

EXTENDING PATENTS TO MEDICAL DEVICES IN EUROPE

INTELLECTUAL PROPERTY AND TECHNOLOGY LAW JOURNAL, FEBRUARY 2011

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Much has been written about extending patents in the pharmaceutical field. There has not been as much published in connection with patent extensions for medical devices. Yet new developments in Europe promise greater opportunities and rewards for innovators in the field of medical devices in extending the periods of their patent-based exclusivities. In particular, with increasingly empty pipelines for innovative pharmaceutical products, there has been increasing interest in drug-device combination products to treat some of the most important indications. For that reason there is added urgency for developers to consider lifetime management issues for these products.

The first part of this article provides a brief description of the system for extending patents that applies in member states of the European Union. The second part of this article discusses issues and considerations of particular interest regarding medical devices, and in particular, drug-device combination medical devices. The last part of the article sets forth its conclusions.

Extending Patents in the European Union

Both the European Union and the United States provide for the potential extension of patents that relate to products that require regulatory approval before they can be marketed. Such extensions are called supplementary protection certificates (SPCs) in the European Union, whereas they are usually called patent term extensions (PTEs) in the United States. The United States additionally provides the potential to extend a patent for unreasonable delays during prosecution at the US Patent & Trademark Office (PTO); such patent term extensions are usually called patent term adjustments (PTAs). Regulation (EC) No 469/2009 of the European Parliament and of the Council (Medicinal Products) (SPC Regulation) is the instrument that provides and specifies the requirements for obtaining an SPC in EU member states. [\[FN1\]](#) The SPC Regulation is substantially similar to its predecessor, Council Regulation (EEC) No 1768/92 of 18 June 1992, which it updates and replaces. The SPC Regulation implements a system for grant of SPCs through applications at the national patent offices of the EU member states when underlying patent coverage exists and when a patent extension is desired. [\[FN2\]](#) The granted SPC provides an extension in only the member state in which it was granted. An SPC may extend the term of a patent by up to five and a half years. [\[FN3\]](#)

Each national patent office and the courts of the corresponding jurisdiction may interpret the provisions of the SPC Regulation as they apply in specific disputes independently of decisions on the same or similar issues taken in other member state patent offices and courts. This has led to inconsistent decisions in various cases. However, the courts of the member states are able to refer

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SPC-related issues in specific cases to the European Court of Justice (ECJ); increasingly frequent use of this device has provided a modicum of harmony regarding SPC law across the EU member states.

What Is Covered?

An SPC may be granted for any product protected by a patent in the territory of an EU member state that is subject to an administrative authorization procedure “as laid down in Directive 2001/83/EC [pertaining to medicinal products for human use] ... or Directive 2001/82/EC [pertaining to veterinary medicinal products]” before being placed on the market as a medicinal product. [\[FN4\]](#)

“Medicinal product” is defined broadly as including products for treating or preventing disease and products administered with a view to making a medical diagnosis or to restoring, correcting, or modifying physiological functions in humans or animals.

Most critically, “product” is defined as meaning “the active ingredient or combination of active ingredients of a medicinal product.” Thus, on its face, the SPC Regulation appears to exclude purely mechanical medical devices from the scope of its coverage. This is unlike the situation in the United States, where patent term extensions for at least some medical devices may be obtained. [\[FN5\]](#) It does not, however, necessarily exclude drug-device combination medical devices, as will be explored further later in this article.

Conditions for Obtaining an SPC

The SPC Regulation requires, for an SPC to be granted in a particular EU member state, that:

- The product is protected by a basic patent in force in that EU member state;
- A valid authorization to place the product on the market in that EU member state as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
- This authorization must be the first authorization to place the product on the market in that EU member state as a medicinal product [\[FN6\]](#); and
- The product has not already been the subject of an SPC in that EU member state. [\[FN7\]](#)

A number of legal issues and disputes have arisen from these requirements that have been resolved by case law. The following discusses some of the most important issues.

The Possibility of Differing Basic Patentees Each Being Able to Obtain an SPC Based on the Same Product

A “basic patent” that may be the basis of an SPC is a patent that protects the relevant product as such, a process to obtain that product, or an application of that product, and which is so designated by its holder in an SPC application. [\[FN8\]](#)

There is, however, often more than one patent that so protects the relevant product and that is thus eligible for designation as a basic patent. The holder of a plurality of such patents may designate only one of them as the basic patent in the SPC application. However, when there are different parties that each hold a candidate patent for a basic patent, then each of the parties may apply and obtain an SPC based on the basic patent that he/she holds. [\[FN9\]](#) The ECJ has held that the SPC Regulation does not prevent the grant of an SPC to the holder of a basic patent if, at the time of submission of the application for a certificate, one or more SPCs have already been granted to one or more holders of one or more other basic patents. [\[FN10\]](#)

