Intellectual Property Office

BL O/466/15

06 October 2015

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

APPLICANT	Angiotech Pharmaceuticals Inc. and University of British Columbia
ISSUE	Whether applications SPC/GB/14/030 and SPC/GB/14/031 meet the requirements of Article 2 and Article 3(b) of the Regulation
HEARING OFFICER	Dr L Cullen

DECISION

Introduction

1 This decision relates to two supplementary protection certificate (SPC) applications identified as SPC/GB/14/030 and SPC/GB/14/031 which were filed by Forresters (the "agent") on 31 March 2014 on behalf of Angiotech Pharmaceuticals Inc. and University of British Columbia (the "applicants"). The product for which the SPC was applied for – as defined in box 6 of Form SP1 filed with each application was "Taxol®" for SPC/GB/14/030 and "Taxol®-eluting stent" for SPC/GB/14/031.

Background

2 The basic patent upon which both SPC applications are based is EP(UK)2226085 B1 entitled "*Anti-angiogenic compositions and methods of use*", which was filed on 9 July 1994, with a priority date of 19 July 1993 and was granted by the European Patent Office (EPO) on 27 November 2013. The expiry date of this patent was 18 July 2014.

3 The patent describes a composition including paclitaxel, which is more commonly referred to by its trade mark Taxol®, which inhibits the formation of new blood vessels and is used in a method for treating non-tumourigenic, angiogenesis-dependent disease[1]. The patent describes coating a coronary stent with a composition that includes Taxol® to prevent stenosis recurring, i.e. restenosis, in

[1] See para **[0043]** of the basic patent EP(UK) 2226085 B1 for details of non-tumourigenic, angiogenesis-dependent disease that can be treated.

vascular arteries and veins in addition to setting out the general use of Taxol® in anti-angiogenic compositions to treat cancer[2].

4 The document identified by the applicant as a Marketing Authorisation and supplied in support of both of the SPC applications (see sections 8 of Forms SP1) was EC Design Examination Certificate No. ID 60004045 0001, dated 21 January 2003. This EC Design Examination Certificate was issued by TÜV Rheinland Product Safety GmbH (hereafter TÜV) which identifies itself as accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG) and notified under No. 0197 to the EC Commission. TÜV is a notified body under the Medical Devices Directive (see below). This EC Design Examination Certificate confirms that the design of the medical device identified as "*Coronary Stent with Delivery system Products: see attachment"* fulfils the requirements of Annex II, Article 4, of Directive 93/42/EEC concerning Medical Devices. The attachment to the certificate lists different models of the Taxus Express Paclitaxel-Eluting Coronary Stent system with 8.8% paclitaxel (slow release formulation). The manufacturer of the medical device identified by this EC Design Certificate is Boston Scientific Ltd. (with an Irish address). The certificate states that its date of expiry is 20 January 2008.

5 The applicant provided more details of the EC Design certificates in force once the first authorisation expired in January 2008 after an official request on behalf of the Hearing Officer was sent by Litigation Section at the IPO asking the applicant to explain what authorisation was in force when the SPC applications were filed. The applicant provided copies and some further details of several more EC Design Examination Certificates granted under Directive 93/42/EEC by TÜV or by one of two notified bodies from the Netherlands, KEMA Quality BV or DEKRA Certifications BV. **Table 1** below summarises the relevant details of all the certificates. As can be seen from this table they all relate to different models of Taxol®-eluting stents and expire at various dates – the last of which expires on 15 December 2015.

6 In the correspondence on file, the applicant provides an explanation of how, what they refer to as a 'Taxol®-eluting stent' works. Paclitaxel has been available as a cancer medicine since 1993 and acts by blocking a stage of cell division in which the cell's internal "skeleton" is dismantled to allow the cell to divide. By keeping the structure intact the cells cannot divide and eventually they die. A detailed description of the authorisation process and uses of Taxol® is available from the European Medicines Agency (EMA).[3]

7 The two SPC applications in question concern the use of Taxol® for treating or preventing restenosis. As the applicant has set out in correspondence, the stent treats restenosis by physically keeping the blood vessel expanded and open. The Taxol® containing coating on the stent diffuses over time and prevents the formation of new blood vessels which would block the passageway in the blood vessel held open by the stent.

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[2] See paras **[0035]-[0042]** and Example 8 of the basic patent EP(UK) 2226085 B1for) for further details about use of anti-angiogenic compositions as coatings for stents in treatment of non-tumourigenic, angiogenesis-dependent disease

[3] It is available online at http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000778/human_med_000620.jsp&mid=WC0b01ac058001d124 .

Table 1: EC Design Certificates provided by applicant in support of UK SPC applications SPC/GB/14/030 and SPC/GB/14/031

#	EC Design Certificate registration Number	Report Number	Product	Identification	Notified body	Date of Grant	Date of Expiry
1.	ID 60004045 0001	21101422 003	Implant: Stent	***Scope:*** Coronary stent with delivery system	TUV (DE)	21.01.2003	21.01.2008
				TAXUS Express (RTM) Paclitaxel-eluting Coronary Stent System with 8.8% Paclitaxel (slow release formulation)			
2.	ID 60004632 0001	21109091 011	Implant: Stent	***Scope:*** Prosthesis: Internal, Stent, Drug Eluting, Cardiovascular. Catheter: Angioplasty, Balloon Dilation	TUV (DE)	24.03.2005	21.01.2008
				TAXUS Express (RTM) Paclitaxel-eluting Coronary Stent System with 8.8% Paclitaxel (slow release formulation)			
3.	ID 60012205 0001	21116468 006; 21116468 010	Implant: Stent	***Scope:*** Prosthesis: Internal, Stent, Drug Eluting, Cardiovascular. Catheter: Angioplasty, Balloon Dilation	TUV (DE)	08.09.2005	07.09.2010
				TAXUS Liberte Paclitaxel-eluting Coronary Stent System with 8.8% Paclitaxel (slow release formulation)			
4.	ID 60030021 0001	21139299 008	Implant: Stent	***Scope***: TAXUS Element Monorail Paclitaxel- eluting Coronary Stent System	TUV (DE)	10.05.2010	09.05.2015
5..	2124428DE05	n/a	Implant: Stent	***Scope***: TAXUS Liberte Paclitaxel Eluting Coronary Stent System	KEMA (NL)	28.05.2010	01.09.2013
6A.	3807055DE14	n/a	Implant: Stent	***Scope***: TAXUS Element MONORAIL (RTM) and Long MONORAIL Paclitaxel Eluting Coronary Stent System	DEKRA (NL)	02.08.2011	15.12.2015
6B.	3807055DE14	n/a	Implant: Stent	***Scope***: TAXUS Element MONORAIL (RTM) and Long MONORAIL Paclitaxel Eluting Coronary Stent System	DEKRA (NL)	29.06.2012	15.12.2015

8 There has been an extensive correspondence between the applicant and examiner concerning these SPC applications. 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") because the marketing authorisations filed in support of these SPC applications do not comply with the requirements of the SPC Regulation under:

(a) Article 2 because, before it was placed on the market as a medicinal product, it was not subject to an administrative authorisation procedure as laid down in Directive 2001/83/EC or Directive 2001/82/EC; and

(b) Article 3(b) in that a valid authorisation has not been granted in accordance with both aforementioned Directives.

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 these SPC applications, **is** equivalent to an authorisation to place the product (for which the SPCs have 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 and hence the requirements of the SPC regulation are met.

9 The applicant, in their letter dated 8 April 2015, requested that a decision be made based upon all the papers on file. My decision is outlined in the following paragraphs.

