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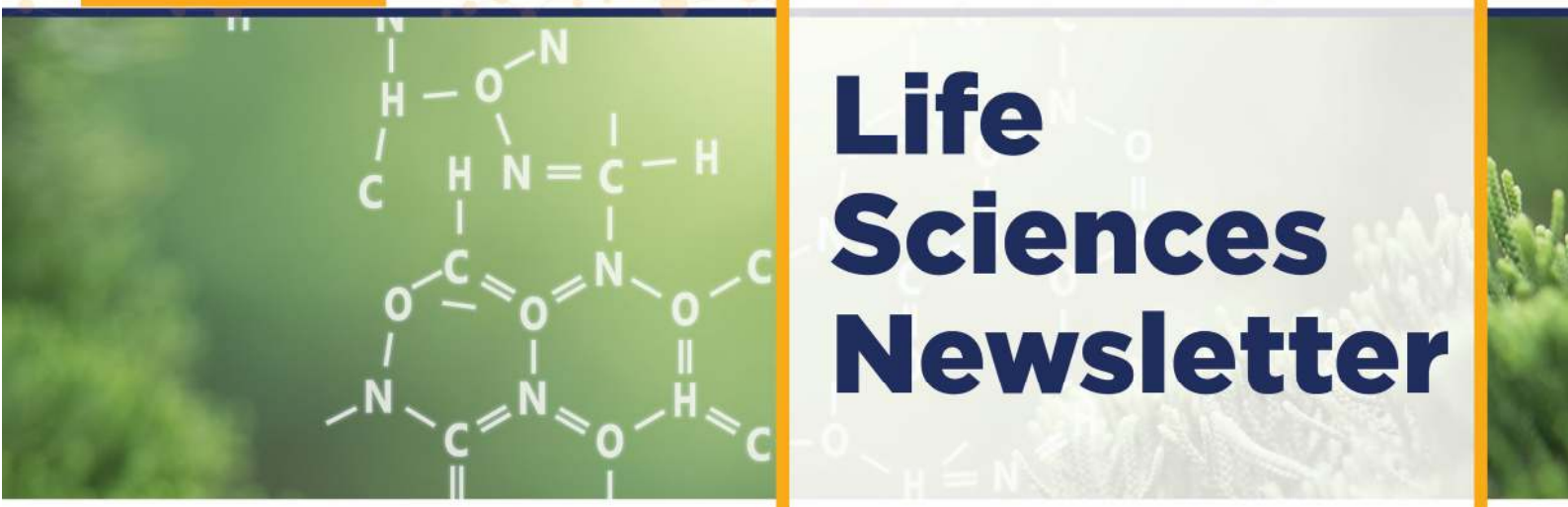

Life Sciences Newsletter

In this issue:

SPCs in Europe: A Primer

What are the essential requirements for obtaining an SPC in Europe?

The European Union (EU) introduced supplementary protection certificates (“SPC”) under EU Regulation 469/2009/EC ("SPC Regulation") for medicinal products and veterinary products and this SPC Regulation can be used to extend the patent term of protection for particular pharmaceutical products.

The purpose of the extension of the patent term is to compensate patent owners who cannot put their product on the market for a significant time of years after a patent application has been filed because the patentee or their licensee must await the grant of a marketing authorization. This could result in a proprietor having a greatly reduced term of patent protection remaining by the time they are able to reach the market with the related product.

The SPC Regulation seeks to address this problem by providing for up to 5 years further monopoly protection for specific patented "products", as defined in the SPC Regulation. The actual period of extension of the patent term for that particular product which is the subject of a specific marketing authorisation, is calculated as follows:

The period 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, less 5 years, and subject to a cap of 5 years.

The formula provides that a patentee does not obtain an extension of its patent monopoly if it has only been eroded by 5 years or less by the wait for the grant of a marketing authorization.