The possibility that differing basic patentees may obtain respective SPCs in an EU member state based on the same marketing authorization is distinctly different from the situation in the United States, where only a single patent term may be extended based on a particular marketing authorization. [\[FN11\]](#)

The Requirement That a Basic Patent in Force “Protect” the Product

Whether a basic patent “protects” a product as set forth in the SPC Regulation is not entirely consistent with patent law notions of coverage of the product (or the method of using the product) by the relevant claim of the patent. For example, UK courts have held that a claim reciting the medicament lansaprazole did not “protect,” in the sense of the SPC Regulation, an authorized product comprising the combination of lansaprazole with another active. [\[FN12\]](#) This was so even though it was clear that the claim covered the authorized product as a matter of patent law. The court found that the fact that neither the claim nor the specification of the patent disclosed or suggested the combination of lansaprazole with another active meant that the patent did not “protect,” for purposes of the SPC Regulation, the combination of lansaprazole with any other active ingredient. [\[FN13\]](#)

Relatedly, the UK Intellectual Property Office has found that the acetate salt of a polypeptide was protected, in the sense of the SPC Regulation, by at least one claim of the basic patent, even though the claims did not literally cover derivatives of the polypeptide. [\[FN14\]](#) The decision was based at least partially on the fact that the specification disclosed the acetate salt of the polypeptide. [\[FN15\]](#)

Other member states have taken differing approaches on when a basic patent “protects” a product in accordance with Article 3(a) of the SPC Regulation. For example, Germany and Norway have adopted a more liberal infringement test, whereby a basic patent is deemed to “protect” a product, when, for example, the product would infringe a claim of the basic patent. In such jurisdictions, a claim in the basic patent reciting the feature A would be deemed to protect a product comprising the combination of features A and B. It is expected that a recent reference to the ECJ from the UK Court of Appeal will eventually resolve this issue and harmonize the rule across the member states of the European Union. [\[FN16\]](#)

Thus, whether a claim of a candidate basic patent “protects” the authorized product under the SPC Regulation is not straightforward and requires consideration and analysis of case law of the EU member state where an SPC is desired.

Where the Marketing Authorization and Patent Belong to Separate Parties

An applicant for an SPC must provide, among other things, a copy of the marketing authorization to place the corresponding product on the market, including a summary of the product's characteristics. [\[FN17\]](#) Given that it is not unusual for differing parties to each have a patent covering a product, this requirement may be problematic for an SPC applicant that does not hold the marketing authorization to place the product on the market. The ECJ has ruled that an SPC application cannot be refused based on only the inability of the SPC applicant to provide the marketing authorization-related information required by the SPC Regulation. [\[FN18\]](#) In *Biogen*, the ECJ stated that the national SPC-granting authority had the option (but not necessarily the obligation) to request and obtain the marketing authorization-related information from the authority that granted the marketing authorization. [\[FN19\]](#)

As an example of the practice of a national patent office in this regard, the UK Intellectual Property Office requires an applicant to provide evidence that the applicant had tried but failed to obtain a

copy of the marketing authorization from its holder before requesting it from the authority that granted it. [\[FN20\]](#)

The possibility that a basic patent holder that is independent of the marketing authorization holder may obtain an SPC in an EU member state is distinctly different from the situation in the United States, where there must at least be an agency relationship between the patent owner and the applicant for marketing authorization during the regulatory review period in order for a term extension to be granted to the patent owner. [\[FN21\]](#)

Importance of the Definition of the “Product”

As indicated earlier, the SPC Regulation defines the product that is eligible for an SPC as “the active ingredient or combination of active ingredients of a medicinal product.” Despite this explicit definition, disputes have often arisen when the applicant applies for an SPC based on a product that is similar to, or a variation or improvement of, a previously approved product. Given the requirement of the SPC Regulation that the marketing authorization required for grant of an SPC be the first authorization to place the product on the market in the relevant EU member state, the SPC applicant will in many cases desire that the SPC-granting authority define the “product” narrowly in a way that does not include within its scope similar, previously approved products. [\[FN22\]](#)

For example, in a case that reached the UK Patents Court, the applicant had applied for an SPC based on a marketing authorization for an unpressurized asthma inhaler containing budesonide in the form of agglomerated micronized particles. However, two earlier marketing authorizations had been granted for inhalers containing budesonide in another form and including a propellant and surfactant. The Patents Court affirmed the decision of the UK Intellectual Property Office that rejected the SPC application, finding that the active ingredient “budesonide” was the relevant “product” as defined by Articles 1(a) and (b) of the SPC Regulation in all three marketing authorizations. [\[FN23\]](#)