The Relevant Law and its interpretation

The SPC Regulation

10 When the SPC applications in question were 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 of 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[4,5]

15 The Medicinal Products Directive has undergone a number of amendments since it came into force[6]. An SPC can only be applied for when a valid marketing authorisation (MA) under this Directive and the basic patent have been granted. In this case, because such a long period of time has elapsed between the date that the first authorisation in the community was issued and the date that the basic patent was granted, and hence the date on which the applications for the SPCs could be made, I will consider both the version of this Directive that was in force on the date when relevant marketing authorisation was issued and the version of this Directive that was in force on the date that the applications for the SPCs were made. In my analysis below, I will then go on to consider which is the correct version of the Directive to apply in this case.

Version of Directive 2001/83/EC in force on date when SPC applications were made

16 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 applications in question in this case were made in March 2014[7].

17 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****.*

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[4] 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.

[5] 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.

[6] 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

[7] 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

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

18 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.*

19 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,.....

20 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.

Version of Directive 2001/83/EC in force on date when first Marketing Authorisation was granted

21 The version of the Medical Products Directive 2001/83/EC which was in force when the first marketing authorisation was granted on 20 January 2003 was the original version of Directive 2001/83/EC which came into effect on 18 December 2001.

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

2. Medicinal product: Any substance or combination of substances presented for treating or preventing disease in human beings.

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to

restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.

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.

23 Article 8 then read as follows:

"*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 in usual terminology, but excluding empirical chemical formulae, with mention of the international non-proprietary name recommended by the World Health Organization where such name exists.
(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) If applicable, 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 any potential risks presented by the medicinal product for the environment.
(h) Description of the control methods employed by the manufacturer (qualitative and quantitative analysis of the constituents and of the finished product, special tests, e.g. sterility tests, tests for the presence of pyrogenic substances, the presence of heavy metals, stability tests, biological and toxicity

tests, controls carried out at an intermediate stage of the manufacturing process).
(i) Results of:
- physico-chemical, biological or microbiological tests,
- toxicological and pharmacological tests,
- clinical trials.
(j) A summary, in accordance with Article 11, of the product characteristics, one or more specimens or mock-ups of the outer packaging and the immediate packaging of the medicinal product, together with a package leaflet.
(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."

The Medical Devices Directive - Directive 93/42/EEC[8]

Relevant Articles from Directive 93/42/EEC

24 The Medical Devices Directive has undergone a number of amendments since it first came into force[7]. An SPC can only be applied for when a valid marketing authorisation (MA) and the basic patent have been granted. In this case, because such a long period of time has elapsed between the date that the first authorisation in the community was issued (i.e., the EC Design Certificate issued under this directive) and the date that the basic patent was granted, and hence the date on which the applications for the SPCs could be made, I will consider both the version of this Directive that was in force on the date when the authorisation filed with these applications was issued and the version of this Directive that was in force on the date that the applications for the SPCs were made. In my analysis below, I will then go on to consider which is the correct version of the Directive to apply in this case.

Version of Directive 93/42/EEC in force on date when SPC applications were made

25 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 applications in question in this case were applied for in March 2014[9].

[8] 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.

26 Directive 93/42/EEC, as amended relating to medicinal devices in general[10], in its preamble and recitals identifies its essential objective thus:

> *"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*;"

27 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****;"*

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[9] 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.

[10] 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 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).

The references to Directive 65/65/EEC in the extract above should be read as references to Directive 2001/83/EC[11]. Similarly, the reference to Directive 75/318/EEC in this extract should also be read as a reference to Directive 2001/83/EC[11]. At the time when the SPC applications in question were made, Directives 65/65/EEC and Directive 75/318/EEC had been replaced by Directive 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.

28 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;"*

29 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;"***

30 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**:*

[11] 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 4-7 above)

*— **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;
.....

31 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) ....”

32 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.”***

33 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).”*

34 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."

.....

35 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.

Annex I of Directive 93/42/EEC

36 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 III of Directive 93/42/EEC

37 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*.'

38 The conformity assessment procedure such as that described in this Annex is carried out by a **notified body** – as defined in Article 16 and Annex XI of the Directive. Any organisation that meets the requirements laid down in Annex XI can be designated as a notified body by a Member State. The manufacturer of the device can select which notified body they want to use based on the tasks that the notified body has been designated for in relation to the procedures identified in Article 11 of the Directive. The notified body carries out a technical assessment of all the material submitted by the manufacturer to demonstrate that their device conforms to the requirements of the directive. If this technical assessment is favourable, the manufacturer can attach the CE mark to their device and place it on the market.

Annex IX of Directive 93/42/EEC

39 Annex IX, entitled 'Classification Criteria', outlines the rules to be used to decide what classification class a 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.

40 Chapter I of this Annex is entitled 'Definitions' and sections 1.2 and 1.8 of this chapter defines 'Invasive Devices' 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

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.

41 There are special Rules in Chapter III of this Annex and rule 13 provides.

"All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III."

Version of Directive 93/42/EEC in force on date when first Marketing Authorisation was granted

42 The version of the Medical Devices Directive 93/42/EEC which was in force when the first authorisation filed with these SPC applications was granted had some different wording. This is the version which came into force on 10 January 2002[12], which I have set out below (my emphasis outlined in bold).

43 Many of the provisions, including the recitals, were no different from the later version, discussed above, but Article 1(5) stated (my emphasis added in bold):

This Directive does not apply to:

(a) in vitro diagnostic devices;

(b) active implantable devices covered by Directive 90/385/EEC;

(c) medicinal products covered by Directive 65/65/EEC, including medicinal products derived from blood as covered by Directive 89/381/EEC;

(d) cosmetic products covered by Directive 76/768/EEC;

(e) human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells, with the exception of devices referred to in paragraph 4a;

[12] Directive 2001/104/EC of the European Parliament of 7 December 2001, amending Directive 93/43/EEC, took effect the date of its publication in the Official Journal of the European Communities i.e. on 10 January 2002.

(f) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin;

(g) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

44 Section 7.4 of Annex I states:

"*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 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified,* ***taking account of the intended purpose of the device,*** *by analogy with the appropriate methods specified in Directive 75/318/EEC.*

Where a device incorporates, as an integral part, a human blood derivative, the notified body shall seek a scientific opinion from the European Agency for the Evaluation of Medicinal Products (EMEA) on the quality and safety of the derivative, taking account of the appropriate Community provisions and, in particular, by analogy with the provisions of Directives 75/318/EEC and 89/381/EEC. The usefulness of the derivative as a part of the medical device shall be verified, taking account of the intended purpose of the device.

In accordance with Article 4(3) of Directive 89/381/EEC, a sample from each batch of bulk and/or finished product of the human blood derivative shall be tested by a State laboratory or a laboratory designated for that purpose by a Member State."

Relevant Case Law

Court of Justice of the European Union (CJEU)

45 In *C-195/09, Synthon BV v Merz Pharma GmbH & Co KGaA,* hereafter *Synthon*, the Court of Justice of the European Union (hereafter CJEU) was 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****."*

46 In *C- 427/09, Generics (UK) Ltd v Synaptech Inc*. hereafter *Generics*, the CJEU was considering what was the first marketing authorisation in the Community and said (my emphasis added in bold):

"36 In the light of the foregoing considerations, the answer to the questions raised is that a product, such as that at issue in the main proceedings, which was placed on the market in the Community as a medicinal product for human use before obtaining a marketing authorisation in accordance with Directive 65/65, and, **in particular, without undergoing safety and efficacy testing, is not within the scope of Regulation No 1768/92, as defined in Article 2 of that regulation, and may not be the subject of an SPC."**

47 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."*

48 In *C-422/10, Georgetown University and Others v Comptroller General of Patents, Designs and Trade Marks,* hereafter *Georgetown,* 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)."

49 In *C-130/11, Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents, Designs and Trade Marks,* hereafter *Neurim,* the CJEU considered 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[13]. 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).***

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

[13] 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

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."

