Patent Focus

Researched and written by Genericsweb

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Strategic use of supplementary protection certificates (Part 2)

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This article follows on from a previous article relating to the grant of multiple supplementary protection certificates (SPCs) in a given country (the United Kingdom)[1] and is part of a series which is intended to represent an observational summary of how the system is being used by the pharmaceutical industry, rather than a legal review. However, it is necessary to refer back to the SPC Regulation in order to draw some parallels between plain reading of the text, and the interpretation of the text by EU member states in determining the right of an application to result in the grant of a SPC. For the purposes of clarity, Article 3 of the codified SPC regulation (EC) No 469/2009 is shown below:

> Article 3
> Conditions for obtaining a certificate
> A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
>
> (a)→the product is protected by a basic patent in force;
> (b)→a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or 2001/82/EC, as appropriate;
> (c)→the product has not already been the subject of a certificate;
> (d)→the authorisation referred to in (b) is the first authorisation to place the product on the market as a medicinal product.

Noteworthy is that since the publication of the previous article the SPC regulation has been codified and some important rulings have been made by the European Court Justice (ECJ) to assist with the interpretation of certain parts of the regulation. How this affects future SPC filings is yet to be seen, but this article will consider the trends of existing filings.

Analysis contained in the first article in this series has identified situations where, for a given International Non-proprietary Name (INN), in a given country, SPCs have been granted based on different first EU marketing authorisation (MA) dates. Such situations arose because the active ingredients sharing an INN could either (a) reasonably be considered to constitute a different 'product' for example Hyaluronic Acid (Synvisc and Hylaform) and Hepatitis B Vaccine (HB-Vax and Engerix B) predominantly cases relating to macromolecular compounds or (b) in the case of small molecules, the grant(s) occurred contrary to the Explanatory Memorandum of the SPC Regulation (COM(90) 101 final) indicating that the use of a different salt or ester of a different pharmaceutical form should not lead to the issue of a new SPC. In these cases, the 'basic patent' was either the same or different for the pair of granted SPCs.

It is quite expected that, upon reviewing the validity of an SPC application, a given country's patent office would have sufficient access to other SPCs, which had been applied for and/or granted with that office for the same product INN. Therefore, the necessary checks would be possible to ensure that the first EU MA referred to in any later application is consistent with that referred to in earlier applications. However, when there is only one SPC application submitted to that patent office for a given INN, it becomes very difficult to verify that the first EU MA referred to in the application is aligned with Article 3(d) of the SPC Regulation. Often the applicant's declaration is relied upon in granting the SPC, as the patent office has no obligation to act otherwise.

In June 2005, AstraZeneca was fined 60 million by the European Commission for misusing patent system to delay market entry of competing generic drugs (IP/05/737). The EU stated that this was achieved by AstraZeneca giving misleading information to several national patent offices in the European Economic Area (EEA) resulting in gaining extended patent protection for Losec through so-called supplementary protection certificates (SPCs). One could imagine that this would serve as a lesson to other patent holders to ensure that the information submitted to the patent offices to support an application for an SPC is accurate. However, analysis of comprehensive SPC data across all EU member states presented in this article will demonstrate that the EU MA referred to in SPC applications submitted to different patent offices for the same INN varies in a large number of cases. The analysis also demonstrates that this widespread practice often results in an extension of the SPC expiry date in that country beyond that found in it's fellow member states for the same INN.

The data studied originally comprised a comprehensive set of filings for SPCs (under the EU Regulation) and was filtered to contain only data for INNs, which have SPCs granted or which are currently pending grant at the time of study. These INNs, numbering nearly 900, were then analysed to determine whether different first EU MA dates were cited. Further analysis involved the number of discrete first EU MA dates used in SPC applications for a given INN, the effect of this variation on the SPC expiry date and the possible reasons for such variation.

Of the 900 INNs studied, 376 had more than one first EU MA date cited in the applications for SPCs that were ultimately granted under Regulation (EC) No 469/2009 (or earlier EU Regulation 1768/92) across the adopting countries. The maximum number of dates used as the basis of the grant of an SPC was 10 (INN: H5N1 Influenza Vaccine – discussed in more detail below), a further 32 INNs were identified having three or more dates. The distribution of the total number of differing dates used across the SPCs for a given INN are shown in Figure 1.