“Product” Does Not Include Uses Recited for the Product in the Claim of the Basic Patent

Relatedly, the ECJ has ruled that, when the marketing authorization is for a particular use of a medicament and the basic patent of the SPC application is based on a use claim, the “product” as defined by the SPC Regulation is only the active ingredient of the medicament and does not include the use recited in the relevant claim of the basic patent. [\[FN24\]](#) In that case, the relevant claim of the basic patent recited the topical use of calcitriol for the treatment of skin disorders, the SPC application was based on a marketing authorization for such topical use of calcitriol and prior marketing authorizations for intravenous and oral administration of calcitriol for treatment of renal failure existed. [\[FN25\]](#) Because the ECJ found that the product of the SPC application was merely calcitriol (and did not include the use of calcitriol as recited in the claim of the basic patent), the applicant's application for an SPC was ultimately rejected. [\[FN26\]](#)

Combination of Substances

The ECJ has also ruled that, when the authorized product consisted of a combination of two substances, one of which is the active ingredient and the other of which is necessary for the therapeutic efficacy of the first substance for the relevant indication, the “product” for purposes of the SPC Regulation is solely the first substance (*i.e.*, the active ingredient). [\[FN27\]](#) In that case, the SPC application was rejected because of a prior marketing authorization to the active ingredient by itself. Once again, the SPC applicant had unsuccessfully advocated for a narrow definition of the product under the SPC Regulation as being the combination of the two substances.

On the other hand, an SPC may be obtained based on a marketing authorization for a combination product comprising two active ingredients (as opposed to a combination comprising an active ingredient and another substance that is not active), despite the grant of an earlier marketing authorization for only one of the active ingredients. [\[FN28\]](#)

SPCs for Medical Devices

At first glance, the requirement of the SPC Regulation that an SPC-protected product include an “active ingredient” appears to rule out SPCs for most or all medical devices. [\[FN29\]](#) However, a large class of medical devices—drug-device combinations—are medical devices that often include active ingredients. Thus, they may, in principle, be eligible for SPC protection. Article 3(b) of the SPC Regulation, however, additionally requires that a grant to place the relevant product on the market in the relevant EU member state have been received “in accordance with Directive 2001/83/EC or Directive 2001/82/EC.” The former relates to the approval process for marketing of medicinal products, whereas the latter relates to the approval process for marketing of veterinary medicinal products. [\[FN30\]](#)

Drug-Device Combination Medical Devices Regulated as Medicinal Products

There is a large class of medical devices that are regulated under Directive 2001/83/EC (MPD) and are thus eligible, consistent with Article 3(b) of the SPC Regulation, for SPC protection. In particular, a drug-device combination medical device will be regulated under the MPD when the device is assisted in its function by pharmacological, immunological, or metabolic means that are not merely ancillary to the principal intended action of the product.

On the other hand, if the assistance by pharmacological, immunological, or metabolic means to the functionality of the device is ancillary, and the function of the medical device is achieved primarily by physical means (such as mechanical action, physical barrier, replacement of or support to organs or body functions), then the MPD does not apply, which appears to, in the first instance, imply that the device is not eligible for SPC protection based on Article 3(b) of the SPC Regulation. For example, Directive 93/42/EEC on medical devices (MDD) and Directive 90/385/EEC on active implantable devices (AIMD) respectively cover medical devices and active implantable devices that may also include medicinal products whose functionality is ancillary to that of the device component. Article 3(b) of the SPC Regulation, through its requirement that marketing authorization be received “in accordance with Directive 2001/83/EC or Directive 2001/82/EC,” at first glance appears to rule out SPCs for devices approved based on the MDD or AIMD.

Examples of Drug-Device Combination Medical Devices and Their Corresponding Regulatory Regimes

Non-binding guidance provided by European Commission illustrates the distinction between devices regulated by the MPD and those that are not so regulated through a number of helpful examples. For example, the following drug-delivery devices are regulated primarily under the MPD: pre-filled syringes, aerosols containing a medicinal product, nebulizers precharged with a specific medicinal product, patches for transdermal drug delivery, plastic bead implants containing an antibiotic for treating bone infections, intrauterine contraceptives whose primary purpose is to release progestrogens, wound dressings containing an antimicrobial agent where the primary action of the device is to administer the agent to the wound for controlling the infection. On the other hand, drug-delivery pumps, implantable infusion pumps, nebulizers, syringes and jet injectors, spacer devices for use with metered dose inhalers are examples of drug-delivery devices that are regulated as medical devices under the MDD and not as medicinal products under the MPD. Furthermore, the following medical devices integrally incorporate ancillary medicinal substances and are primarily regulated under the MDD but not the MPD: catheters coated with heparin or an antibiotic agent,

bone cements that contain an antibiotic, root canal fillers with ancillary medicinal substances, soft tissue fillers containing local anesthetics, bone void fillers that contain a medicinal substance that assists or complements the primary bone-growth function of the corresponding bone void filler, condoms coated with spermicides, wound dressings coated with an antimicrobial agent, drug eluting coronary stents.