50 In *C-109/12 Laboratoires Lyocentre v Lääkealan turvallisuus ja kehittämiskeskus, Sosiaali ja terveysalan lupa ja valvontavirasto* (hereafter referred to as *Laboratoires Lyocentre),* the CJEU was asked whether the classification of a capsule as a medical device under Directive 93/42 in some members states prevented it being classified as a medical product under Directive 2001/83 in others. The CJEU stated (my emphasis added in bold):

"41 Consequently, a product that falls within the definition of a 'medicinal product' within the meaning of Directive 2001/83 must be regarded as a medicinal product and may not be classified as a medical device within the meaning of Directive 93/42.

42 Whether a product falls within the definition of a medicinal product by virtue of its function for the purposes of Directive 2001/83 ***must be determined by the national authorities on a case-by-case basis,*** *acting under the supervision of the courts, taking account of all the characteristics of the product, in particular its composition, its pharmacological, immunological or metabolic properties, to the extent to which they can be established in the*

present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (C-140/07 Hecht-Pharma [2009] ECR I-41, paragraph 39, and C-27/08 BIOS Naturprodukte [2009] ECR I-3785, paragraph 18).

43 In the context of that case-by-case examination, the pharmacological, immunological or metabolic properties of a product constitute the factor on the basis of which it must be ascertained, in the light of the potential capacities of the product, whether it may, for the purposes of Article 1(2)(b) of Directive 2001/83, be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions (BIOS Naturprodukte, paragraph 20).

44 As regards more particularly the distinction between medicinal products and medical devices, ***Article 1(5)(c) of Directive 93/42 specifically requires the competent authorities to take particular account of the principal mode of action of the product. It thus follows from Article 1(2)(a) of that directive that only a product which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means may be classified as a medical device.***

45 None the less, as Union law currently stands, until harmonisation of the measures necessary to ensure the protection of health is more complete, it will be difficult to avoid the existence of differences in the classification of products as between Member States in the context of Directive 2001/83 (see, to that effect, inter alia, Case C-201/96 LTM [1997] ECR I-6147, paragraph 24, and Hecht-Pharma, paragraph 28).

46 As the Advocate General has stated in point 63 of her Opinion, asymmetries in scientific information, new scientific developments and differing assessments of risks to human health and the desired level of protection can explain why different decisions are taken by the competent authorities of two Member States as regards the classification of a product.

47 In addition, ***the fact that a product is classified as a medical device in accordance with Directive 93/42 in one Member State does not prevent it being classified, in another Member State, as a medicinal product in accordance with Directive 2001/83*** *if it displays the characteristics of such a product (see, by analogy, Case C-150/00 Commission v Austria [2004] ECR I-3887, paragraph 60, and HLH Warenvertrieb and Orthica, paragraph 56).”*

The CJEU also went on to say:

“55 *In the light of the foregoing considerations, the answer to the second question is that, in order to classify as a medicinal product in accordance with Directive 2001/83 a product already classified in another Member State as a medical device bearing a CE marking in accordance with Directive 93/42, the competent authorities of a Member State must, before applying the classification procedure under Directive 2001/83, apply the procedure under Article 18 of Directive 93/42 and, where appropriate, the procedure under Article 8 of Directive 93/42.”*

54 In *C-631/13 Arne Forsgren v Österreichisches Patentamt* (hereafter referred to as *Forsgren*) the CJEU had to consider the definition of product when considering whether a substance should be granted an SPC. The CJEU stated (my emphasis added in bold):

> "23 *'[P]roduct' is defined in Article 1(b) of Regulation No 469/2009 as 'the active ingredient or combination of active ingredients of a medicinal product'. However, the term 'active ingredient' is not defined in that regulation. That term also appeared in Article 1(b) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1), which was repealed by Regulation No 469/2009, and a question relating to that provision has already been referred to the Court. The Court held on that occasion that it is generally accepted in pharmacology that the term 'active ingredient' does not cover substances forming part of a medicinal product which do not have an effect of their own on the human or animal body (see judgment in Massachusetts Institute of Technology, EU:C:2006:291, paragraph 18).*
>
> *24 That interpretation was subsequently reproduced, in essence, by the EU legislature. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 (OJ 2011 L 174, p. 74) amended Article 1 of Directive 2001/83 to the effect that the term 'active substance' — which must be understood as meaning 'active ingredient' (judgment in Massachusetts Institute of Technology, EU:C:2006:291, paragraph 21) — is defined therein as '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'.*
>
> *25 It follows that the term **'active ingredient', for the purposes of applying Regulation No 469/2009, concerns substances producing a pharmacological, immunological or metabolic action of their own.** Since Regulation No 469/2009 does not draw any distinction according to whether an active ingredient is covalently bound with other substances, it is not appropriate to exclude, on that ground, the grant of an SPC for such an active ingredient.*
>
> *26 On the other hand, the Court has held that a substance which has no therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the term 'active ingredient' and, consequently, cannot give rise to the grant of an SPC (judgment in Massachusetts Institute of Technology, EU:C:2006:291, paragraph 25).*
>
> *27 The answer to the question whether a substance which is part of a medicinal product is an active ingredient within the meaning of Article 1(b) of Regulation No 469/2009 **depends, therefore, on whether that substance has a pharmacological, immunological or metabolic action of its own,** independently of any covalent binding with other active ingredients."*

Intellectual Property Office (IPO)

55 There have been two relevant IPO decisions issued by this hearing officer acting for the Comptroller-General of Patents, Designs and Trade Marks 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.

56 The IPO decision *Cerus Corporation (BL O/141/14)*[14]*,* hereafter *Cerus*, concerned two SPC applications. 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.

57 There has also been the IPO decision in *Leibniz-Institut für Neue Materialien Gemeinnützige GmbH (BL O/328/14)*[15]*,* hereafter *Leibniz.* EC Design Examination Certificate No. 11870GB411100614, dated 14 June 2010 was filed in support of SPC application SPC/GB/10/051 for "*Aqueous dispersion of iron oxide nanoparticles*". The product acted through physical means: the nano-sized particles are introduced directly into a cancer tumour and subjected to an alternating magnetic field which causes the particles to heat up and this results either in irreparable damage to the tumour cells or their sensitization to additional treatment. The assessment criteria used to obtain an EC Design Examination Certificate under Directive 93/42/EEC was not considered to be the same as to obtain a marketing authorisation under Directive 2001/83/EC or Directive 2001/82/EC partly because the objectives of the systems are different given the differing uses of products and devices. Also, the product exercised its action by physical means as opposed to by pharmacological, immunological or metabolic means and therefore was not within the scope of the Medicinal Products Directive (Directive 2001/83/EC).

[14] For a full text of the *Cerus* decision see https://www.ipo.gov.uk/p-challenge-decision-results/o14114.pdf

[15] For a full text of the *Leibniz* decision see https://www.ipo.gov.uk/p-challenge-decision-results/o32814.pdf

58 I discuss the relevance of these decisions and quote from them in my analysis below.

Issues to be decided

59 There are several issues to be decided in this case: (a) whether, or not, the SPC applications applied for meet the requirements of the SPC Regulation in that the product, which is the subject of the SPC application, was the subject of an administrative authorisation procedure as set out in Article 2 of the SPC Regulation; (b) whether, or not, a valid authorisation under Article 3(b) has been provided in support of the product for which the SPCs have been applied for; (c) whether, or not, the marketing authorisation needs to be in force when the SPC applications were filed; and (d) what is the correct product for which an SPC may be granted under the SPC Regulation.

60 However, I also note in this regard that if I find that the applications are considered not to meet the requirements of the SPC regulation, then, as is clear from the decision of the CJEU in the *Sumitomo*[16] case, the SPC applications fail. I do not then need to go on and consider whether the marketing authorisation needs to be in force when the SPC applications were filed or to determine what is the correct product for which an SPC may be granted.

