product. The former is focused on making sure that exposure to the physical elements of the device does not cause any problems for the user and that there are no unintended side effects arising from the normal use of the device. As Article 3 of the Medical Devices Directive makes clear the devices must meet the essential requirements laid down in the directive "*taking account of the intended purpose of the devices concerned*".*

*93. To me this is an overall question of degree. I do not consider that the acceptance by a notified body of an opinion from a competent body in relation to the assessment of a substance incorporated into a device under Directive 93/42/EEC is the same or can be considered to be equivalent to the authorisation granted under Directive 2001/83/EC by a competent body. I do not consider that the requirements to carry out the assessment "*by analogy with appropriate methods specified under Directive 75/318/EC (now Directive 2001/83/EC)*" is the same as carrying out the assessment of a medicinal product in accordance with Directive 2001/83/EC where its principal action is by pharmacological, immunological or metabolic means and is not ancillary. Article 3(b) of the SPC regulation makes clear that a valid authorisation is one that is granted "*in accordance with Directive 2001/83/EC*". While the overall approach or framework that the competent body may use in both cases is based on their experience of*

dealing with medicinal products, the assessment carried out for each is for a different objective and each assesses performance in a different way under the two systems."

81 Therefore, although it may take a long time and, may as the applicant argues be considered onerous to obtain an EC Design Examination Certificate, I do not think that the assessment criteria used is the same as under Directive 2001/83/EC, in part because the objectives of the systems for carrying out the respective assessments under each Directive are not the same given the differing uses of products and devices. I would also like to note here that I consider that the assessment of the purpose and objectives of the two systems that has led me to this conclusion, in this case and previously in the *Cerus* case, is, in my view, fully consistent with a teleological interpretation of the respective EU legislation.

82 Section 7.4 of Annex I of Directive 93/42/EEC (this section was amended between the date of the SPC applications in *Cerus* and the SPC application in this case) means that the opinion of a competent authority under Directive 726/2004[20], or of the European Medicines Agency (EMA), is required where a device incorporates, as an integral part, a product which if used separately may be considered as a medicinal product under Directive 2001/83/EC. In the case of *Cerus,* the authorisation process under Directive 93/42/EEC included a consultation with the competent body to answer the requirements of Annex I, Section 7.4, who then made an assessment in line with Directive 2001/83/EC. I note that the amendments to Directive 2001/83/EC since the applications in *Cerus* have expanded section 7.4 to include more detail on this process. However, this is not relevant in this case because the medical device at issue does not incorporate a substance which if used separately would be considered as a medicinal product under Directive 2001/83/EC. Therefore the competent authority was not consulted as part of the procedure to obtain authorisation under Directive 93/42/EEC for the iron oxide nano-particle device. This means that an assessment in line with Directive 2001/83/EC was not undertaken as part of the approval process for the device in the present case.

Views of the European Commission and MHRA

83 The European Commission have stated their view that SPCs cannot be granted based upon an authorisation under Directive 93/42/EEC. This was reported in the note of the Third Meeting of National Supplementary Protection Certificate Experts held on 26 September 2008 at the European Medicines Agency (EMA) in London (see page 15 at section VI) as follows:

> *"The representative of DG MARKT of the Commission emphasised that marketing authorisations granted according to Directive 90/383/CEE and Directive 93/42/EC (related to medical devices) cannot be eligible for the purposes of Regulation 1768/92 [*i.e. now codified and superceded by Regulation 469/2009*], notwithstanding the fact that these Directives, as well as Directive 65/65, were jointly repealed by Article 128 of Directive 2001/83/EC, as amended. Some MS might have wrongly, according to the representative of the*

[20] Regulation (EC) No 726/2004 of the European Parliament and the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency.

Commission, granted SPCs related to marketing authorisations granted under those Directives.

The Commission representative drew the attention of participants to the explanatory memorandum of the proposal for a Council Regulation (EEC) concerning the creation of an SPC for medicinal products presented by the European Commission (COM(90) 101 final – SYN 255) on 11 April 1990. In particular, paragraph 30 of this document reads: "It is specified that the authorisation concerned is that provided for in Directives 65/65/EEC and 81/85/EEC, thereby making it clear that the proposal applies only to medicinal products for human or veterinary use".

I appreciate that these views were expressed some time ago but there have been no reasons to suggest that the views of the Commission have changed.