Are Drug-Device Combination Medical Devices Not Regulated as Medicinal Products Eligible for SPC Protection?

The requirement of Article 3(b) of the SPC Regulation that a product intended for humans be authorized in accordance with the MPD for SPC protection appears, at first glance, to rule out SPC protection for devices not regulated under the MPD. However this provision merely requires that marketing authorization “*in accordance with Directive 2001/83/EC*” be received for such a product for eligibility for SPC protection. (Emphasis added.) This raises the issue of whether, for example, the MDD and the AIMD (under which medical devices that include medicinal products whose functionality is ancillary to that of the device component are approved) are marketing authorizations “in accordance with” the MPD.

There have been at least two court decisions that have reversed a rejection of a SPC application by the national patent office that found that a product that had been approved under either the MDD or the AIMD was not approved “in accordance with” the MPD. These decisions suggest that at least some national patent offices may permit SPC protection for medical devices approved under the MDD or the AIMD. However, neither of these decisions involved drug-device combinations in the traditional sense.

The German Federal Patent Court's Yttrium-90 Decision

The German Federal Patent Court recently overturned a decision of the German Patent and Trademark Office rejecting an application for an SPC for a radioactive microsphere product for implantation in cancer therapy that had been approved in accordance with the AIMD (the *Yttrium-90* case or *Yttrium-90*). [\[FN31\]](#)

The device in question contained the stable isotope yttrium-89 within glass microspheres, which would be placed in or near cancerous tissue in the patient. Then, the yttrium-89 in the device would be irradiated using a neutron beam, which would lead to formation of the radioactive isotope yttrium-90, which in turn would radioactively decay and produce radiation that destroyed the cancerous tissue. [\[FN32\]](#)

The German Patent and Trademark Office originally rejected the SPC application on the basis that it had been approved pursuant to the AIMD, and not pursuant to the MPD. The German Federal Patent Court reversed this decision, finding that although authorization to market the product had been obtained under the AIMD, the product in activated form contained the active ingredient yttrium-90, which was also a radioactive medicinal product in accordance with the MPD. The court in particular cited the AIMD provision that states “[w]here 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 the [MPD] 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” Thus, it was important to the court in reaching its decision that (i) the product in question contained a medicinal component that would normally have required authorization under the MPD, (ii) but that the AIMD explicitly required approval under the cited AIMD provision despite that fact. Based on this rationale, the court found that approval under the AIMD was “in accordance with” the MPD, consistent with Article 3(b)

of the SPC Regulation, and reversed the German Patent and Trademark Office's decision to not award and SPC.

The Court of Hague's Genzyme Decision

The Court of Hague had in 2004 indicated that a medical device that was regulated in accordance with the MDD and that included, as an integral part, a substance (i) which if used separately, would be considered to be a medicinal product under the precursor EU Directive to the MPD, [\[FN33\]](#) and (ii) which is liable to act upon the body with action ancillary to that of the device, could in principle be granted an SPC. The medical device in question was Synvisc, which is a replacement joint fluid for body joints such as the knee. The court found that whether Synvisc had been subjected to the analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products required by the MDD (for substances that act upon the body with action ancillary to the device) was the determinative factor for whether an SPC could be granted. The court remanded the case to the Dutch national patent office for a new decision based on the court's holding (the *Genzyme* case or *Genzyme*). [\[FN34\]](#)

Thus, based on the *Genzyme* and *Yttrium-90* decisions, it may be possible to obtain SPC protection for a medical device, regardless of whether the MPD or the MDD and/or the AIMD is the applicable regulatory statute. However, whether courts in jurisdictions other than Holland and Germany adopt the rationale of the *Genzyme* and *Yttrium-90* decisions remains to be seen.

Drug-Device Combinations

Neither the *Yttrium-90* decision of the German Federal Patent Court nor the *Genzyme* decision of the Court of Hague dealt with a drug-device combination product. The product in the former case, microspheres made using yttrium-89 (which would be transformed into yttrium-90 and activated by irradiation after placement in the patient's body), did not include separable drug and device components and was instead an integral product that simultaneously exhibited features of a device and a drug. The product in the latter case was a medical device consisting of a fluid, that arguably was, at the same time, a drug. Thus, arguably neither of these products included separate drug and device components, unlike most drug-device combination products.

