IS THERE A FUTURE FOR MEDICAL DEVICE SPCs? PAST, PRESENT AND FUTURE PERSPECTIVES

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Introduction

The Supplementary Protection Certificate (or 'SPC') system in Europe provides a means of compensating pharmaceutical patentees for the period of lost protection between patent filing and obtaining regulatory approval, during which they are unable to market the products of their invention.

When the legislation governing SPCs was proposed in 1990, it expressly referred to two types of products which could benefit from such compensation: medicinal products (for human or veterinary use) and plant protection products. The main proposal for the SPC system[1] made no mention of medical devices at all; and, indeed, medical device regulation was not harmonised in Europe at the time.

Since then, legislation governing medical devices across Europe has become more harmonised, and, furthermore, more rigorous. First, around the same time in the 1990s, three European Directives were implemented governing medical devices ('MDD'), active implantable medical devices ('AIMDD') and *in vitro* diagnostic medical devices ('IVDMDD'), respectively. This legislation included cross-references to the harmonised legislation governing medicinal products. More recently, the entire legislative framework for medical devices has been overhauled with the entering into force of two regulations for medical devices ('the MDR') and *in vitro* diagnostic medical devices ('the IVDMDR') on 25 May 2017.[2]

The harmonised and heightened regulation of medical devices has led to longer time periods for obtaining marketing approval and, as a result, medical device manufacturers and patentees have sought compensation for their loss of patent protection by way of the SPC system.

In this article, we review the cases which have examined attempts to obtain SPCs for medical devices and consider whether medical devices in any event now qualify for their own SPC system.

Background: Medical Device and Medicinal Product Regulation

Medicinal products for human use are governed by the provisions of Directive 2001/83/EC ('the MPD'), including to the extent incorporated into Regulation 726/2004 ('the MPR') for centrally authorised products.

As noted in the introduction, medical devices are now to be governed by the MDR and IVDMDR (succeeding the previous directives).

Determining whether a product is a medical device ('MD') or medicinal product ('MP') is based upon its '*principal intended action*'. Therefore the types of claims made for a product, in accordance with its method of action, represent an important factor when looking at its classification. MDs typically act by physical means (including mechanical action, physical barrier and replacement of, or support to, organs or body functions). MDs are often assisted in their function by pharmacological,

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1) Explanatory Memorandum to the Proposal for a Council Regulation (EEC) of concerning the creation of a supplementary protection certificate for medicinal products – COM(90) 101 final, 11 April 1990.

2) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

immunological or metabolic means, but as soon as any such means become more than ancillary and the product achieves its principal intended function through them, it will be classified as an MP. However, a product intended to administer a medicinal product or which incorporates a medicinal product may nevertheless be classified as an MD.

Even for products classified as an MD, they may nonetheless be treated as MPs in certain circumstances, in particular drug-delivery products where the device and MP form a single integral product. Examples of these include pre-filled syringes, aerosols containing a medicinal product, patches for transdermal drug delivery, nebulisers precharged with a specific medicinal product, intrauterine contraceptives releasing progestrogens, and plastic bead implants containing an antibiotic.[3]

'Borderline' is a self-evident term used to describe products which balance on the border between MD and MP classification. In fact, recent case law before the Court of Justice of the European Union ('the CJEU') has held that a single product may traverse the borderline and be classified as an MD or an MP depending on the approach of different Member States. This principle was confirmed by the CJEU in *Laboratoires Lyocentre*.[5]

In any event, there are many sophisticated devices used for therapeutic applications which are classified as MDs and not MPs, notwithstanding that they still require substantial clinical trials and assessment before approval. Examples of such devices include heparin-coated catheters, bone cements containing antibiotics, intrauterine contraceptives containing copper or silver, certain cancer treatments using nanoparticles, and drug eluting coronary stents.[4] It is the delays caused by the trials needed for some devices which have driven the case law in this area, as discussed below.

The SPC System

SPCs for MPs are governed by EU Regulation 469/2009/EC ('the SPC Regulation'). Key terms of the legislation are contained in the definitions in Article 1, in particular those for 'medicinal product' and 'product', and in the requirements for validity in Article 3, which require that:

> *(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; and*
>
> *(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.*

Based on the different regulations governing MDs compared to MPs (set out above), it is clear first and foremost that reference to 'medicinal products' in Article 1 and the MP legislation referred to in Article 3(b) present significant hurdles for an applicant seeking to obtain an SPC for an MD under the SPC Regulation. This is because, by its very definition, an MD is distinct from an MP (under regulatory legislation at least) and will not have been directly governed by the MP legislation set out in Article 3(b). Nonetheless, certain cases have tried to jump these hurdles by way of a teleological interpretation of the SPC legislation. We consider and review these cases below, along with how issues may arise under the Article 1 definitions and the requirements of Article 3.