84 The MHRA, the relevant competent body in the UK for authorisation of both medicinal products and medical devices has also given its view regarding the status of an authorisation granted under Directive 93/42/EEC as compared to that granted under 2001/83/EC. The MHRA view is as follows:

"The Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority for medicines and medical devices regulation in the UK. It is the MHRA's view that the Medicines Directive (2001/83/EC) provides a clear definition of a medicinal product and clearly sets out the requirements for a marketing authorisation for such a product. Where a medical device incorporates a drug substance with action ancillary to that of the device, then that product is still a medical device (regulated in accordance with Directive 93/42/EEC) and not a medicinal product. It is also MHRA's view that European Guidance and the relevant Directives, in particular Article 2(2) of the medicines Directive, are clear that there are not products which might be considered both medicinal products and medical devices since, in cases of doubt that Article says that the provisions of that Directive shall apply.

In accordance with Directive 93/42/EEC the MHRA, as a medicines competent authority, does carry out an evaluation, on request, on behalf of a Notified Body where a medicinal substance is to be incorporated into a medical device. Following its evaluation, the MHRA issues an opinion on the quality, safety and clinical benefit/risk profile of the incorporation of that substance into the device. That opinion, provided to the Notified Body, does not constitute a marketing authorisation and is not based on a full assessment of the quality, safety and efficacy of the medicinal substance component or of the medical device in its entirety. It is the responsibility of the Notified Body to take account of that opinion in deciding whether to issue its certification."

85 I note that the examiner also brought these views to the attention of the applicant during their correspondence on this application. The applicant has pointed out that the views of the European Commission and the MHRA have no legal basis. This is, of course, true but the views do represent the considered views of experts in the fields and thus I consider them very helpful in pointing out how the systems are supposed to work.

86 In the *Cerus* decision, the Hearing Officer considered the relevance of such views as well as the relevance of guidance issued by the European Commission (see paras

47 & 48 and 84 in *Cerus*)[21]. The European Commission guidance document entitled "*MEDICAL DEVICES: Guidance document - Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative"* deals specifically with the issue of deciding whether or not a product is to be dealt with under the Medical Devices Directive or under the Medicinal Products Directive.[22] This guideline has been developed by an expert group including experts from the Competent Authorities of the Member States and the European Commission, as well as industry trade associations. The current version of the guideline is MEDDEV 2.1/3 rev 3 and it became available in March 2010, i.e., within the time period that has elapsed between the filing of the SPC applications in the *Cerus* case (August 2007) and the filing of the SPC application in the present case (December 2010)[23].

87 As noted in *Cerus*, the guidance from the Commission itself makes clear in the foreword, that it is not legally binding and it is only the CJEU that can give an authoritative interpretation of Community law, such as the Directive on Medical Devices, but nevertheless the guidance is proposed as a means to ensure uniform application in the Member States. This MEDDEV guidance note points out the following under "General Principles[24]:

(i) in order to fall under the Medical Devices Directive (MDD), a product must fulfil two prerequisites – it must meet the definition of a medical device and it must also not be excluded from the scope of the MDD. In general a product is regulated either by the MDD or by the Medicinal Products Directive (MPD).

(ii) The conformity assessment procedure or the marketing authorization procedure to be followed prior to placing a given product on the market will therefore be governed **either** by the MDD or by the MPD. The procedures of both these Directives do **not** apply cumulatively.

(iii) In deciding whether a product falls under the MDD, **particular account shall be taken of the principal mode of action of the product**. Typically, the medical device function is achieved by physical means (including mechanical action, physical barrier, replacement of or support to organs or body functions ...).

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[21] The European Commission has produced a set of Guidelines relating to questions of the application of EC Directives on medical devices, referred to as MEDDEVs. The Guidance MEDDEVs are guidelines to promote a common approach by manufacturers and Notified Bodies involved in the conformity assessment procedures according to the relevant annexes of the Medical Devices Directives, and by the Competent Authorities charged with safeguarding Public Health. For a full list of the Guidance MEDDEVs see http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm.

[22] For the current version of this MEDDEV Guideline see http://ec.europa.eu/health/medical-devices/files/meddev/2_1_3_rev_3-12_2009_en.pdf; this document also refers to the earlier version of this MEDDEV Guideline.