These facts about the products involved in the *Yttrium-90* and *Genzyme* decisions raise the issue of under what circumstances an SPC could be granted to a drug-device combination product. In a typical case, the product may involve the combination of a known compound A and, for example, mechanical medical device D.

First Scenario: Existing SPC to Drug

In one scenario under this typical case, an applicant may apply for an SPC based on a marketing authorization directed to compound A by itself (without any medical device component) and a claim of a basic patent directed to the compound per se. This, of course, is the usual scenario in which an SPC is sought that covers the drug itself (without any medical device component). Such an SPC would likely also cover the combination of compound A and medical device D, given Article 4 of the SPC Regulation, which states that “[w]ithin the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorizations to place the corresponding medicinal product on the market and *for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.*” (Emphasis added.)

Second Scenario: Application for an SPC for Device Given Earlier SPC for Drug

It will sometimes be the case, however, that a company will develop commercial interest in a combination product including compound A and medical device D long after the marketing authorization for the drug product including only compound A is received. In such a case, an SPC may have already been applied and received for the drug product including only compound A by the time the combination product including compound A and medical device D becomes of interest. Any such SPC that had been earlier received may, for example, have expired by that time. In that case, a new SPC cannot be obtained for purposes of protecting the drug-device combination product, given the requirement of the SPC Regulation that “the product [not have already] been the subject of a certificate” (and given that Article 1 of the SPC Regulation limits the eligible “product” to only the active ingredient or combination of active ingredients of a medicinal product).

Third Scenario: Application for SPC for Device Long After Marketing Authorization for Drug

If, however, the company, despite having obtained marketing authorization for and marketed the drug product comprising compound A, has not yet applied for an SPC, then it is likely that any such application made after it develops interest in a combination product will be too late. This is because the SPC Regulation requires that any application be made within six months of the later of the grant of the basic patent and the grant of the relevant marketing authorization. [\[FN35\]](#) Further, a later marketing authorization for the combination product comprising the compound A and medical device D cannot be the basis for the application for an SPC in this case, given the SPC Regulation's requirement that the marketing authorization forming the basis for the application be “the first authorization to place the product on the market as a medicinal product.” [\[FN36\]](#)

Fourth Scenario: Application for SPC Based on Basic Patent Claiming the Device

In another scenario, an applicant may wish to obtain an SPC based on a basic patent that claims the medical device D in combination with the known compound A. [\[FN37\]](#) The underlying marketing authorization in this scenario may be directed to either (i) compound A by itself, or (ii) the combination product comprising compound A and the medical device D. However, an SPC likely cannot be granted in this scenario. This is because of the requirement of Article 3(a) of the SPC Regulation that the basic patent “protect” the “product.” Given the SPC Regulation's definition in Article 1(b) of “product” as the active ingredient or combination of active ingredients of the medicinal product, that product, regardless of whether the underlying marketing authorization is of type (i) or (ii), will be taken in such a scenario to be compound A by itself. However, it is likely that the basic patent will be found to not “protect” this product, because the claim narrowly recites the combination of compound A and medical device D and would not cover compound A by itself. [\[FN38\]](#)

Fifth Scenario: Application for SPC Based on Basic Patent Claiming Use of the Compound with the Device

In arguably the most interesting scenario, the applicant may apply for an SPC based on a basic patent that contains a claim such as:

“Compound A for use with medical device D for curing disease X.” [\[FN39\]](#)

The applicant or a third party in such a scenario may have first obtained marketing authorization for compound A by itself as a medicinal product, and the applicant may have thereafter obtained marketing authorization directed to the medical device product comprising compound A and medical device D in order to be able to actually market such a medical device product.

In this case, the applicant may apply for SPC protection based on the older marketing authorization directed to compound A by itself, and the patent containing the claim set forth above. Such an SPC may be granted, assuming the application for an SPC is made within six months of the later of the date of grant of the patent and the grant of the earlier marketing authorization in the relevant EU member state. [\[FN40\]](#) Such a patent should be considered to be a basic patent under Article 1(c) of the SPC Regulation, because the claim set forth above arguably protects an application of the product consisting of compound A, in compliance with Article 1(c) of the SPC Regulation.