Role of the IPO is to grant SPCs

61 It is appropriate at this point to observe and make clear [as did this Hearing Officer in the *Cerus* and *Leibniz* decisions] 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 of time, 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 provides the applicant with an additional period of exclusivity after the patent expires to balance the loss of patent term they have experienced while gaining 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 or its equivalent for a medical device. The latter is the responsibility of the Medicines and Healthcare Products Regulatory

[16] *Sumitomo Chemical Co. Ltd v Deutsches Patent- und Markenamt, C-210/12: (i)* see para 32 for first of three referred questions i.e., "*Is Article 3(1)(b) of [Regulation No 1610/96] to be interpreted as not precluding the grant of a supplementary protection certificate for a plant protection product if a valid marketing authorisation was granted in accordance with Article 8(4) of [Directive 91/414]?*" *(ii)* see paras 33-38 for discussion of this question, and especially para 37 which states that "....***it is not possible to apply Article 3(1)(b) of Regulation No 1610/96 to an emergency MA*** [marketing authorisation]*,* ***which is restricted to products which do not comply with the requirements of Article 4 of Directive 91/414*** *and in respect of which that directive does not require a prior scientific evaluation of the risks*". *(iii)* No Advocate-General's Opinion was issued in this case.

Agency (MHRA) at the national level in the UK[17] and of the European Medicines Agency (EMA) at the European Community wide level[18].

62 The analysis presented below is based on my consideration and comparison of Directive 2001/83/EC and Directive 93/42/EEC, the relevance of the cited CJEU and IPO decisions and my consideration of all the correspondence regarding the two SPC applications at issue in this case which were on file at the IPO.

Views of the Applicant and the Examiner

63 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

64 The applicant is seeking the grant of an SPC for the Taxol® or Taxol®-eluting stent 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 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.

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

Firstly, in relation to whether or not an assessment procedure under Directive 93/42/EEC meets the requirements of the SPC Regulation:

a) The SPC Regulation should be interpreted teleologically and refusal of these SPC applications would be contrary to the fundamental objective of the SPC Regulation. Otherwise, a patentee looking to take advantage of the SPC Regulation may seek authorisation for a product separately from the device even if this is not the most efficient thing to do and means two separate treatments for a patient. For example by seeking separate authorisation for antibiotics used in bone cement (a product) as opposed to antibiotics within the bone cement (a device). This would create a conflict between the patentee being able to obtain SPC protection for their investment in research and public health grounds for delivering the most efficient therapy. This is analogous to the arguments presented in *Medeva* and *Georgetown*. In those cases public health reasons preferred that multiple vaccines were contained in one dose as opposed to having to administer multiple single vaccines. The CJEU found that part of the marketing authorisation can be ignored because it would be unfair to

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

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

deny SPC protection where pharmaceutical companies went down the combination route for public health reasons. Similarly, in this case the applicant could have sought to use the stent without Taxol® and for the Taxol® to be implanted separately. Then the Taxol® would have been treated as a medicinal product and obtained an SPC. But this would be contrary to public health reasons and increase the chances of infection. Therefore, not granting an SPC in this case will force patentees to split up devices and products to get SPC protection which would be contrary to public health reasons. SPC protection should be given to medicinal products authorised in medical devices where the medical devices incorporates a substance which, if used separately, would be considered as a medicinal product.

b) The fundamental objective of the SPC Regulation is to ensure sufficient protection to encourage pharmaceutical research. The CJEU decision of *Neurim* means that a full marketing authorisation is not required in order to obtain an SPC. The MHRA explain on their website that there are various types of applications. Those for new substances are described as "full applications" and applications containing existing active ingredients are described as "abbreviated" or "abridged applications". Following the decision in *Neurim*, any of these marketing authorisations can form the basis for an SPC. The decision in *Cerus* is incorrect in that it interprets MHRA advice to mean that because a full assessment of the quality, safety and efficacy of the medicinal substance component of the medical device in its entirety is not performed, it is not the same as a full medicinal marketing authorisation and thus it is not equivalent to a marketing authorisation under the Medical Products Directive. *Neurim* means that a full authorisation is not required.

c) Article 3(b) of the SPC Regulation says "*in accordance with Directive 2001/83/EC or Directive 2001/82/EC*". This means that it applies to authorisations for a medical device, where the active component has undergone the same level of safety and efficacy testing as required by Directive 2001/93/EC or Directive 2001/82/EC. The European Commission Guidance on medical devices (MEDDEV 1.1/3 rev 3) which applied from 21 March 2010 provides that drug eluting coronary stents fall into a special criteria as Class III medical devices under Directive 93/42/EEC and have to undergo the highest level of safety and efficacy testing. Directive 93/42/EEC and Directive 90/836/EC require that the safely, quality and usefulness of a device containing an active ingredient must be verified by analogy with the methods specified in Directive 2001/83/EC. This means that the authority issuing marketing authorisations for medical products, in this case, the EMA, must be contacted concerning the quality and safety of the integral product. Thus the testing is in accordance with Directive 2001/83/EC. This, in turn, means that the equivalent safety and efficacy testing must be performed and so these products are indirectly regulated under Directive 2001/82/EC or Directive 2001/83/EC. The level of safety and efficacy testing of the Taxol®-eluting stents was equivalent to that which medicinal products undergo. They were tested in clinical trials which lasted many years and included randomised double blind clinical trials to prove that the improved results were due to the Taxol®-eluting stent. The applicant also referred to a *Summary of safety and effectiveness of data* which was

prepared for the US regulatory approval system but said that as it met international standards it also meets the European requirements.

d) The safety, quality and usefulness test that must be carried out for a medicinal product incorporated into a medical device is equivalent to the safety and efficacy testing carried out for a medicinal product. The IPO is incorrect that usefulness and efficacy are different. In medicine "efficacy" indicates the capacity for beneficial change of a given intervention. During the regulatory process a bare metal stent was directly compared to the same stent eluting Taxol® and the effects on restenosis assessed with positive results. Thus in this case the usefulness and efficacy assessments would be the same.

e) Taxol® has previously undergone safety and efficacy testing and received a marketing authorisation as a medicinal product, for example in treating breast neoplasms. Therefore, if it was going to be authorised for restenosis without the stent it would have had to be authorised under the abridged procedure. Full preclinical and clinical dossiers would not have been required and an SPC could have been obtained.

f) The principle intended action of the stent and the Taxol® are the same, to treat or prevent restenosis. The Taxol® achieves this by pharmacological means but the stent does so by physical means. This distinguishes these SPC applications from the *Cerus* case in which the principle intended actions of the device and of the product were different. In *Cerus* the active ingredient was acting to neutralise, by photochemical activation and destruction, pathogens in a blood product isolated from a person before the treated blood product was introduced into the body. The blood product itself was intended for giving as a blood transfusion and so physically replacing blood volume in the human body.

g) In *Laboratoires Lyocentre,* the CJEU held that it was possible for the same product to be considered a medicinal product in one country and a medical device in another country. It also found that similar products can be classified differently in the same country. Unless SPCs are allowed irrespective of the authorisation route then the system will be fragmented with the same product getting an SPC in one country because it is a medicinal product and not getting one in another country because it is a device. This would deter companies from pursuing research, contrary to the fundamental objectives of the SPC Regulation to encourage pharmaceutical research.

h) In these applications, Taxol® is an active ingredient which, if used separately, would be considered an active ingredient. This makes it different to the application in *Leibniz* where there was no active ingredient. Therefore, the facts of *Leibniz* are irrelevant to this application.

i) The German Federal Patent Court in decision *14 Q (pat) 12/07*, dated 26 January 2001, found that an approval under Directive 90/835/EEC was in accordance with Directive 2001/83/EC or Directive 2001/82/EC and, as a result, granted the SPC. The Netherlands District Court followed a similar line of reasoning in *Genzyme Biosurgery Corp v Industrial Property Office (Netherlands)* BIE 70(2002) 360 – 362 (Netherlands) DC (the Hague) and granted an SPC.