If the practice of citing a later first EU MA dates were to have no material effect on the expiry date of the SPC granted as a result, then this issue would not be a significant concern to the European Commission, or to generic manufacturers who await expiry of the SPC to enter the market. However, in only 81 of the above-mentioned 376 cases, the SPC granted for that INN in those countries did not result in an SPC expiry date later than in the other countries, that is the monopoly period has been extended for nearly 300 INNs by the practice of the patent holder not providing a uniform first EU MA date across all patent offices when applying

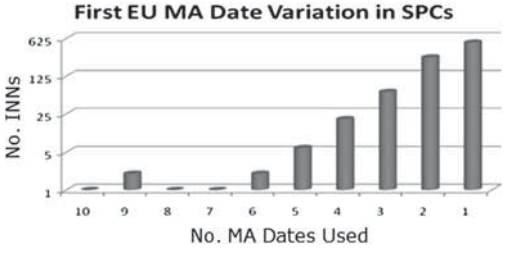

Figure 1: First EU MA date variation in SPC applications.

for an SPC on a product containing a given INN. To add more fuel to the fire, 230 of the INNs affected have at least one SPC that expires in the future, hence there is a great deal of benefit to be obtained by public health authorities and generic pharma in reviewing this practice.

The purpose of this article is not to question the validity of SPCs granted in such circumstances, but to study trends in the filings, to look for possible reasons why the first EU MA date cited should vary and to highlight some areas where pharmaceutical monopolies are perhaps being granted in contrast to the true spirit of the SPC Regulation. The following analysis draws on the data in a little more depth and, with reference to some specific examples, reviews some possible reasons why this practice may occur.

INN BASIS

It is recognised that the INN system is not flawless and that a single INN could encompass the active ingredients of several different 'products' when considering the first EU MA date to use as the basis of an SPC application. This problem may be particularly prevalent in the case of vaccines where combinations of strains of vaccine are used in different products, each strain being protected by a single patent. In the case of H5N1 Influenza Vaccine, four separate first EU MA have been cited based on five different patent families according to Table 1.

Thus, four of the dates used in this case are owing to the INN system not recognising the different strains of vaccine. The point of discussion here is not whether these products are each worthy of a separate SPC (this was discussed in the previous article in this series), but why there are an additional six variations in the MA date used when citing the same centralised EU MA, extending the life of certain SPCs from 2 to 20 days beyond their counterparts with an accurately cited date. This may seem like an insignificant amount of time, but in the life of a drug product monopoly it is a very lucrative amount of time for the patent holder.

Table 1: EU marketing authorisations for H5N1 Influenza Vaccine

MA date	*MA number*	*Product*
21 March 2007	EU/1/06/381/001	Daronrix
2 May 2007	EU/1/07/385/001	Focetria
14 May 2008	EU/1/08/453/001	Prepandrix
20 May 2008	EU/1/08/452/001	Pandemrix

CLERICAL ERRORS IN WRITING MA DATES

It is possible that slight variations in the MA dates used in SPC applications are due to clerical error. Given the exacting nature of the work of the patent attorneys who generally file SPC applications, it is unforgivable that such errors be made on critical documents and therefore incorrect dates slip through to give the patentee an inadvertent extension of their monopoly period. It is interesting to note that, of the many hundreds of cases that the possibility of clerical error applies to, very few cases were identified in the data analysed which resulted in an inadvertent shortening of the SPC expiry date when compared to the majority of the SPC counterparts and to the date to which the SPC was seemingly entitled, rather the error predominantly appeared to be in the patentee's favour.

INCORRECT IDENTIFICATION OF THE ACTUAL MA DATE

Given that each EU member state undergoes different processes to bring a product to market, it could be argued that some confusion arises over what the actual date of the MA is where an MA is published in a journal after the effective date of grant. However the same SPC regulation is applied to all adopting countries, hence the use of a first EU MA date in one country should result in the use of that same date in all other SPC applications, even though agent filing the application may be different, the patentee is often not. In some identified cases, the

2005 ECJ ruling[2] (that a Swiss MA recognised in Liechtenstein should be considered to be a MA in the EU for the purposes of determining the expiry of an SPC) does not appear to have been accounted for. For example, the combination of Metformin and Sitagliptin is the subject of a number of SPC applications by the patentee. Some of these SPC applications are based on the (seemingly correct) Swiss MA date, however seven others are based on the later centralised EU MA date, resulting in more than 3 months' additional monopoly in cases where the SPC is already granted. These applications were all made in 2008, more than 3 years after the ECJ ruling, so even if those responsible for the filing of SPCs in respective markets did not discuss the first EU filing date with their counterparts in other markets, they should have been aware of the legislation and how it is to be interpreted. Similar situations occur in SPC filings with respect to several other INNs having expiry dates in the future such as Nitenpyram, Fluticasone (Furoate) and Insulin Aspart (Biphasic) to name just a few.