[23] For the current version of this MEDDEV Guideline see http://ec.europa.eu/health/medical-devices/files/meddev/2_1_3_rev_3-12_2009_en.pdf; this document also refers to earlier versions of the MEDDEV Guideline. The current guidance applies from 21 March 2010.

[24] See Section A: entitled Borderline Products: Medcial Devices/medicinal Products – especpoaiily A.2 General principles and

(iv) The principal intended action of a medical device may be deduced from the scientific data regarding mechanism of action and the manufacturer's labelling and claims.

(v) Although the manufacturer's claims are important, it is not possible to place the product in one or other category in contradiction with current scientific data. Manufacturers may be required to justify scientifically their rationale for the qualification of their product.

(vi) Medical devices may be assisted in their function by pharmacological, immunological or metabolic means, but as soon as these means are not ancillary with respect to the principal intended action of a product, the product no longer fulfils the definition of a medical device. The claims made for a product, in accordance with its method of action may, in this context, represent an important factor for its qualification as a medical device.

(vii) The following definitions for pharmacological, immunological or metabolic means are intended only to provide guidance as to the meaning of these terms: **"**Pharmacological means**"** is understood as an interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-response correlation is indicative of a pharmacological effect; **"**Immunological means**"** is understood as an action in or on the body by stimulation and/or mobilisation of cells and/or products involved in a specific immune reaction; **"**Metabolic means**"** is understood as an action which involves an alteration**,** including stopping, starting or changing the speed of the normal chemical processes participating in, and available for, normal body function.

(viii) The fact that a product is, or is not, itself metabolised does not imply that it achieves, or does not achieve, its principal intended action by metabolic means.

The Guidance note provides a useful example to illustrate these general principles using bone cements: A Plain bone cement without antibiotics is a medical device because it achieves its principal intended action (the fixation of prosthesis) by physical means. Bone cements containing antibiotics, where the principal intended action remains fixation of prosthesis, are also medical devices. In this case the action of the antibiotic, which is to reduce the possibility of infection being introduced during surgery, is clearly ancillary. If however the principal intended action is to deliver the antibiotic, the product no longer fulfils the definition of a medical device.

88 I have referred to and summarised the general principles from this guidance because, I consider that it helps in confirming the best approach to be taken when trying to decide if the conformity assessment procedure for a medical device can be considered to be the same as, or equivalent to, the marketing authorisation procedure for a medicinal product for the purpose of applying Article 3(b) of the SPC regulation to grant an SPC. While I accept (as I did in *Cerus*) that this guidance is not legally binding, it does represent the clearest indication (in the absence of any such legal decision) of how the experts in the field of medical devices regulation consider these issues should be addressed. Also, in the absence of a decision from

the CJEU or from the UK courts on whether an authorisation under Directive 93/42/EEC can fulfil the requirements for the grant of an SPC under Article 2 and Article 3(b) of the SPC Regulation, I consider that it is appropriate to take into account the views of those public bodies at the European and/or national level that have responsibility for the regulation of medical devices, medicinal products and/or SPCs. As a consequence, I am of the opinion that the views of the Commission and MHRA mentioned above (and referred to by the examiner in his correspondence with the applicant) do provide additional support for my view that Article 2 of the SPC Regulation does not provide for SPCs where the authorisation is based on an EC Design Examination certificate issued under Directive 93/42/EEC, as in the present application

89 The approval procedure for a device and that for a medicinal product are indeed different and cannot be considered to be equivalent. In the situation such as the present case, when the device exercises its action by physical means and it does not relate to any of the scenarios described in Articles 1(3), 1(4), 1(4a) and 1(5) and in Section 7.4 of Annex I of the Medical Devices Directive which are also discussed in the above MEDDEV guidance note, then it appears to me that this is an even more straightforward conclusion than that in the case of the *Cerus* applications where the device, unlike in the present case, incorporated, as an integral part, a substance that, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device.