For example:

- A patent application filed on 1 November 2005 and marketing authorization granted on 1 November 2010; the calculation for duration of the SPC = 5 years difference - 5 years means that SPC would have 0 duration so the patent has a maximum term expiring on 31 October 2025 with no extension of the term due to any SPC protection. However, if a Paediatric extension is applied for, and is granted, then there will be a term of 6 months due to the grant of the Paediatric extension of the SPC even though the SPC term is 0. Case Law also supports that, even if the SPC is calculated as having a negative term of example -2 or -3 months, that the Paediatric extension can still add 6 months to that SPC calculated term.
- A patent application filed on 1 November 2000 and marketing authorization granted on 1 November 2010; the calculation for duration of the SPC = 10 years difference – 5 years = 5 years SPC protection commencing immediately when the patent expires on 31 October 2020.
- A patent application filed on 1 November 1995 and marketing authorization granted on 1 November 2010; calculation for duration of SPC = 15 years difference - 5 years but subject to 5 years maximum term so the SPC can only last a maximum of 5 years. Thus, the SPC protection will be the maximum term of 5 years commencing immediately when the patent expires on 31 October 2015.

Conditions for obtaining an SPC:

However, in order to obtain an SPC, there are essential conditions that must firstly be satisfied including the following conditions set down in Article 3 of the SPC Regulation and can be summarised as follows:

1. **Protection by a basic patent in force**
   The product must be protected by a basic patent in force (Article 3(a)).

2. **First Authorisation to place product on the market in the European Economic Area (EEA)**
   A valid authorisation to place the product on the market as a medicinal product must have been granted (Article 3b). This must be the first authorisation to place the product on the market in the EEA as a medicinal product; and

3. **No pre-existing SPC**

The medicinal product must not already have been the subject of an SPC (Article 3(c)). The purpose of this provision is to prevent further SPCs being granted for variations of the same product. This is subject to case law and is a complex area. Specific advice should be sought in particular circumstances.

In accordance with Article 7(1) and 7(2) of the SPC Regulation, an SPC application must be filed within 6 months of the date of grant of the marketing authorisation referred to in Article 3(b) to place the product on the market as a medicinal product in the EU (or EEA) Member State for which the SPC is filed, or within 6 months from the date of grant of the basic patent, whichever is later. Therefore, if the basic patent was granted before the issue of the marketing authorisation in the Member State, an SPC application must be filed within 6 months of the issue of the first marketing authorisation in that Member State. If these above conditions are satisfied, the EU Regulation provides SPC protection for specific patented products. However, it should be noted that the SPC Regulation does not extend the patent protection itself, but instead extends the term only in relation to the product that is the subject of the marketing authorisation. Thus, other products that fall within the scope of protection of the patent are not covered by a particular SPC.

SPCs in Europe: Legal Update

EU SPC Manufacturing Waiver Proposal – full steam ahead!

As reported in our Summer 2018 Life Sciences Newsletter, the European Commission proposed a change (the so-called 'SPC manufacturing waiver') to SPC Regulation 469/2009. This SPC manufacturing waiver will allow the manufacture of generic and biosimilar medicines in the EU for export and stockpiling during this period of extended patent protection provided for by SPCs. In this manner, European generic and biosimilar industries will be able to benefit from sales outside the EU in countries where patents have already expired, and will be able to prepare to provide the EU market as soon as the SPC period expires.

In April 2019, the European Parliament reached agreement on this SPC manufacturing waiver. EU Regulation 2019/933 was published in the Official Journal of the European Union on 11 June 2019. The Regulation will have direct effect across all Member States from the 20th day following publication - 1July 2019. It should be noted that SPCs already granted will not be affected by the waiver and that SPCs which have been applied for, but are not yet granted, will be subject to the waivers from July 2022.

SPCs in Europe :Case Law Update

Which marketing authorisation is the first marketing authorisation?

Article 3(d) of the SPC Regulation requires that an SPC be based on the first authorisation to place a drug on the market as a medicinal product (the earliest marketing authorisation). The proper identification of the earliest marketing authorisation may be an issue when a patent protecting a second or subsequent medical use of a particular drug is used as the basis for an SPC application.

Historically, it had been thought that a patent to a new medical use of a drug could form the basis of an SPC, but that SPC had to be based on the earliest marketing authorisation for that drug, even if the earliest authorisation was for a different disease or condition from that specified in the patent[1].

However, in **C-130/11 Neurim**, the CJEU, has indicated that, in certain circumstances, it may be possible to base an SPC application on an authorisation which is not the first marketing authorisation to place a particular drug on the market[2]. Thus, it may be possible for Patentees to obtain SPCs on the basis of (1) a patent to a downstream development of a known drug, for example, a patent for a new medical use or a new formulation of a known active ingredient, and (2) a second or subsequent marketing authorisation for a medicinal product containing the active ingredient at issue.