On a related note, while key issues arise under Articles 1 and 3, Article 2 of the SPC Regulation should not be forgotten and sets out the scope of the whole system:

> *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*

3) The European Commission has published guidance on borderline products in MEDDEV 2.1/3 rev.3 – Borderline products, drug-delivery products and medical devices incorporating, as integral part, an ancillary medicinal substance or an ancillary human blood derivative (December 2009).

4) MEDDEV 2. 1/3 rev 3.

5) *Laboratoires Lyocentre v Laakealan turvallisuus – ja kehittamiskeskus* (Case 109/12) [2013] ECR 0.

> *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.* (emphasis added)

The references to MP and the MPD give rise to parallel issues as between Article 2 and Articles 1 and 3(b) (and in effect compounds the issues as between the two). Therefore, should an MD fail to satisfy the definitions under Article 1 and/or the requirements for validity under Article 3(b), it would follow that it would not satisfy Article 2 either. Thus, it would fall outside of the scope of the SPC system altogether. This fundamental objection, which has arisen in recent cases in Germany and the United Kingdom, highlights the need to consider whether a new and separate system for MD SPCs is needed, as we consider at the end of this article.

Question (1): Can a Device Satisfy the Definitions of 'Product' and 'Medicinal Product'?

The terms 'product' and 'medicinal product' are two of the key definitions in the SPC Regulation and are set out in Article 1:

> *(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 …*

There is no further guidance in the SPC Regulation on the meaning and scope of the term 'product', or 'active ingredient'. The case law in this area is reviewed in the recent UK case *Abraxis*.[6] In short summary, the case law has adopted a strict interpretation of '*product*' being an active ingredient (or combination thereof) which has (or each has) a pharmacological, immunological or metabolic action of its own in the authorised indication in question.

It is common practice, therefore, for an SPC applicant to name its product as the international nonproprietary name (INN) of the active ingredient in its marketing authorisation (that is, according to what is set out in section 2 of the Summary of Product Characteristics), in a consistent (or largely consistent) manner with the 'active substance' of the 'medicinal product' according to the MPD. While appearing to provide a broader coverage by referring only to the 'active ingredient', the scope of protection for an SPC is nonetheless conformed to that of the basic patent (according to Articles 4 and 5 of the SPC Regulation).

Considering an MD, this raises two key issues: first, the need for a *product*, or more specifically one or more *active ingredients*; and second, that such active ingredient be *of a medicinal product*. These issues are compounded under the definition of 'active ingredient' which refers to both. In effect, what is critical for the SPC Regulation is the definition of 'product', as exemplified by Article 4, which sets out the scope of protection for an SPC and refers specifically to the product (and not the medicinal product).

Although the definition of '*medicinal product*' in Article 1(b) of the SPC Regulation does not go as far as the corresponding definition in Article 1(2) of the MPD, which requires that the substance exert a pharmacological, immunological or metabolic action, such effects have nonetheless been incorporated into the law governing SPCs via the definition of product/active ingredient applied by CJEU case law (discussed below). Further, recent attempts in cases to suggest that the difference provides a distinction to the MPD and opens the door for MD SPCs have also been rejected and closed.

Notwithstanding the potential issues in squaring MDs with the SPC system, this may not be an issue in all cases, in particular if the MD in question comprises an active ingredient. In such cases the applicant is free to list the INN of that active ingredient as its 'product', which should not cause problems per se (and, for example, the scope of protection is nonetheless restricted to that of the basic patent, which in the case of an MD is likely to restrict it to use with the device in

6) *Abraxis Bioscience LLC v Comptroller General of Patents* [2017] EWHC 14 (Pat).

question). This draws a parallel to the usual approach for product definitions used for MP SPC applications, which typically refer only to active ingredients (and salts and esters thereof) notwithstanding other substances in the MP, and with reference to its therapeutic use (as confirmed by the CJEU in *Yissum*[7]).