Secondly, in relation to whether or not an SPC can be granted when the marketing authorisation has expired before the SPC application:

j) It is irrelevant whether or not the first authorisation is in force when the SPC application is filed. Article 3(b) of the SPC Regulation merely states that "a validation authorisation to place the product on the market as medicinal products has been granted." It does not say it must still be in force, as is re-iterated in Chapter SPM3.03 of the Manual of Patent Practice.

k) At the time of filing of the SPC applications on 31 March 2004 the products "Taxol" and "Taxol-eluting stent" were covered by authorisations that were in force.

Finally, in relation to whether the product protected by the SPC should be Taxol® or Taxol®-eluting stent or both:

m) The applicant has indicated that they are willing to withdraw the SPC application for the "Taxol-eluting stent" in favour of the application for "Taxol" in light of the Hearing Officer's comments in *Cerus.* However, the German Federal Patent Court in decision 14 Q (pat) 12/07 dated 26 January 2001 granted an SPC where the product included the device. Claims 5 and 7 mention stents and grafts coated with Taxol®.

The Examiner's view

66 The examiner considers that these two SPC applications are out of scope of the SPC Regulation as they do 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.

67 In addition, the examiner considers that these SPC applications do 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).

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

a) The examiner considers that these SPC applications cannot be distinguished and should not be decided differently from the *Cerus* decision which concluded that the tests that form part of the assessment of 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. There is no provision in Directive 93/42/EEC to consider this device to be a further distinguishable type of device within the class and there does not appear to be a reason to distinguish it from *Cerus*.

b) The Hearing Officer's comments in *Cerus* about 'principle intended action' were made in the context of considering a device where the active ingredient, if used separately, would fall within Directive 2001/83/EC as a medicinal product. The applicant's applications cannot be distinguished as they also contain a chemical element and a physical element. Taxol® itself has not been subject to any authorisation for treating restenosis. There are different legal regulatory processes for medical devices and medicinal products, but it is the intention of the regulators and legislators that these systems are distinct and do not in practice overlap. The presence of Taxol® on the surface of this device has been found ancillary to its function rather than its primary agent. As the case of *Laboratoires Lyocentre* makes clears where there is doubt about which regulatory process should be used the provisions of the Medicinal Products Directive apply.

c) Case law from the CJEU [see, for example, *Generics (UK) Ltd v Synaptech Inc (*C-427/09*) and Synthon BV v Merz Pharma Gmbh & Co KG (*C-195-09*)*] is clear that it is a requirement that any authorisation relied upon is in accordance with Directive 2001/83/EC. There are different detailed routes by which an authorisation may be obtained under Directive 2001/83/EC (such as national procedures) but they all result in an authorisation granted under that Directive.

d) Following *Neurim,* it is possible to grant an SPC for a further distinct use but this is only where such a use has been subject to its own approval.

e) In *Laboratoires Lyocentre,* the CJEU recognised that different jurisdictions may take different approaches to approving one and the same product or one and the same device. The CJEU did not find that if both medical product marketing authorisations and medical device approvals exist in different member states, then they are deemed to be equivalent to each other.

f) Many products show usefulness in treating a condition but their efficacy will be determined by a number of other factors – for example, a vaccine for influenza may be useful but the specific patient group being vaccinated and the nature of the viral strains present will determine the efficacy of the vaccine.

In relation to whether the product protected by the SPC should be Taxol® or Taxol®-eluting stent or both:

g) The case of *Arne Forsgren v Österreichisches Patentamt* C-631/13 provided that an active ingredient must have "*a pharmacological, immunological or metabolic action of its own*". Therefore, the product definition should be Taxol® alone.

Analysis

69 The issues raised in these applications 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 the SPC applications.

70 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 decisions, *Cerus* and *Leibniz,* as referred to above. As the hearing officer who decided both of those cases, I reviewed the SPC Regulation, the relevant parts of the Medical Devices Directive (Directive 93/42/EEC) and the Medicinal Products Directive (Directive 2001/83/EC) and I took into account the purpose of each of these pieces of European Community legislation. I concluded that assessment under Directive 93/42/EEC is not the same as or equivalent to the process carried out to authorise a medicinal product for human use under Directive 2001/83/EC.

71 The applications before me now also concern an EC Design Examination Certificate filed in support of two different SPC applications. The applicant has suggested some reasons why such a 'marketing authorisation' should be deemed to meet the requirements of the SPC Regulation.

72 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 date the application was filed in the *Leibniz* case (14 December 2010). The SPC applications I am now considering were filed on 31 March 2014. The latest amendments to the Medical Devices Directive took effect in October 2007[19]. However, the first marketing authorisation was granted on 21 January 2003 when the version of the Medical Devices Directive which took effect on 10 January 2002[20] was in force. In light of this, I will consider whether or not there are substantive differences between the version of Directive 93/42/EEC when these SPC applications were filed and when the first marketing authorisation was granted.

Teleological Approach

73 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. As I have set out in the previous decisions on *Cerus* and *Leibniz* such an interpretation is a well established principle of European Union law and requires one to take into consideration the purpose and objectives of the relevant piece of European Union legislation. In the *Cerus* decision (see the whole decision, but especially paragraphs 61-63), I explained in some detail that 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

[19] 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.

[20] Directive 2001/104/EC of the European Parliament of 7 December 2001, amending Directive 93/43/EEC, took effect the date of its publication in the Official Journal of the European Communities i.e. on 10 January 2002.

Certificates in *Cerus* was that, as in the applications before me now, 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).

74 The applicant has also referred to the reasoning in *Medeva* and *Georgetown.* These cases both concerned combination vaccines which protected against multiple diseases in one injection. In both cases the CJEU discussed that the fundamental objective of the SPC Regulation is to "*is to ensure sufficient protection to encourage pharmaceutical research*" (*Medeva* paragraph 30). The applicant set out why these applications were similar to the applications at issue in this case. Without an SPC there would not be any encouragement to put products into devices, but instead there would be an incentive to provide the device and product separately which may be less beneficial to the patient. However, in both *Medeva* and *Georgetown* the decisions concerned new active ingredients in combination with other active ingredients in contrast to the situation here where the active ingredient of interest, taxol, has already been authorised for many years and for the same use. I do not consider that the decisions in *Medeva* and *Georgetown* are helpful in this case.

75 The applicant and the examiner have also discussed the relevance of the *Synthon* case (*C-195/09)* from the CJEU 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 was also case-law that this hearing officer considered in paragraph 72 of *Leibniz:*

> *"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."*

76 Similarly, the facts of these applications are similar to those in my decisions in *Leibniz* and *Cerus* and I think the *Synthon* and *Neurim* CJEU decisions raised different issues. The applicant and the examiner have also discussed the *Generics*

CJEU case. That case was about what was the first marketing authorisation in the Community, which is a different issue than that in these applications which are about whether the marketing authorisation filed meets the requirements of the SPC Regulation.