Note that in this case a previously obtained SPC (e.g., that was obtained based on the earlier marketing authorization directed to compound A by itself and an older patent containing a claim that per se covers compound A) would be fatal and would prevent issue of a later SPC directed to the drug-device combination medical device. Additionally, even assuming no such prior SPC exists, the SPC directed to the drug-device combination would have to be applied for based on the earlier marketing authorization (directed to compound A by itself), because Article 3(d) requires the marketing authorization that serves as the basis for an SPC to be the first authorization to place the product on the market as a medicinal product. [\[FN41\]](#)

Finally, obtaining an SPC of non-zero term in this scenario requires that the basic patent be filed at least four and a half years before grant of marketing authorization in the Community for the product (i.e., the compound A). [\[FN42\]](#) This requires that the SPC filer anticipate potential commercial interest in a drug-device combination medical device product years in advance of obtaining marketing authorization for the drug on its own. [\[FN43\]](#)

Therefore, it may be advisable for applicants for patents directed to drug-device combination medical devices to include use claims as set forth above in addition to any apparatus or other claims they may file. Doing so may be helpful in obtaining effective SPC protection that covers the combination medical device.

Conclusion

Recent decisions from national courts of EU member states suggest that SPC protection may be obtained for particular types of medical devices obtained under any of the MPD, MDD, or AIMD. However, SPC protection may be more broadly available for a drug-device combination medical device where the basic patent contains use claims covering the drug and the device. Given these developments and possibilities, medical device manufacturers should consider patent extension through an SPC as part of the life cycle strategy for medical devices in Europe.

Table 1

Table Summarizing the Scenarios in Considering an SPC for a Drug-Device Combination Product

Marketing Authorization that is the Basis for the SPC Application	"Product" Under the SPC Regulation	Claim of the Basic Patent	Can an SPC be Granted?	Comments and Considerations
A formulation comprising active ingredient A for treating indication X	Compound A	Compound A	Yes	In many cases, the utility of a product comprising medical device D in combination with compound A will be realized long after the utility of compound A by itself is realized
Medical device D including a formulation comprising active ingredient A for treating indication X	Compound A	Compound A	Yes, but an important consideration is whether this is the first marketing authorization directed to compound A. Article 3(d) of the SPC Regulation requires that the timing requirements for applying for an SPC be calculated based on the first authorization to place the "product" on the market as a medicinal product	In many cases, an earlier marketing authorization to a formulation comprising active ingredient A will have been granted. Frequently, for such cases, an SPC will not be grantable, given the requirement that the SPC application be submitted within six months of the later of the basic patent and the earliest marketing authorization.

Marketing Authorization that is the Basis for the SPC Application	"Product" Under the SPC Regulation	Claim of the Basic Patent	Can an SPC be Granted?	Comments and Considerations
Formulation including active ingredient A for treating indication X	Compound A	Medical device D in combination with compound A	No The claim of the patent does not "protect" the "product" under Article 3(a) of the SPC Regulation. See, e.g., Centocor's SPC Application ^{FN} [FN44]	Under the usual canons of claim construction, the claim of the patent would not read on compound A by itself, and so the patent does not "protect" that "product" under Article 3(a) of the SPC Regulation
Medical device D including a formulation comprising active ingredient A for treating indication X	Compound A	Medical device D in combination with compound A	No. Under Article 1(b) of the SPC Regulation, the "product" will be considered to be compound A by itself, and the patent claim does not "protect" this "product" under Article 3(a) of the SPC Regulation	See entry above
Formulation including active ingredient A for treating indication X ^{FN} [FN45]	Compound A	Compound A for use with medical device D for curing disease X ^{FN} [FN46]		

[FN1]. A Regulation is a European Union legislative act that becomes law in all EU member states as soon as it is enacted.

[FN2]. Article 9 of the SPC Regulation.

[FN3]. The duration of an SPC may normally extend the term of a patent by up to a maximum of five years. However, the duration of an SPC may be extended by another six months when the SPC is for a human medicinal product for which data from clinical trials conducted in accordance with an agreed Paediatric Investigation Plan (PIP) have been submitted, as set forth in Article 36 of Regulation (EC) No 1901/2006.

[FN4]. Article 2 of the SPC Regulation.

[FN5]. US law explicitly provides that medical devices subject to regulation under the Federal Food, Drug and Cosmetic Act (Act) are eligible for patent term extensions. [37 C.F.R. § 1.710\(b\)\(3\)](#). More precisely, medical devices that are subject to premarketing approval under section 515 of the Act (*i.e.*, Class 3 medical devices) are eligible for patent term extensions. 20 C.F.R. § 60.3(b)(13).

[FN6]. This requirement makes the most sense when considered in conjunction with the separate requirement that the SPC application be filed at the national patent office of the EU member state within six months of the later of the date on which authorization to place the product on the market as a medicinal product was granted in the relevant EU member state and the date the basic patent issued. Article 7 of the SPC Regulation. Thus, in the more likely case of the marketing authorization being granted after the basic patent issues, Article 3 and 7 of the SPC Regulation together require that the application for an SPC be filed within six months of the date on which *first authorization* to place the product on the market as a medicinal product was granted in the relevant EU member state.