This poses an interesting question as to whether an applicant might be able to go one step further than the above-mentioned scenario, and define its 'product' using a combination of the active ingredient and the device. For example, an applicant could distinguish the use of a well-known active ingredient in its product from the active ingredient alone, which might help to distinguish it from earlier authorisations and/or SPCs (see Article 3(b) and (c) and 3(d) discussed below). However, the scope of 'active ingredient' and combinations thereof has been interpreted narrowly. For example, in *Abraxis* (Note 6 above), the UK IPO rejected arguments that the 'product' was anything other than the known active ingredient in question (that is, paclitaxel) and not that active ingredient associated with albumin nanoparticles (nab-paclitaxel).

This view was supported by an analysis of the description of the product in the Summary of Product Characteristics and the European Public Assessment Report ('EPAR') underlying the marketing authorisation, which in this case referred to paclitaxel as the active ingredient of the MP in question (Abraxane), suggesting that nab-paclitaxel was the formulation. Further, in combination cases such as *GSK*[8] and *Forsgren*,[9] the CJEU has confirmed that each active ingredient in a combination must produce a pharmacological, immunological or metabolic effect of its own. Thus an excipient, which renders possible the pharmaceutical form of a product necessary for its therapeutic efficacy but which does not have any therapeutic effect of its own, cannot be considered an active ingredient.[10] In the same way, difficulties will likely arise in trying to incorporate a device in a product definition.

This difficulty would be compounded further if the device in question did not contain an active ingredient in the typical sense (for example, a chemical compound) at all. Again, it follows from *Forsgren* that if the device in question achieves its action via a physical means then it may be precluded from protection as simply having no pharmacological, immunological or metabolic effect of its own.

This issue was raised in the *Leibniz*[11] case before the German Federal Patent Court ('BPatG'). In this case, Leibniz filed an SPC application for '*aminosilane-coated iron oxide nanoparticles*', covering its NanoTherm product used for the treatment of brain tumours. The magnetic nanoparticles are injected directly into a tumour and then heated via magnetic induction, which results in the tumour cells being either irreparably damaged or sensitised for additional therapies. Applying the CJEU's decision in *Forsgren*, the BPatG refused the SPC application on the basis that the therapeutic effect of the NanoTherm product is achieved by physical means only, and therefore could not be considered a medicinal product, or indeed contain an 'active ingredient' at all. Therefore, the application fell at the first hurdle, and the court did not need to consider Article 3(b).

The *Leibniz* case also came to be rejected in the United Kingdom under the scope of the SPC Regulation according to Article 2 and also for failing the provisions of Article 3(b), as it was not deemed approved under the MPD. Notably, it was granted in the Netherlands, despite being initially rejected under Article 3(a), because the product '*aminosilaan coated fero-oxide nano particles*' was held not to be protected by the claims of the basic patent.

Leibniz is, therefore, an interesting case which illustrates the diversity (and lack of harmony) in the approaches to the SPC Regulation across Member States, as well as the difficulties which may be faced by an applicant seeking an SPC for a medical device.

Question 2: Can a Device Satisfy Article 3(b)?

Article 3(b) of the SPC Regulation requires that a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with the MPD (relating to human products) or Directive 2001/82/EC (relating to veterinary medicinal products), as appropriate.

7) *Yissum Research and Development Company of the Hebrew University of Jerusalem v Comptroller-General of Patents* (Case 202/05) [2007] ECR I–2839.

8) *GlaxoSmithKline Biologicals SA v Comptroller-General of Patents, Designs and Trade Marks* (Case 210/13) [2013] ECR 0.

9) *Arne Forsgren v Österreichisches Patentamt* (Case 631/13) [2015] ECR 0.

10) *Massachusetts Institute of Technology* (Case 431/04) [2006] ECR I-4089.

11) *Leibniz-Institut für Neue Materialien gemeinnützige GmbH* (14 W (pat) 45/12).

The difficulties faced in fitting an MD into this requirement are similar to those above given the reference in Article 3(b) to '*as a medicinal product*', thereby drawing close parallels with the definition in Article 1. However, the principal hurdle is the express reference to the MPD in Article 3(b) and not the MDD or other medical device legislation, which on its face may appear to exclude medical devices.

Two well-known cases concerning class III medical devices, *Genzyme* and *Yttrium*, arose in the early 2000s and offered hope for MD SPCs. In these cases, certain national patent offices adopted a broad, teleological approach to Article 3(b) on the basis of equivalence between the MD and MP regulatory procedures. Since then, however, there have been several decisions, in particular in the United Kingdom and Germany, which have adopted an arguably stricter approach and created a dimmer outlook for MD SPCs. We consider this landscape from the glimmer of hope to the more negative recent developments below.