Conflict between national decisions on marketing authorisations

77 The applicant has said that the CJEU decision of *Laboratoires Lyocentre* illustrates that an item may be authorised as a device in one member state but as a product in another member state. Therefore, the applicant says that SPCs should be granted on the basis of authorisations under Directive 2001/83/EC and Directive 93/42/EEC otherwise an SPC may be available in some member states but not others for the same product. In the case of *Laboratoires Lyocentre,* the CJEU did provide that an item may be authorised differently in different member states. However, in paragraphs 40 and 41 of the *Laboratoires Lyocentre* decision, the CJEU set out that, if there is any doubt, the item should be classified as a medicinal product under Directive 2001/83/EC. The CJEU also set out in paragraph 55 that if a product has already been classified as a medicinal product under Directive 2001/83/EC in one member state then another member state wishing to classify it as a medical device under Directive 93/42/EEC must apply the procedure in Article 18 of Directive 93/42/EEC and, where appropriate, the procedure under Article 8 of Directive 93/42/EEC. Given these procedures and, that in the case of doubt, they should be classified as medicinal products under Directive 2001/83/EC, it appears that it would be unusual that the same item is classified differently in different member states. The CJEU is clear that the two regimes are distinct and do not overlap. Therefore, the rare occasion when different regulatory approaches are applied would not appear to be a reason for saying that all marketing authorisations under Directive 2001/83/EC meet the requirements of the SPC Regulation as the applicant appears to imply in their argument. In the two SPC applications before me in this case, the applicant has indicated that they have had to seek authorisation under Directive 2001/83/EC and has not indicated that they are one of those unusual cases where in other member states the item has been authorised under Directive 93/42/EEC. Therefore, I do not consider the case of *Laboratoires Lyocentre* to be helpful in deciding that the approval procedure in place for medical devices is appropriate to meet the requirement for a valid authorisation under Article 3(b) of the SPC Regulation.

Previous IPO Decisions

78 The applicant has set out why the facts of these applications differ to the recent *Leibniz* decision from the IPO by pointing out that in these applications the product, if used separately from the stent, could have been authorised under the Medicinal Products Directive. In *Leibniz,* in paragraph 68, I set out why I concluded that there was not a substance which if used separately may be considered a medicinal product within the meaning of Directive 2001/83/EC (as had been in the case of *Cerus* (see paragraph 77 of that decision). In that respect, the facts of the applications I am now considering are more similar to the situation in *Cerus* than *Leibniz.* That said, whilst the facts of the cases may differ similar arguments are relevant.

79 One of the differences between the *Cerus* and *Leibniz* cases were that different versions of Directive 2001/83/EC and 93/42 were relevant given the dates of grant of the authorisations and the dates of filing of the SPC application.

Does the authorisation filed with the SPC applications meet the requirements of the SPC Regulation?

80 The Taxol®-eluting stent was approved under Directive 93/42/EC as a class III medical device. In the previous cases of *Leibniz* and *Cerus* I have set out in detail why it is necessary for me to consider whether or not the authorisation under Directive 93/42 filed with the SPC application is equivalent to the valid authorisation under Directive 2001/83/EC and so fulfil the requirements of the SPC Regulation, in particular Articles 2 and 3 (see paragraphs 60 – 53 of *Cerus* and paragraphs 71 – 72 of *Leibniz*). It is now necessary for me to undertake the same assessment in these applications to determine whether the Design Certificate filed is equivalent to an authorisation under Directive 2001/83/EC. In *Cerus* and *Leibniz* the patents had been granted before or at a similar time to the grant of the marketing authorisation. Therefore, the SPC applications were been made quite quickly after the marketing authorisation has been granted (as per the SPC Regulation). However, in the applications I am now considering the patent was granted some time after the market authorisation. See the table below for a comparison:

Case	***Cerus, BL O141/14[14]***	***Leibniz, BL O/328/14[15]***	***Angiotech***
SPC applications	**(i) SPC/GB/07/043 (ii) SPC/GB/07/044**	**SPC/GB/10/051**	**(i) SPC/GB/14/030 (ii) SPC/GB/14/031**
Basic Patent Number	**EP(UK) 0707476 B1**	**EP(UK) 0636111 B1**	**EP(UK) 2226085 B1**
First authorisation date	**(i) 31 May 2002 (ii) 21 November 2006**	**14 June 2010**	**21 January 2003**
Patent Filing Date	**24 June 1994**	**8 April 1993**	**9 July 1994**
Patent Grant date	**14 February 2007**	**22 July 1998**	**27 November 2013**
Patent Expiry Date	**23 June 2014**	**7 April 2013**	**16 July 2014**
SPC Application date	**9 August 2007**	**14 December 2010**	**31 March 2014**

81 Both Directive 93/42/EEC on medical devices and Directive 2001/83/EC on medicinal products were amended several times between the date the authorisation was granted and the date on which the SPC applications were filed. In the previous cases before me already referred to above, this has not been an issue but, in this instance, the first marketing authorisation was granted over a decade before the two SPC applications in question were made. This is a consequence of the length of time it took for the basic patent to be granted – over 19 years from date of filing. This means that the first marketing authorisation was granted on the basis of the law in force in January 2003 but that by the time the SPC applications were made in

March 2014, Directive 93/42/EEC had been amended. As a result, in the same manner as I have done in the two previous cases before me concerning SPC applications for medical devices, I need to consider which version of the Directive applies in this case. I will first consider the version in force when the SPC applications were made, which was the version that the applicant has referred to in all their correspondence. However, it will also be necessary for me to consider if the version of the Directive in force when the first authorisation was granted is more appropriate given that this is the version that set out the procedures which the applicant had to meet in order to gain the authorisation in the first instance.

Version of Directive 93/42 and Directive 2001/83/EC in force at the date of the SPC applications

82 The SPC applications were made on 31 March 2014 and, as set out above, both Directive 93/42/EEC and Directive 2001/83/EC have been updated several times. The version of Directive 93/42/EEC in force at the date of the SPC applications is the same as the version which was relevant in *Leibniz*. However, in October 2012 there were further amendments to Directive 2001/83/EC and so the version of that Directive which is relevant to these applications is not identical to the one used in *Leibniz*. Throughout the correspondence with the IPO the applicant has referred to the version of the Directives and relevant guidance which were in force at the date when the SPC application was filed on 31 March 2014.

Definition of medicinal product

83 In *Cerus* and *Leibniz* I considered in detail the issue of the definition of medicinal product. The applicant has not raised this in these applications but for completeness it is worth noting that the definition of medicinal product in Directive 2001/83/EC was not amended in the version relevant to these applications and the wording of the directive is still the same as applied in the *Leibniz* decision. Therefore, my conclusion in paragraph 67 of *Cerus* is still relevant where I said "*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."*

Authorisation procedure as laid down under Directive 2001/83/EC

84 The CJEU in *Laboratoires Lyocentre, C-109/12,* made it clear that the differing procedures for authorisation of medicinal products under Directive 2001/83/EC and for authorisation of medical devices under Directive 93/42/EEC do not overlap. 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. 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.*" In *Cerus* the version of

Directive 93/42/EEC which I used did not contain the second part[21] of Article 1(5)(c) but, at this time there was European Commission Guidance referring to the "*principle mode of action*" and, in paragraph 88 in *Cerus,* I made reference to this when I said:

> *"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."*

85 The applicant for the two SPC applications at issue in this case says that they are distinguished because the principle action of both the stent and the Taxol®-coating on the stent are the same (i.e., to treat or prevent restenosis) whereas in *Cerus* the active ingredient and device had different actions. This was an issue which I dealt with in paragraph 77 of my *Cerus* decision:

> *"If the amotosalen was used separately, I agree that it would fall within the meaning of Article 1 of Directive 2001/83/EC, as a medicinal product, because it has the properties of being able to intercalate into the helical regions of DNA and RNA which occurs in humans as well as in bacteria and viruses. Thus if exposed to ultraviolet light, it would likely exert a* 'pharmacological or metabolic action'. *My understanding is that this substance is acting on the human body in a manner ancillary to the device because, it carries out its action on any viral and bacterial contaminants in the samples outside the body (in order to remove them from the platelets or plasma), and the resultant reaction products are removed from the platelet or plasma solution that the device produces, before either of these products is then used to treat the human body, i.e. to provide a transfusion. The amotosalen does not act directly on the human body. The applicant refers to a number of trials of both devices that were conducted in clinical setting with healthy subjects and patients to confirm that the device works as intended, e.g., can treat and store plasma and platelets, does not have any side-effects or risks that outweigh its benefits."*

86 The applicant refers to the above paragraph and seems to have interpreted it as meaning that: if the intended action of both the product and the device are the same then the medicinal product should be entitled to SPC protection. As the examiner has said, my comments should be taken in the context of the facts of the *Cerus* case where the device and product did have different actions, they are not a general statement to the effect that where the product and the device have the same action then the product should be entitled to an SPC. In the two SPC applications at issue in this case, there is a stent, a physical element, which keeps the blood vessel open, and there is Taxol®, a biologically active element, which prohibits the formation of new blood vessels which could block the blood vessel that the stent is keeping open.

