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The importance of Supplementary Protection Certificates in protecting the EU PPP market from generic competition

Supplementary Protection Certificates (SPCs) for Plant Protection Products (PPPs) became law in 1997 following the entry into force of Regulation (EC) No 1610/96 of the European Parliament (see J A Kemp¹ “Introduction to Supplementary Protection Certificates for Plant Protection Products” for a good overview of SPCs for PPPs). This was a result of lobbying by the R&D sector of the PPP companies arguing that it should be treated in a similar manner to pharmaceuticals which already had SPCs in force in 1993 following Regulation (EC) 1768/92, the medicinal product SPC regulation.

The EU recognised that differences between plant protection, pharmaceutical and animal health products existed and hence a separate Regulation for PPPs was required. For an excellent review of some of these differences see Arunasalam and De Corte². The fundamentals for all three sectors are, however, similar in that SPCs are an intellectual property right that aims to offset the loss of patent protection which occurs due to the mandatory testing required to obtain regulatory marketing approval.

SPC protection is available in all EU member states and is also available in the following non-EU States which may nonetheless be covered by a European patent application granted by the EPO:

- Norway and Iceland (EEA member states, apply the EU regulation)
- Switzerland (national law based on the EU regulation)
- Liechtenstein (SPC issued in Switzerland automatically takes effect)

The objectives of this article are to:-

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- highlight the importance of accurate data gathering in order to identify actual expiry dates of SPCs and thus identify market entry dates for generics
- review the filing activities of the R&D sector since 1997
- highlight the importance of mixture products and associated patents/SPCs for PPPs
- identify gaps in SPC portfolios.

Briefly, SPCs for PPPs:-

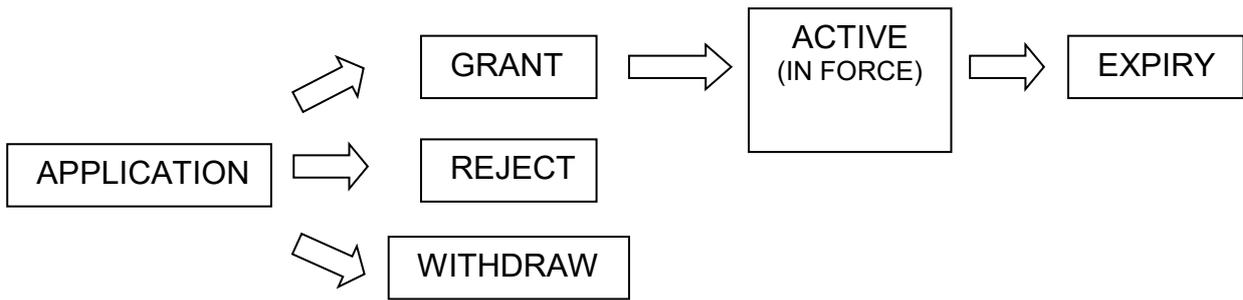
- apply to a specific product within a patent which is on the market,
- come into effect upon patent expiry
- last for up to a maximum of five years from date of patent expiry
- are granted in Europe on a national basis.

The actual term of the extension depends on a number of issues, key being the first marketing date of the product in an EU country and an SPC will expire at whichever is the earlier of:

- 15 years from the first Marketing Authorisation in the EU/EEA*
- 5 years from the expiry of the basic patent

*Switzerland is not an EU/EEA member, therefore the first Marketing Authorisation in Switzerland is a national authorisation granted by the local authorities.

Major Stages in the Life Cycle of an SPC



By October 2018, over 2,200³ PPP SPCs records exist, of these 1,732 (77.6%) are granted SPCs, 262 are applications and the balance have either been rejected or withdrawn.

Analysing granted SPCs by applicant shows a discrepancy compared to turnovers.

Company [#]	Number of granted SPCs ³	Turnover 2017 \$m ⁴
Bayer CropScience	508	9,103
Syngenta	391	9,731
BASF	310	5,569
Corteva (DowDuPont)	226	6,161

includes acquired and/or merged companies

Very few Japanese companies seem to have realised the potential additional protection that SPCs can achieve as the following table demonstrates.

Company	Number of granted SPCs ³
ISK	70
Sumitomo	32
Nippon Soda	29
Nihon Nohyaku	18
Nissan	7

The importance of mixture products and associated patents and SPCs for PPPs

The decline in the discovery of new active ingredients has been compensated by an increased development of mixture (combination) products over the last 20 years. In addition to the technical advantages (improved application, synergism, the fight against resistance etc) that mixture products provide there are obvious commercial advantages such as market segmentation/differentiation, brand awareness and additional IPR. 43%³ of all granted SPCs are to mixture products.

Prothioconazole is an extremely important fungicide for the European market and the following mixture products that have SPCs demonstrate how important they are. Not only does this portfolio present a very complex market situation but segments the market making it very difficult for the generic sector to take significant market share.