[FN7]. Article 3 of the SPC Regulation.

[FN8]. Article 1 of the SPC Regulation.

[FN9]. This is based on Recital (17) and Article 3(2) of Regulation (EC) No. 1610/96 (Plant Protection Regulation). Recital (17) of the Plant Protection Regulation states that Article 3 of the SPC Regulation is to be interpreted in accordance with Article 3(2) of the Plant Protection Regulation. Article 3(2) of the latter states that the holder of more than one candidate basic patent may be granted only one SPC for the relevant product. Article 3(2) further states that separate applicants for an SPC based on the same product who hold candidate basic patents may each be granted an SPC, as long as the second application was filed before the first was granted.

[FN10]. *AHP Manufacturing BV v. Bureau voor de Industriële Eigendom* [2009] C-482-07. This appears to conflict with the language of Article 3(2) of the Plant Protection Regulation, which requires, for a second SPC to a second party to be granted, that the first SPC application of the first party not be granted before the SPC application of the second is filed.

[FN11]. [35 U.S.C. § 156\(c\)\(4\)](#).

[FN12]. *Takeda Chemical Industries Ltd's Applications* [2004] RPC 3.

[FN13]. In a more recent case, the UK Patents Court found that a claim reciting the combination of a specific active ingredient and an unspecified additional ingredient protected, in the sense of the SPC Regulation, an authorized product comprising the combination of the specific active ingredient and

another specifically stated active ingredient. In re Council Regulation (EEC) No. 1768/92 [2008] EWHC 1902 (Patents Court) (the *Gilead* case).

[FN14]. Takeda Chemical Industry's Application (unreported oral decision relating to SPC application SPC/GB93/017).

[FN15]. *Id.*

[FN16]. Medeva's SPC Applications [2010] EWCA Civ 700.

[FN17]. Article 8(1)(b) of the SPC Regulation.

[FN18]. Biogen Inc v SmithKline Beecham Biologicals SA [1997] RPC 833 (ECJ Case C-181-95).

[FN19]. *Id.*

[FN20]. Section 8.04.1 of the SPC chapter of the UK Manual of Patent Practice.

[FN21]. US PTO Manual of Patent Examining Procedure § 2752.

[FN22]. See supra n.6 and corresponding text..

[FN23]. Draco AB's SPC Application [1996] RPC 417.

[FN24]. Yissum Research & Development Co., Patents Court [2004] 2880 (ECJ case C-202/05).

[FN25]. In this case, the UK marketing authorization for topical use of calcitriol for skin order indications was granted in December 2001, whereas the UK marketing authorization for intravenously administered calcitriol for renal indications was granted in June 1994. Given that the application for an SPC was filed in June 2002, an SPC application based on the June 1994 marketing authorization would have been rejected, given the requirement of Article 7 of the SPC Regulation that an application for an SPC be filed within six months of the later of the issue date of the basic patent and the first marketing authorization. (The basic patent directed to the topical use of calcitriol had been granted in July 1989.)

[FN26]. *Id.*

[FN27]. Massachusetts Institute of Technology, ECJ case C-431/04.

[FN28]. Article 1(b) of the SPC Regulation.

[FN29]. As discussed earlier, US law explicitly provides that certain classes of medical devices are eligible for patent term extension. See supra n.5.

[FN30]. This article is focused on medicinal products intended for humans and will not discuss veterinary medicinal products in the remainder of this article.

[FN31]. Decision in the Appeal Regarding the Application for an SPC for a Medicament, 14 W (pat) 12/07, 14th Board of the Federal Patent Court (January 26, 2010) A link to an English translation of this decision is available on the SPC Blog at <http://thespcblogger.blogspot.com>.

[FN32]. See p.4, lines 32-50 of European Patent No. EP0201601 B1.

[FN33]. Article 3(b) of the previous version of the SPC Regulation, Regulation (EEC) No. 1768/92, stated that grant of an SPC required a valid marketing authorization to place the relevant product on the market in the relevant EU member state as a medicinal product in accordance with Directive 65/65/EEC. This Directive was later replaced by the MPD. Article 3(b) of the current version of the SPC Regulation, Regulation (EC) No. 469/2009, now requires a valid marketing authorization in accordance with the MPD.

[FN34]. *Genzyme Biosurgery Corp. v. Dutch Intellectual Property Office*, Court of the Hague, Sector Administrative law (June 3, 2004). A link to an English translation of this decision is available on the SPC Blog at <http://thespcblog.blogspot.com>. The European patent granted for Synvisc, EP0466300 B1, was opposed and eventually cancelled by the European Patent Office.