Genzyme

This case relates to an SPC application for a replacement joint fluid specified as a combination of '*Hylan A and Hylan B*', which was marketed by Genzyme as Synvisc.

One of the leading, more detailed decisions in this case (which proceeded in parallel jurisdictions in Europe) was by the District Court of the Hague (in 2004).[12] In this case, the Court of the Hague indicated that a medical device could in principle form the basis for an SPC, where an integral part of the device is a substance which:

(i) if used separately, would be considered to be a medicinal product as defined in the SPC Regulation; and

(ii) is liable to act upon the body with action ancillary to that of the device.

The court also considered that the safety, quality and usefulness of Synvisc had been verified under the MDD to a comparable degree of testing under the MPD. It held the view that the mere fact that no reference is made to the MDD in the SPC Regulation does not preclude it from being applied to MDs.

Overall, therefore, the District Court seemed to feel able to overcome the issues concerning the definitions of 'product' and the 'medicinal product' in Article 1(b) by referring to the product which it considered was nonetheless a medicinal product working ancillary to a device. Indeed, the decision does not contain any discussion on Article 1(a) and (b). Instead, the District Court focused on the issue of Article 3(b), which it felt was satisfied based on sufficient parity between the stringency of procedure underlying the MD legislation.

However, when the case was referred back to the Dutch patent office for a new decision based on the findings, the application was again denied on the basis that the patent office did not consider that the procedure for the safety, quality and usefulness of the active ingredient had been carried out in accordance with the procedures set out in the MPD. Therefore, despite the promise of the positive decision by the District Court, the Dutch SPC was in fact rejected.

In the meantime, the SPC proceeded to grant in other countries, including the United Kingdom,[13] France and Italy.[14] We are not aware of substantive decisions in these countries, but the UK IPO granted an SPC for the Hylan products, entitled 'Hylan A (rooster comb hyaluronan cross-linked with formaldehyde) and Hylan B (Hylan A further cross-linked with divinyl sulfone)', on the basis of concomitant approvals under the MDD. The UK SPC entered into force in October 2010 and expired in September 2012.

Similarly to the Dutch case, the SPC was refused in Germany under Article 3(b) on the basis that the authorisation procedure under the MDD was not equivalent to that required by the MPD (and the fact that SPCs had been granted in the United Kingdom and France did not matter).[15]

Yttrium

The SPC in this case covered a radioactive microsphere for use in cancer therapy. The device consisted of glass microspheres containing the stable isotope yttrium-89, which when irradiated would lead to the formation of a radioactive isotype yttrium-90, thus causing damage to cancerous tissue. The product was approved under the AIMDD and marketed as Therasphere.

12) *Genzyme Biosurgery Corp v Industrial Property Office*, BIE 70 (2002) 360–362 (Netherlands).

13) SPC/GB96/012 and SPC/GB96/013.

14) UB2007CCP983.

15) BPatG, decision of 8 March 2010 – 15 W (pat) 25/08.

In this case, a leading reasoned decision arose in Germany. Following the rejection of the application by the German Patent and Trademark Office (with a similar reason to that given in the German *Genzyme* decision above), the decision was reversed on appeal to the German Federal Patent Court.[16] The granting of the application was based on reasoning that the definition of medicinal product under the MPD could be extended to cover radioactive materials under the definition of 'radiopharmaceutical' in the MPD. The German Federal Court applied the extension similarly to Article 1(b) of the SPC Regulation and, further, was satisfied that the requirement under Article 3(b) was met because the assessment procedure undertaken for the product under the AIMDD was sufficient for the approval obtained to be considered equivalent to an authorisation under the MPD.

Interestingly, the equivalent SPC was nonetheless refused in the Netherlands, Italy and the United Kingdom, again highlighting the differences in approach taken by national patent offices.

Recent UK Decisions

In 2014/2015, three lengthy and reasoned decisions were handed down by the UK IPO rejecting SPCs for medical devices in *Cerus*,[17] *Leibniz*[18] and *Angiotech*.[19]

Cerus

This decision concerned two SPC applications for devices covering Cerus' Intercept System, a class III MD that used light-activated compounds to decontaminate blood. The SPC applications sought to protect an amotosalen-treated platelet product and an amotosalen-treated plasma product.