BENZOINDIFLUPYR + PROTHIOCONAZOLE
BIXAFEN + FLUOXASTROBIN + PROTHIOCONAZOLE
BIXAFEN + PROTHIOCONAZOLE
BIXAFEN + PROTHIOCONAZOLE + SPIROXAMINE
BIXAFEN + PROTHIOCONAZOLE + TEBUCONAZOLE
FLUDIOXONIL + PROTHIOCONAZOLE + TEBUCONAZOLE
FLUOPYRAM + FLUOXASTROBIN + PROTHIOCONAZOLE + TEBUCONAZOLE
FLUOPYRAM + PROTHIOCONAZOLE
FLUOPYRAM + PROTHIOCONAZOLE + TEBUCONAZOLE
FLUOXASTROBIN + PROTHIOCONAZOLE
IMIDACLOPRID + PROTHIOCONAZOLE
ISOPYRAZAM + PROTHIOCONAZOLE
PENCYCURON + PROTHIOCONAZOLE
PENFLUFEN + PROTHIOCONAZOLE
PROTHIOCONAZOLE + SPIROXAMINE
PROTHIOCONAZOLE + TEBUCONAZOLE
PROTHIOCONAZOLE + TRIADIMENOL + TRIAZOXIDE

Certain mixture products have been granted patents based on synergistic effect resulting in relatively old active ingredients gaining a new lease of protected (IPR) life.

Metazachlor (BASF) is a relatively old active ingredient, the basic patent has expired and it had no SPCs to the single active ingredient, however, a number of mixture products have been granted patents and SCPs are in force in a number of countries.

Mixture product	Patent Number	Date of patent Application	Typical expiry of SPCs ³
CLOMAZONE + DIMETHENAMID-P + METAZACHLOR	EP1656021	15/07/2004	2029
DIMETHENAMID-P + METAZACHLOR	EP1810570	15/02/1994	2019
IMAZAMOX + METAZACHLOR	EP1734823	30/03/2005	2025
IMAZAMOX + METAZACHLOR + QUINMERAC	EP1980149	30/03/2005	2027

Identifying gaps in SPC portfolios

One of the key steps in obtaining a SPC in a particular country is the need to apply for the SPC within 6 months of the first marketing date in that country. Thus if patent departments are not vigilant and thorough then mistakes might be made resulting in countries not getting SPC protection. Analysing SPCs can identify gaps in SPC portfolios and therefore markets which might be entered prior to SPC expiry in the major markets.

For example, bixafen is protected by EP1490342 (and other equivalent national patents) which is due to expire 06/02/2023. Granted SPCs, extending protection to 2025, exist in the following countries:-

AT, BE*, BG, CH, DE, EE, ES, FR, GB, HU, IE, IT RO, SE*, SK

*SPC application only at this stage

Are there other markets beyond these where bixafen is used and can generic companies exploit these? Other issues such as data protection will also help protect the market from generic competition and the process for a generic company to determine whether a market is firstly legally accessible and secondly economically worth developing is complex.

In the EU, 139³ SPC applications have been rejected for one reason or another. Analysis of these rejections may identify gaps in the market for other companies to exploit. For example, the market for single active prothioconazole is protected by SPCs in 17 countries, demonstrating how important the product is, however the application for Poland was rejected – why? and is the market worth pursuing in Poland? If so an eagle eyed company might have been able to consider entering the Polish market, and other

countries, when the original patent expired in 2015 instead of waiting until 2019 when SPCs expire.

The future?

Delays in authorisation of PPPs are unlikely to get shorter as registration requirements increase resulting in longer waits for the first marketing authorisation. Thus, SPCs will become even more important as the R&D sector seeks to defend market share and recoup R&D investment. The relative small size of the PPP market compared to pharmaceuticals means that PPP R&D companies need to maximise IPR and thus the increase in mixture products and SPCs is likely to continue.

For the generic sector, any company planning to enter the PPP market in Europe must not only establish when the patent for the active ingredient, mixture products or other secondary patents expire, but also whether SPCs have been granted and, if so, when they expire.

With 31 national offices the European patent system is complex and makes the retrieval of SPC information into a time consuming, uncertain and costly exercise.

In addition, analysing SPCs is an extremely useful tool for competitor intelligence as it clearly shows which markets in Europe companies are targeting for increased protection and where gaps in IPR portfolios might exist.

It is important to understand that patent information is only a snapshot in time and it is essential to continuously track SPCs.

The data used in this article are taken from Enigma Marketing Research's database, **AgSPC.db** it delivers SPC data to the PPP industry for the first time.

For further information on **AgSPC.db** contact:

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1. J A Kemp: Introduction to Supplementary Protection Certificates for Plant Protection Products.
2. Arunasalam and De Corte: Supplementary protection certificates for plant protection products: the story of "The Ugly Duckling", Journal of Intellectual Property Law & Practice, Volume 11, Issue 11, pages 833-840.
3. Source Enigma Marketing Research.
4. Source Informa.