Such SPCs may be granted if: (1) the downstream patent does not cover the medicinal product specified in the original marketing authorisation; and (2) the second or subsequent marketing authorisation is the first authorisation for a medicinal product which is protected by the downstream patent.

Thus, the CJEU Neurim decision appeared to expand the possibilities for obtaining SPC protection for previously authorised active ingredients. The national patent offices have applied the "*Neurim* test" for identifying the first authorisation in varying extents. Some national patent offices have suggested that the CJEU's references to "a case such as that in the main proceedings" and "an earlier marketing authorisation obtained for a veterinary medicinal product" bring into question how broadly the Neurim decision can be applied. Two issues in particular seem unclear.

[1] C-202/05 Yissum
[2] C-130/11 Neurim

The first is whether, in the case of a new therapeutic use, a variation of an earlier MA can be the "first authorisation" required under Article 3(d) or whether a separate MA is required. The second issue is whether *Neurim* applies only in the case where a new therapeutic use has been discovered, or whether a new formulation of a previously authorised active ingredient is enough for SPC eligibility. The approach of the national patent offices to these questions has not been consistent and further clarification is long overdue.

In March 2019, the CJEU handed down judgment in the case C-443/17 (Abraxis Bioscience), link here.

The CJEU's full answer is as follows:

> *"Article 3(d) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, read in conjunction with Article 1(b) of that regulation, must be interpreted as meaning that the marketing authorisation referred to in Article 3(b) of that regulation, relied on in support of an application for a supplementary protection certificate concerning a new formulation of an old active ingredient, cannot be regarded as being the first marketing authorisation for the product concerned as a medicinal product in the case where that active ingredient has already been the subject of a marketing authorisation as an active ingredient."*

The main points of the Abraxis Bioscience decision are that:

- MAs for "new formulations" of 'old' active ingredients do not qualify for "first MAs" under Article 3(d) (or 3(b));
- However, the CJEU did not go so far as to overrule Neurim; and
- The CJEU does not state that Neurim is limited to its facts (i.e. veterinary-to-human formulation and use), but the reasoning indicates that the CJEU took a very narrow interpretation.

Further clarification is now awaited in the pending Santen referral to the CJEU; this referral was made by the Court of Appeal of Paris with decision of 9 October 2018 in *Santen v. INPI* (RG no. 17/19934). This awaited ruling of the CJEU will have major significance for the availability of SPCs for new therapeutic applications of "old drugs", and possibly even beyond that.

In the case underlying this referral, an SPC application was filed by Santen SAS, the French subsidiary of Japanese company Santen Pharmaceutical, for "ciclosporin for use in the treatment of keratitis" (SPC no. 15C0040), relying on a marketing authorization for the medicinal product "Ikervis".

This authorization was granted in 2015 for the treatment of severe keratitis, an inflammation of the cornea in patients with dry eye disease.

The SPC application was rejected by the French Patent Office (INPI) for lack of compliance with Article 3(d) of the SPC Regulation, which requires that the marketing authorization relied upon must be "the first authorization" to place the product of the SPC on the market in the respective member state. An earlier marketing authorization had already been granted for the medicinal product "Sandimmun" in 1983, containing the same active ingredient ciclosporin, for various therapeutic indications including the prevention of graft rejection and the treatment of endogenous uveitis (an inflammation of the uveal layer of the eye).

Santen lodged an appeal against the rejection of its SPC application with the Court of Appeal of Paris, arguing that the active ingredient ciclosporin in the earlier authorized medicinal product "Sandimmun" must be distinguished from that of the later authorized "Ikervis". This is because the earlier formulation does not fall within the claims of the basic patent underlying the SPC application, the approved therapeutic indications of "Sandimmun" and "Ikervis" are different, and the dosage and mode of administration of the respective formulations are different.

We will let you know when the CJEU has handed down its decision in this case.

Sequence Listing Requirements at the EPO

A practical note for European Regional Phase entry

For all PCT application for European Regional Phase entry disclosing unbranched sequences of *four or more amino acids* or unbranched sequences of *ten or more nucleotides*, the EPO must be provided with an electronic version (.txt) of the sequence listing according to WIPO Standard ST.25; and a statement that the sequence listing does not add subject-matter beyond that of the application as filed. The EPO's free BiSSAP software or PatentIn software is recommended to generate the sequence listing.