Cerus relied on EC design examination certificates granted under the MDD as the relevant marketing authorisations for the purposes of Article 2 and 3(b) of the SPC Regulation, and argued that, as the devices incorporated, as an integral part, a medicinal product (amotosalen) which had to be assessed in accordance with the principles of evaluation of new active substances (that is, pursuant to the MPD), the two procedures should be given equivalence.

However, after a thorough examination of the MPD and MDD approval regimes, the UK IPO refused the applications on the basis that the assessment carried out in relation to the class III medical device, that is, the safety, quality and usefulness of the substance, is not the same as or equivalent to the process carried out to authorise a medicinal product for human use. Cerus did not appeal the decision.

The UK IPO commented on the previous *Genzyme* and *Yttrium* decisions allowing MD SPCs, stating that due to their date (the UK *Genzyme* SPC was granted in 1998) and as no consensus was reached they should not be treated as binding.

Interestingly, SPCs for the Intercept system were granted in Germany and Italy. In the case of Germany, it is tempting to speculate that this followed the reasoning in *Yttrium* (but no decisions are available in either Germany or Italy).

Leibniz

Already mentioned above, this case relates to an SPC for Leibniz's NanoTherm product, a formulation of iron oxide nanoparticles which are injected directly into a tumour and heated by an electromagnetic field to destroy the tumour cells. The particles were authorised under the MDD as class III medical devices.

Taking a similar approach to *Cerus*, the UK IPO again rejected the applications under Articles 2 and 3(b), on the basis that the respective objectives of the procedures for carrying out assessments under the MDD and MPD were not the same. In particular, the mode of action of NanoTherm was highlighted as being more akin to MDs, where the principal mode of action is physical, as opposed to MPs that act by pharmaceutical, immunological or metabolic means. Therefore, this case was further distinguished from *Cerus* on the basis that the mode of action of the NanoTherm product was purely physical. Again, like Cerus, Leibniz has not appealed this decision.

While, unlike the German decision already mentioned above, there was no detailed discussion of Article 1(b), the decision makes reference to Leibniz's arguments that the scope of the definition of 'medicinal product' is narrower in the SPC Regulation compared to the MPD. Therefore, Leibniz argued, it should include substances which treat diseases by physical means and not just by pharmacological, immunological or metabolic means. However, it was the view of the Hearing

16) Case 14 W. (pat) 12/07.

17) *Cerus Corporation* (BL O/141/14).

18) *Leibniz-Institut für Neue Materialien Gemeinnützige GmbH* (BL O/328/14).

19) *Angiotech Pharmaceuticals Inc. and University of British Columbia* (BL O/466/15).

Officer that the differences between the definitions are immaterial and essentially relate to the same thing. Therefore, products which act only by physical means, which is of course part of the assessment in classifying an MD, would fall outside the definition. In this way, the UK decision chimes strongly with the basis for rejection in Germany, despite strictly speaking being under a different part of the SPC Regulation.

Angiotech

In this case, the SPC applications in question referred to the use of Taxol® (paclitaxel) for treating or preventing restenosis. Taxol®-coated stents treat restenosis by physically keeping the blood vessel open, and over time prevent the formation of new blood vessels around the stent. The application was based on an EC Design Examination Certificate authorised under the MDD as a class III medical device.

As with the *Cerus* case, the applicant argued that the procedure for obtaining an EC Certificate is sufficiently identical to the procedure under the MPD such that it could be used to support an SPC application under Article 3(b). Relying on the decision in *Laboratoires Lyocentre* (Note 5 above), Angiotech also argued that if the same product can be classified as a medical device in one country and a medicinal product in another, this implies equivalence between the two authorisation procedures and so SPCs should be granted for authorisations under the MDD and the MPD.

Further, Angiotech tried to distinguish its application from *Cerus* and *Leibniz* on the basis that (i) the principal intended action of the stent and Taxol® were the same, namely to treat and prevent restenosis (compared to *Cerus* where the principal intended actions of the device and product were different); and (ii) unlike the iron oxide nanoparticles in *Leibniz*, Taxol® was an active ingredient which, if used separately, would be considered an active ingredient.

However, following its earlier decisions in *Leibniz* and *Cerus*, the UK IPO rejected the application on the basis that the SPC Regulation only covers products authorised under the MPD and, in any event, the underlying objectives and assessment criteria used under the MDD are not the same as the MPD.