[21] The second sentence i.e. "*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",* in Directive 93/42/EC came into effect on 21 September 2007.

While it is the case that the taxol is exerting this effect within the human body in the same location as the stent, it is still acting in an ancillary manner. The clinical tests which the applicant referred to in their correspondence compared a bare stent, i.e. the physical element alone, with a stent with Taxol®, i.e. the physical element and the biologically active element in combination – thus illustrating that the Taxol® has an ancillary effect and the principle intended effect or purpose or 'mode of action' of the device is achieved by the physical placement of the stent to keep the blood vessel open. The presence of the Taxol® keeps the blood vessel open for longer and so has an ancillary function or contribution to the work of the device, increasing its usefulness. However, without the physical stent element, the device would not be able to keep the blood vessel open. Hence the Taxol®-eluting stent is authorised as a medical device under Directive 93/42/EEC and is not within the authorisation procedures in Directive 2001/83/EC.

87 These two applications concern medical devices that fall within class III, 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. As Rule 13 of Annex IX of Directive 93/43/EEC indicates: "*All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III*." The applicant considers that the steps taken to gain approval for such a Class III device mean that the Taxol®-eluting stent has indeed undergone relevant clinical testing and that the safety and efficacy testing carried out in relation to such a device is equivalent to that required for medicinal products under Directive 2001/83/EC.

88 The applicant has set out how difficult, time consuming and arduous it was to obtain an authorisation under Directive 93/42/EC. In support of this the applicant has filed a statutory declaration, dated 30 March 2014, by Trevor Lewis, a consultant on medical device development and regulatory approval matters. This statement sets out the pre-clinical and clinical trials which the product which is the subject of these two SPC applications has undergone. In paragraph 8, he says "*This is a long and expensive process. ... The above studies are entirely comparable to the studies required for pure medicines before they received marketing approval."* He sets out why he thinks it can take 8 to 10 years to get from concept to market and that this is equivalent to a medical product. This was an issue that was also put before me in *Leibniz* and, in dealing with this argument, I note again what I (as Hearing Officer) said at paragraph 79 of that decision:

> *"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 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)."*

Again, in these applications I cannot just consider the length of time it has taken to obtain the authorisation under Directive 93/42/EEC but I must consider whether or not that authorisation is equivalent for the purposes of the SPC Regulation to an authorisation under Directive 2001/83/EC.

89 I have considered this issue of equivalence in some detail in both my *Cerus* and *Leibniz* decisions and, in particular, the difference between usefulness (in relation to a medical device) and efficacy (in relation to a medicinal product). The *Cerus* decision states, at paragraphs 92 and 93, that (my emphasis added in bold):

*"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."*

90 In reaching that conclusion in *Cerus* I drew upon comments provided by the MHRA (the body responsible for dealing with the approvals of both medicinal products and medical devices in the UK) and said, in paragraph 82 of the decision, that:

"I draw support for this view from the comments provided by the MHRA and quoted by the examiner in his official letter dated 7 October 2010, i.e.

"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/EC) 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 no 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 [the Medicines Directive] shall apply.

In accordance with directive 93/42/EC 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.""

91 The applicant in the present case disagreed with this advice in their correspondence with the examiner and said the IPO appeared to have interpreted it as meaning that because a full assessment of the quality, safety and efficacy of the medicinal substance is not performed, it is not equivalent to a marketing authorisation under Directive 2001/83/EC. I did note in my earlier decisions that this advice has no legal authority but that it does represent the considered views of relevant experts in the fields and thus I considered it helpful in pointing out how the systems are supposed to work. The applicant says that a full marketing authorisation is not required to get an SPC and relies upon the *Neurim* decision as support for this. But, as I have stated above, the *Neurim* decision was about a different issue and does not mean that a marketing authorisation is not needed to meet the requirements of the SPC Regulation. The applicant also referred to the fact that where a new product contains an active ingredient which has already been tested and approved then it is possible to submit an "abridged marketing authorisation application" under Directive 2001/83/EC. However, such an abridged authorisation is still a marketing authorisation granted under Directive 2001/83/EC. As such, it meets the requirements of that Directive and is within the ambit of Articles 2 and 3(b) of the SPC Regulation. I am being invited by the applicant to agree that the process involved in gaining an EC Design Certificate for a device under Directive 93/42/EEC is equivalent to the process for obtaining a marketing authorisation for a medicinal product under Directive 2001/83/EC as they both involve carrying out clinical testing.

92 The issue to be resolved with these applications is, as in *Cerus*, whether or not the test of usefulness under Directive 93/42/EEC is equivalent to the test of efficacy under Directive 2001/83/EC. The applicants have argued that efficacy and usefulness testing is the same with efficacy indicating the capacity for beneficial change, and, the implication I draw from this is that such a beneficial change is thus

a beneficial use. The examiner disagreed with this and pointed out that a flu vaccine may be useful but depending upon the nature of the viral strain present it may or may not have the desired efficacy. The applicant said that the Taxol®-eluting stent was directly compared in testing with a bare stent, with positive results for the Taxol®-eluting stent and so, in this particular case, the usefulness assessment was the same as the efficacy assessment which would have been required under Directive 2001/83/EC – it related to the active ingredient part of the device. That said, the assessment of the Taxol®-eluting stent still had as its objective (or purpose) a consideration of the usefulness of the entire device, including both the physical stent and active ingredient, Taxol®. An assessment of efficacy under Directive 2001/83/EC would consider the efficacy of the active ingredient alone and would relate to the ability of the active ingredient to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions. The assessment of the stent with the Taxol® coating in these applications carried out under Directive 93/42/EEC was to determine if the whole device achieves the performance claimed by its manufacturer and if it provides a benefit for the person it is being applied to while taking into account the "*the vulnerability of the human body"* to the device in operation and *"taking account of the potential risks associated with the technical design and manufacture of the device".* The assessment in each instance is for a different purpose, which means that meeting this purpose is judged differently in both situations and, is in particular one of degree, where the investigation of the active ingredient under the Medical Devices Directive will always be in relation to its ancillary role to that of the whole device. Therefore, I do not consider that the assessment on the basis of version of the Medical Devices Directive in force on the date of the two SPC applications were made can be considered equivalent to an authorisation under Medicinal Products Directive.

Version of Directive 93/42/EEC and Directive 2001/83/EC in force at the date when the first authorisation was granted.

93 The analysis above of whether or not the first authorisation under Directive 93/42/EEC is equivalent to the authorisation under Directive 2001/83/EC was on the basis of the Directives in force on the date that the SPC applications were made. However, the situation differs for these applications when compared to my earlier decisions in *Leibniz* and *Cerus* because both Directives (i.e., the medicinal products directive and the medical devices directive) had been amended between the date on which the authorisation was granted and the date the SPC applications were made. Therefore, the versions of the Directives in force at the date of the SPC applications were not the versions under which the first authorisation, filed with the SPC applications, was granted. I have been considering whether or not the authorisation filed is equivalent to an authorisation under Directive 2001/83/EC and that has involved considering what the applicant had to do to get the authorisation. In order to obtain the authorisation, the applicant had to meet the requirements of the Medical Devices Directive that was in force on that date (and not any later or future date). Therefore, I think it is appropriate to consider whether or not the first authorisation the applicants submitted, dated 21 January 2003, is equivalent to an authorisation under Directive 2001/83/EC.