[FN35]. Article 7 of the SPC Regulation. In any case, if the basic patent is filed *after* marketing authorization is received, an SPC having a non-zero term can likely not be received. Article 13(1) of the SPC Regulation states that the term of an SPC is the period that elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years. Article 13(3) states that this term may be extended by another six months when the SPC is for a human medicinal product for which data from clinical trials conducted in accordance with an agreed Paediatric Investigation Plan (PIP) have been submitted, as set forth in Article 36 of Regulation (EC) No 1901/2006. Based on these two provisions, EU member state courts have given varying answers to the question of whether an SPC may be awarded (and, if so, with what duration) where the first Community authorization was received less than five years after filing of the basic patent. In any case, it is unlikely that any European or EU member state courts would award an SPC of non-zero duration where the basic patent was filed *after* the first Community authorization (even when the basic patent was filed within six months after that authorization was obtained), given that, in such a case, the primary goal of compensating the basic patent holder for regulatory delay would not be applicable.

[FN36]. Article 3(d) of the SPC Regulation.

[FN37]. It is assumed here that the previously discussed basic requirements for grant of an SPC are satisfied. That is, no SPC had been previously granted (Article 3(c) of the SPC Regulation); the application for an SPC is filed within six months of the later of the date of grant of marketing authorization in the EU member state in which the SPC application is being filed and the issue date of the basic patent (Article 7(1) and 7(2) of the SPC Regulation); and the basic patent is filed at least four and a half years before grant of marketing authorization in the Community (Article 13(1) and 13(2) of the SPC Regulation). See *supra* n.35.

[FN38]. The issue of whether a claim of the candidate basic patent “protects” the relevant product is to be determined in accordance with the usual canons of claim construction. *Farmitalia Carlo Erba S.r.l.’s SPC Application (2)* [2000] RPC 580, ECJ Case C-392-97. It follows from such usual canons of claim construction, that a claim reciting features A and B does not cover a product that only includes feature A. *Centocor Inc’s SPC Application* [1996] RPC 118 (finding that a claim reciting a combined preparation of a monoclonal antibody and an anti-microbial agent did not “protect” the product consisting of a monoclonal antibody).

[FN39]. The EPO Enlarged Board of Appeals recently held that use claims of the form “compound A for curing disease X” were permissible for protecting not only a first medical use of compound A, but also second or subsequent uses. *Dosage Regime/Abbott Respiratory*, G02/08 and G01/07 (EPO Enlarged Board of Appeal 2010). In the same decision, the EPO Enlarged Board of Appeals indicated that the previously permissible Swiss-form claim for claiming second medical uses would, after a

three-month long transitional period, no longer be permissible. However, it is not certain that the EPO would grant a claim reciting “compound A for use with medical device D for curing disease X,” which would contain structural limitations (directed to medical device D) that were not considered in the *Dosage Regime/Abbott Respiratory* case.

[FN40]. Article 7(2) of the SPC Regulation.

[FN41]. The “product” in this case will be taken as compound A by itself, because Article 1(b) of the SPC Regulation specifies that “product” means the active ingredient or combination of active ingredients of the medicinal product.

[FN42]. Strictly speaking, this is true only for SPC applications in the EU member states that grant negative or zero-term SPCs, and where data from clinical trials conducted in accordance with an agreed Paediatric Investigation Plan (PIP) was submitted, as set forth in Article 36 of Regulation (EC) No 1901/2006. See supra n.35. If a compliant PIP was not submitted in such a jurisdiction (or, in an EU member state that does not grant zero or negative-term SPCs), the basic patent would need to have been filed more than five years before grant of marketing authorization in the Community to obtain an SPC with non-zero term. Article 13(1) and 13(2) of the SPC Regulation; see supra n.35.

[FN43]. Additionally, assuming the rationale of the *Genzyme* and *Yttrium-90* decisions discussed earlier are adopted widely across the EU, it may be possible to obtain an SPC in this scenario based on a single marketing authorization obtained based on the AIMD or the MDD.

[FN44]. In *Centocor*, the UK IPO held that a claim reciting a combined preparation of a monoclonal antibody and an anti-microbial agent did not “protect” the monoclonal antibody product on its own. See supra n.38.

[FN45]. In order to market the actual product of this entry, which is the medical device D in combination with compound A, a separate marketing authorization to this medical device may be required. However, under Article 3(c) of the SPC Regulation, any earlier marketing authorization to compound A or a formulation including compound A must be the basis of the SPC application.

[FN46]. It is not certain that the EPO would grant such a claim. See supra n.39.

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