In contrast to the UK decision, Angiotech's SPC has been granted in the Netherlands and Italy (and is pending in Germany).

Summary

The above cases set out the hurdles faced by companies trying to obtain MD SPCs, and particularly how divergent decisions across Europe have created uncertainty for MD patentees. Table 1 summarises the key information in these SPC decisions, and compares how they have been treated in different jurisdictions.

Table 1

Applicant	Patent	Medical device	SPC Product	SPC granted?			
				UK	DE	NL	IT
Genzyme Biosurgery Corp	EP0320164	Synvisc (Hylan A and B)	Hylan A (rooster comb hyaluronan cross-linked with formaldehyde) and Hylan B (Hylan A further cross-linked with divinyl sulfone)	✓	✗	✗	✓
University of Missouri	EP0201601	Therasphere®	Yttrium-90 glass microspheres	–[a]	✓	✗	✗
Cerus Corporation	EP0707476	Intercept system for plasma and platelets	Two SPCs: (1) Platelet preparation obtainable by addition, and subsequent photoactivation, of amotosalen or its salt, to a suspension of platelets in plasma (2) Platelet preparation obtainable by addition to plasma, and photoactivation, of amotosalen or its salt	✗	✓	–	✓
Leibniz-Institut für Neue Materialien Gemeinnützige GmbH	EP0636111	NanoTherm	Aqueous dispersion of iron oxide nanoparticles	✗	✗	✓	✗
Angiotech Pharmaceuticals Inc.	EP2226085	Taxol®-eluting stent	Two SPCs for: (1) Taxol® (2) Taxol®-eluting stent	✗	*Pend.*	✓	✓

a) Information on the UK IPO register notes that an SPC application was lodged, but there is no further information on whether it was granted or rejected.

The three UK decisions in quick succession have created a negative environment for MD SPCs. In the case of *Leibniz*, this has been matched by negative decisions in Germany and Italy, but unmatched by the grant in the Netherlands. Indeed, equivalent treatment for both MDs and MPs under Article 3(b) seems complex, a point which was recognised by the German Federal Patent Court in the *Leibniz* appeal, which considered that it was not the discretion of the national courts to extend the scope of SPCs to MDs, as this can only be done by the regulatory authority. However, when the perspective is broadened to other Member States, the landscape becomes more fragmented and diverse as shown by the diverse decisions above.

Articles 3(a), (c) and (d): Straightforward if Article 3(b) can be Satisfied?

While the most material hurdles to MD SPCs are presented by Articles 1 and 3(b) (and 2), assuming that an MD SPC application was able to overcome them, we briefly consider (Table 2 below) how MD SPCs may nonetheless face challenges under the remaining parts of Article 3.

Table 2

Article	Issue
Article 3(a) – basic patent protection	To satisfy Article 3(a), the product specified in the SPC application must be protected by a basic patent in force. The correct interpretation of Article 3(a) has been the subject of several CJEU and national decisions; it is currently the subject of a referral to the CJEU[20] made by the UK court (Arnold J) on the basis of a lack of clarity in the correct interpretation of the test. In that case Arnold J has proposed his preferred test, that the product must: (i) fall within the scope of the claim; and (ii) do so because it contains an active ingredient or combination of actives which embodies the inventive advance (or technical contribution) of the patent. In the context of an MD, where the basic patent contains a claim for an MD together with an active, Article 3(a) may not pose an issue (provided the active is 'specified in the wording of the claim'[21] or that the claims 'relate, implicitly but necessarily and specifically' to the active[22]). In this way, if the MD is excluded from being applicable as part of the product definition for the purpose of the SPC Regulation, then it may also be discounted from impacting on the Article 3(a) test despite appearing in the claim. However, considering at least Arnold J's test, the inventive advance (or technical contribution) of such patents might encompass only the device and not any active ingredient at all. Further issues may also arise which concern any SPC application and not just MDs, which relate to use of any broad definitions (either for the device and/or the active ingredient component) and whether such terms sufficiently 'specify' the product in question.

20) *Teva UK Limited and Others v Gilead Sciences Inc* (Case 121/17) [2017] EWHC 13 (Pat).

21) *Medeva BV v Comptroller General of Patents, Designs and Trade Marks* (Case 322/10) [2011] ECR I–12051.

22) *Eli Lilly and Company Ltd v Human Genome Sciences Inc* (Case 493/12) [2013] ECR 835.