The status of the notified body - MEDCERT

90 Article 2 of the SPC Regulation refers to "*an administrative authorisation procedure as laid down in Directive 2001/83/EC*". The EC Design Examination Certificate in this case was issued by MEDCERT which is a notified body with an address in Germany (see Article 16 and Annex XI of Directive 93/42/EEC). Article 16(1) provides for "notified bodies" which are the bodies which the Member States notify the Commission as being designated for carrying out the procedures set out in Article 11 of the medical devices directive. This means that in accordance with Article 16(6) that the notified body can also suspend and withdraw an EC Design Examination Certificate. The Official Journal of the European Union dated 12 December 2003[25] (number C302/1) sets out which bodies are notified and for which products, procedures and Annexes under Directive 93/42/EEC. MEDCERT is notified for a wide range of products, procedures and Annexes as are other bodies in Germany (such as Dekra Certification Services GmbH). I note also that there are several notified bodies in the UK for differing ranges of products, procedures and annexes under this directive, including SGA (United Kingdom) Limited, Lloyd's Register Quality Assurance (LRQA) Ltd and the British Standards Institution (BSI).

91 The applicants has stated that because MEDCERT performs acts of public administration then they are a public authority under German law and so in Germany issuing an EC Design Examination Certificate under Directive 93/43/EEC is an "administrative authorisation procedure" under Article 2 of the SPC Regulation. However, I do not think that you can separate this phrase from the remaining part of

[25] Available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52003XC1212(04)&from=EN

it in Article 2 which goes on to say "as laid down in Directive 2001/83/EC". Thus what is important is that the product is subject to an "administrative authorisation procedure as laid down in Directive 2001/83/EC" and I think that this is an important part of Article 2; otherwise **all** administrative authorisation procedures could potentially form the basis for SPCs.

Experience in other jurisdictions & previous practice at the IPO

92 The applicants have referred to the fact that SPCs based upon a marketing authorisation granted under Directive 93/42/EEC have already been granted in several Member States, including previously by the Intellectual Property Office (IPO). As hearing officer in *Cerus* decision, I considered this issue in some detail (see paras 94-99) and concluded that:

> *"I do not find the fact that two SPCs were granted by the UK Intellectual Property Office 16 years ago based on approvals under Directive 93/42/EEC to be persuasive. As noted above these products were also the subject of litigation in the courts in Netherlands and in Germany and a consensus view was not achieved regarding whether SPCs had been validly granted in this case. The situation under which I am considering the present cases is very different to that that existed in 1998."*

I note that the SPC applications in question in *Cerus* were filed over 2 years before the SPC application in question in the present case and, as such, I do not think that this argument in relation to these older cases is any more relevant in this case than it was in *Cerus.*

Article 3 of the SPC Regulation

93 In light of the views I have set out above in relation to Article 2 of the SPC Regulation I do not need to consider the arguments put forward by the applicants as to whether or not the EC Design Examination Certificate and associated Declaration of Conformity is a valid authorisation for the purposes of Article 3(b). However, I think it may be useful if I indicate my thoughts on the issue raised in relation to Article 3.

94 The applicant has said that Article 3(b) should be interpreted teleologically. As I have said already above this is a general principle of EU law. The applicant considers that this means that, where Article 3(b) says that there must be a valid authorisation "*in accordance with*" Directive 2001/83/EC (or Directive 2001/82/EC) then synonyms for "*in accordance with*" can be used, including "*analogously*" or "*correspondingly*". I think that the overriding principle of EU law must be applied such that the whole Regulation is interpreted in a teleological manner. I do not think that this means that individual words can be exchanged for synonyms, it is necessary to look at the overall purpose and objective of the SPC regulation. As I have stated above the purpose of the SPC Regulation is to provide protection where the necessary authorisations have been obtained. Therefore, Article 3(b) must be considered as a whole so that the entire phrase is interpreted teleologically. As I have come to the view above that the product was not subject to an administrative procedure laid down in Directive 2001/83/EC (under Article 2), then I consider that this would also inevitably lead me to the view that the EC Design Examination Certificate and

associated Declaration of Conformity is not a valid authorisation for the purposes of Article 3(b).

Conclusion

95 Taking all of the above into account, I do not consider that the product for which an SPC has been applied for in this application, SPC/GB/10/051, has been subject to an administrative procedure as laid down in Directive 2001/83/EC, therefore the product is not eligible under Article 2 of the SPC Regulation to be the subject of an SPC certificate.

96 As a consequence, application SPC/GB/10/051 does not meet the requirements laid down in the SPC regulation and is rejected under Article 10(2) of the SPC Regulation.

Appeal

97 Any appeal must be lodged within 28 days.

Dr L Cullen
Deputy Director, acting for the Comptroller