If the EPO decides that a WIPO Standard ST.25 compliant sequence listing is not available at the time of entering the European Regional Phase, the applicant will be invited to furnish a compliant sequence listing and pay a *late furnishing EPO official fee* within a period of two months. Additionally, the failure to provide the EPO with the required sequence listing may result in the potential refusal of the application.

Furthermore, although the EPO has confirmed that prior art sequences which have been identified by their database accession number and either the version number or database release number do not need to be included in the sequence listing, we would strongly advise including the full sequence data in the application. This will avoid any doubt over the specific sequence information and permit the recitation of the specific nucleotide or amino acid sequences in the claims whilst complying with the strict European added subject-matter requirements.

Additionally, for any divisional patent application, at present, an applicant cannot rely on the sequence listing filed in relation to the parent application; it is very important that applicants must file a sequence listing together with the other documents that comprise the divisional application. However, this requirement may be abolished by the EPO in the future and we will keep you updated on any changes.

In order to ensure the sequence listing requirements are met on European Regional Phase entry to avoid the requirement to pay a late furnishing fee, when instructing us to enter the European Regional Phase it is preferable to provide the following information:

1. provide a sequence listing in text format (.txt) in accordance with WIPO Standard ST.25;
2. confirm that all sequences of four or more amino acids or of ten or more nucleotides are included in the sequence listing; and
3. confirm that the sequence listing does not add subject-matter beyond that of the application as filed.

EPO Board of Appeal Decision T1085/13

Purity of chemical compounds

EPO Board of Appeal Decision T1085/13, which issued on the 9 November 2018, is of significant interest to practitioners, and concerns the patentability at the EPO, of claims directed to higher grades of purity of known compounds. This decision has clarified the conditions under which European patents can be granted for known compounds of higher grades of purity. The patent application concerned amorphous lercanidipine hydrochloride at a purity of at least 99.5%, and containing less than 0.5% crystalline lercanidipine hydrochloride. The EPO Examining Division had refused the application based on the legal tests set out in earlier decision T990/96, which had been the leading decision in the assessment of purity claims at the EPO. This decision was then appealed, and the Board of T1085/13 remitted the case to the Examining Division with the order to grant. Therefore, T1085/13 has shifted the question of patentability of known compounds at higher purity from a focus on assessment of novelty to instead focusing on inventive step (non-obvious).

The earlier EPO Board of Appeal decision T990/96 had examined whether a specific level of diastereomeric purity was novel. The Board stated that any chemical compound obtained by a chemical reaction normally containing impurities was part of the common general knowledge; and that it therefore followed that, for a skilled person in the art of preparative organic chemistry, purification was a matter of common practice and was not novel. The Board decided that a document disclosing a compound for the first time, renders that particular compound available in all desired grades of purity. The Applicant would thus face the burden of complying with the “special criteria” of demonstrating that the claimed purity could not be achieved, by any and all known conventional purification techniques. It followed that, in general, a disclosure of a small molecule and its manufacture, rendered the compound available to the public, in all grades of purity.However, fortunately for innovators who appreciate the difficulties in achieving higher levels of purity of a compound, in decision T1085/13, the EPO Board of Appeal was critical of the existing relevant case law. The Board decided that, in order to find that there is a lack of novelty, there must be at least an implicit disclosure in the state of the art of subject matter falling within the claimed scope, and that such an implicit disclosure would mean no more than the clear and unambiguous consequence of what is explicitly mentioned in the prior art.

Thus, in T1085/13, the Board has clearly shifted the issue of whether purification of the known chemical compound to the higher level of purity was possible, away from being a question of novelty, to a question of inventive step. It has thus been clarified by the Board that when well-known purification techniques are relied upon to obtain a compound with a certain purity, it is now a question of novelty, and not inventive step. This decision is evidently patentee-friendly and removes the burden previously presented to the applicant, according to T990/96.

Meet the HMC Team

Upcoming International Events

Philadelphia, USA	Anna Hally will be attending the **BIO International Convention**	3-6 Jun 2019
London, UK	We will be attending the **AIPPI World Congress**	15-18 Sep 2019
Shanghai, China	Marie Walsh will be attending the **4th China Pharma IP Summit**	23-25 Oct 2019

We would love to connect, please reach out to meet up if you are attending these events.

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For any further specific questions, please contact any one of our team at Hanna Moore + Curley. This guidance document provides general information only and does not constitute legal advice.

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