94 On 21 January 2003, the version of Directive 93/42/EEC which was in force was the version which came into force on 10 January 2002. The same general principles

applied as I set out above. However, Article 1(5)(c) only said "*medicinal products covered by Directive 65/65/EEC*" (Directive 2001/83/EC superseded Directive 65/65/EEC) and the second part of Article 1(5)(c) referred to principal mode of action was not included[22]. This is also how Article 1(5)(c) was worded in the version of Directive 93/42/EEC which I considered in the *Cerus* decision. In that decision, I referred, in paragraph 84, to the wording in the European Guidance, dated July 2001, which referred to "*principal purpose of a product*" and was also in force in January 2003. Therefore, as I determined in *Cerus*, it was relevant to consider the principal purpose of the product, i.e., the Taxol-eluting stent. Further, I do not think that the difference in wording in Article 1(5)(c) makes a difference to whether or not the first authorisation is equivalent to an authorisation under Directive 2001/83/EC.

95 Rule 13 of Annex IX*,* which determines that all devices incorporating, as an integral part, a substance which, if used separately, can be considered to be medicinal product, is the same in both versions of Directive 93/42/EC. The Taxol®-eluting stent has always been considered a Class III device and, as I have said above, before I do not think that the mere fact it takes a long time to get the authorisation means that an SPC must be granted.

96 The test of "*usefulness*" is found in section 7.4 of Annex 1 of Directive 93/42/EEC. The version in force at the date of the grant of the authorisation said "*the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC*." [Directive 2001/83/EC superseded Directive 75/318/EEC] Whereas the version in force at the date of the SPC application said "*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.".* Thus, the test was and, is still, one of "*usefulness*" and, as I said in paragraph 93 of *Cerus,* I do not consider "by analogy" to be the same as carrying out an assessment under Directive 2001/83/EC. The test of efficacy for medicinal products has always been in Directive 2001/83/EC and also its predecessors, Directive 75/318/EEC and Directive 65/65/EC. However, some of the details of the procedure have changed, for example the earlier version of the Directive did not require, in section 7.4, consultation with one of the competent authorities. But I do not think that these details change the fundamental difference that it is a usefulness test for medical devices and an efficacy test for medicinal products. Therefore, I think that my analysis above in relation to the tests is relevant irrespective of which version of each of these Directives is used. My conclusion is the same that the first authorisation filed with these SPC applications does not meet the requirements of the SPC Regulation as it is not an authorisation in accordance with Directive 2001/83/EC.

Experience in other jurisdictions and previous practice at the IPO

97 The applicant pointed to a decision from the Courts in Germany and from the Courts in the Netherlands which have allowed for the grant of SPCs based upon authorisations granted under Directive 93/42/EEC. There have also been some

[22] The second sentence of Article 1(5)(c) i.e. "*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",* in Directive 93/42/EC came into effect on 21 September 2007.

SPCs granted by the IPO. I dealt with this issue in detail in the *Cerus* decision (see paragraphs 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 consider that that conclusion applies equally in this case. I have to evaluate each application for an SPC based on the facts and the situation that exists at the time that the SPC applications were made, e.g. the relevant legal provisions.

Expiry of the first marketing authorisation

98 In light of the views I have set out above in relation to whether or not the first marketing authorisation meets the requirements of the SPC Regulation, I do not have to decide whether or not the marketing authorisation needs to be in force when the SPC applications were filed. As set out above, by the time the SPC applications were filed, the first marketing authorisation had expired, but there were related later marketing authorisations still in force. The applicants have said that they think it is irrelevant whether or not the first marketing authorisation is still in force at the date of filing.

99 Article 3(b) of the SPC Regulation requires that a valid authorisation to place the product on the market must have been granted. It does not say explicitly that it has to be in force on the date that the SPC application is made. In *Sumitomo*[23], the CJEU were asked whether it was necessary for the marketing authorisation to still be in force at the time of application for the certificate but decided that, in light of their answers to the previous question referred, they did not need to answer this question. Article 14 of the SPC regulation indicates that the SPC lapses "*if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation*". The Office Manual of Patent Practice says, at SPM3.03, *"Although Article 3(b) requires a valid authorisation to have been granted, there appears to be no requirement that the authorisation should still be in force at the date of making the application for a certificate (e.g. it may be withdrawn or have lapsed before the date of the application for the certificate)."*[24] It would appear that, although, Article 3 may allow for the grant of an SPC in the situation where the first marketing authorisation is no longer in force at the time that

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[23] see *Sumitomo Chemical Co. Ltd v Deutsches Patent- und Markenamt, C-210/12*, see para 32 for second of three referred questions i.e., "*If Question 1 is answered in the affirmative, is it necessary under Article 3(1)(b) of [Regulation No 1610/96] for the marketing authorisation to be still in force at the time of application for the certificate?*"; see para 39 for conclusion that this question did not need to be answered in light of the answer given to the first of the three referred questions in para 32. No Advocate-General's Opinion was issued in this case. See also footnote 14 above in relation to first question referred.

[24] See chapter on SPCs in the Office Manual of Patent Practice at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/436997/mopp.pdf

the SPC application is made, the impact of Article 14 would likely mean that in such cases, unless the same or a subsequent authorisation was granted before the SPC was due to come into force, the SPC would lapse because, in the absence of an appropriate authorisation, the product covered by the SPC could not be placed on the market.

The product under the SPC Regulation

100 Given the view I have reached above, I do not need to decide what the product should be in this case for the purposes of the SPC Regulation. However, I will offer the following comment given that the applicant offered to withdraw the Taxol®-eluting stent application (SPC/GB/14/031) in favour of the Taxol® application (SPC/GB/14/030) in an effort to progress the case. A similar issue was raised in *Cerus*, in which I concluded that the SPC, if it had been granted, should have been for the product that falls within the meaning of Article 1(b) of the SPC Regulation. The SPC Regulation provides for an SPC in relation to the product, i.e., active ingredient or active substance in the medicinal product that has been authorised for human use under Directive 2001/83/EC. Article 1(b) defines product as the active ingredient or combination of active ingredients of a medicinal product. In *Forsgren,* the CJEU confirmed that, for the purposes of the SPC Regulation, the active ingredient concerns "*substances producing a pharmacological, immunological or metabolic action of their own*." If an SPC were to be granted in this case, it should be for Taxol® alone, as per application SPC/GB/14/030, because this would be, in my view, the appropriate product within the meaning of Article 1(b) of the SPC Regulation. In application SPC/GB/14/031 where the product is defined as the Taxol®-eluting stent, the stent portion of the device is acting by physical means alone and so would not, in my view, fall within the definition of active ingredient under Article 1(b) of the SPC Regulation as it does not produce a pharmacological, immunological or metabolic action of its own.

Conclusion

101 Taking all of the above into account, I do not consider that the products for which the two SPC applications have been applied for in this instance, Taxol® in SPC/GB/14/030 and Taxol® eluting-stent in SPC/GB/14/031, have been subject to an administrative procedure as laid down in Directive 2001/83/EC. Thus, the product is not eligible to be the subject of an SPC certificate under Article 2 of EC Regulation 469/2009, the SPC Regulation.

102 Given the conclusion in relation to Article 2 above, it also follows that SPC applications SPC/GB/14/030 and SPC/GB/14/031 do not meet the requirements laid down in the SPC regulation, in particular, Article 3 thereof. As a consequence, they are rejected under Article 10(2) of the SPC Regulation.

Appeal

103 Any appeal must be lodged within 28 days.

Dr L Cullen
Deputy Director, acting for the Comptroller