Article	Issue
Article 3(d) – earlier marketing authorisations?	Assuming a scenario where an applicant is able in principle to obtain an SPC for active ingredient X based on an MD marketing approval, it is possible that this will not be the first approval for that active ingredient, which may well have been developed and marketed in the past as a medicinal product on its own. Therefore, the applicant would need to argue that its approval (as an MD) was the 'first authorisation' for the purposes of its SPC application under Article 3(d). *Neurim* is the significant case on Article 3(d).[23] The case related to the Circadin product, a formulation of the hormone melatonin which was marketed by Neurim for use in treating insomnia in humans. However, an authorisation for the use of melatonin in veterinary medicine, marketed as 'Regulin', had already been granted in 2001. Following a referral by the UK courts, the CJEU held that the earlier authorisation did not preclude the grant of an SPC for a different application of the same product (provided that new application is covered by the basic patent). That case therefore held that a second medical use was able to satisfy the test for a 'different application' of an active ingredient. The pending referral in the *Abraxis* case raises the question of whether a new formulation may also qualify as a 'different application' according to the principle in *Neurim*. This begs the question of whether an MD SPC application may also qualify for the benefit of the principle in *Neurim*. Should an MD SPC get this far, it is tempting to speculate that it would do so but this will depend on the facts and may be strongly influenced by the outcome in *Abraxis* as to how far the principle in *Neurim* extends.
Article 3(c) – earlier SPCs	Article 3(c) requires that the product of an SPC application has not already been the subject of an SPC. There has been extensive case law on the interpretation of this provision; clarifying that multiple SPCs may be granted to different parties for the same product – a so-called 'one SPC per product per patentee' rule. This has been further tested in combination case law addressing whether a patentee may have more than one SPC per patent, and whether a combination SPC is distinct from a previous mono-SPC. In the MD context, a similar issue arises under Article 3(c) to that under Article 3(d) concerning earlier authorisations, which is that where an active ingredient is involved (as with any 'follow-on' invention), what happens if it is the subject of a prior SPC? Provided that any earlier SPC is held by another patentee, this should not be a problem. However, if the same applicant has developed a device-based invention for an active ingredient for which it had a previous patent and SPC, this would raise an unanswered question as to whether such invention would be eligible for an SPC. Indeed, the question did not arise in *Neurim* and it remains to be seen whether, in the hands of the same applicant, *Neurim* can be relied upon and whether it might extend the scope of Article 3(c) as well as Article 3(d).

23) *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents* (Case 130/11) [2012] ECR 489.

Looking to the Future

It is no secret that the European Commission is looking into potential reform of the SPC system, in particular following the publication of a consultation roadmap in February 2017.[24] In that roadmap, the EC highlights the fragmentation caused by inconsistent approaches to interpretation of the SPC Regulation by national patent offices. Such fragmentation clearly applies to the differing treatment of MD SPC applications by national patent offices, as discussed above.

In the legal study being coordinated by the Max Plank Institute commissioned as part of the EC's investigations, industry bodies and other stakeholders are participating in a questionnaire in which one of the questions asks whether the SPC system should be expanded to include other areas, of which one is medical devices. It will be interesting to see what kind of response is received from stakeholders on this issue, with the results expected later in 2017.

Based on the issues highlighted in this article, it would seem to be a much cleaner and manageable fit to, if it is deemed justified, adopt a new purpose-built SPC system for medical devices much like the current distinction between medicinal and plant protection products. Not only would this allow the existing SPC Regulation to remain focused on MPs, it would enable fundamental issues of scope and other key areas to be tailored to fit the medical device field. For example, the US Patent Term Extension (or 'PTE') system provides for PTEs for medical devices – a noteworthy point in itself, when considering whether Europe should also have such a system – but only for Class III devices (according to the US FFDCA classification system). Applying the same scope to Class III MDs (according to the European classification) is therefore an obvious consideration.

While not fundamentally creating an obvious inlet for SPCs which was not there before, the new MDR presents a new dawn for medical device regulation in Europe which creates a uniform and harmonised basis that could be used for a new SPC regulation for MDs. In light of these recent developments in the medical device field, and especially considering the divergent treatment of MD SPCs across Europe, there remains considerable momentum for further reform to the SPC system. While some of the sentiment underlying the EC's investigations into SPCs might be perceived negatively by patentees in the life sciences field, the prospect of expanding the SPC system to MDs offers a more positive outlook.

24) http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_grow_051_supplementary_protection_certificates_en.pdf.