EU ENLARGEMENT

The enlargement of the EU meant that those joining countries would benefit from the SPC system, however the provisions set out in Article 20 of the SPC regulation (EC) No 469/2009 contains any transitional provisions for the application of SPCs. Further, in countries such as Greece and Portugal the SPC regulation was not applicable retroactively for MA granted before accession, hence the ability to apply for an SPC was enabled only by the grant of a basic patent and/or a first EU MA after that date. In such circumstances, patentees have been identified as selecting later EU MA dates on which to base applications in these countries. One example of this is the SPC applications for Olanzapine in Greece and Portugal, which cite the same 'basic patent' as for many of their European counterparts, but are based on a first EU marketing date in 2001, after adopting the SPC regulation. The 2001 MA cited in the applications is for the amorphous form of Olanzapine rather than the crystalline form authorised in tablet form in 1996. Although similarly based SPCs were applied for in many other countries in Europe, these applications were mostly unsuccessful because the respective patent offices had internal prior knowledge of the previous SPC application and thus the previous MA (although this did not deter Austria, Italy and Luxembourg from granting a second SPC). However, in Greece and Portugal the SPCs were also granted, possibly because the patent offices had no way of verifying the submitted first EU MA date on the application. Not only did this provide the patentee the opportunity of obtaining an SPC in Greece and Portugal, but also in such countries the SPC expires 4.5 years after the SPC in most other EU countries.

ERRORS IN PUBLISHED DATA

The above information is based on information published by the respective patent offices and verified using online registers where possible. However, it must be recognised that patent offices are not always reliable in re-publishing information that forms the basis of SPC applications, or advising of changes in the respective expiry dates. Thus, the data analysed may contain some basic errors that account for a small portion of the cases identified in this analysis. It is considered that the numbers quoted above for variation of SPC dates for a single INN are representative of the scale of the situation, even after compensating for any such errors found in the published data.

CONCLUSION

The above analysis demonstrates that there is a serious problem in harmonisation of the EU patent system when the patent offices involved in granting SPCs do not have complete visibility of MA and other SPC filings within the community. Such a lack of visibility, combined with the burden of

accuracy and candour resting with the patentee means that the SPC system is open to abuse and/or an unfair result in terms of monopoly protection.

The question over whether this is abuse of the SPC system is a contentious one, hence it is preferred to consider it as 'strategic use' of an inherently flawed system. It seems fair to say that many patentees are obtaining additional monopoly periods above and beyond that provided for in the SPC regulation based on non-uniform selection of first EU MA dates to include in their SPC application. Based on previous action taken by the European Commission and current close scrutiny of the pharmaceutical sector, it is no doubt a practice that will warrant some additional attention.

What solutions are there for the flawed SPC system that allows such non-harmonised patent protection to be granted across the EU? Systems such as a duty of candour are already factored into the SPC regulation to a certain extent under Article 15, however the process of invalidating an SPC is a potentially long and expensive one, especially if a question is to be referred to the ECJ as is often the case. This is also an action that would need taking in every relevant member state with a corresponding prohibitive drain on resources, particularly finance. If such penalties were to be introduced where a finding of invalidity of an SPC because of the filing of inaccurate or misleading first EU MA date resulted in the revocation of other SPCs that had been filed for the same INN by the same patentee with similar inaccuracies but in other countries, then the risk/reward profile for a generic challenger may be higher and the incentive for the patentee to use the right first EU MA date would increase. Thus the EU would be one step closer to harmonisation of patent expiries.

A further way of tackling this issue may be to ensure that patent offices which review SPC applications have complete visibility of SPC applications made at other patent offices, and the burden of verification of the SPC application before them against such data. GenericsWeb has spent many years identifying and analysing SPC filing data from patent offices around the world and structuring such information in a format that allows comparisons to be made of applications for SPCs of INNs across all adopting countries. The fact that such a system is so difficult and time consuming to build is indicative of the array of database formats and publication systems used to make SPC application data public, however the use of such a system would likely have a significant effect on the harmonisation of pharmaceutical monopoly terms in the EU.

REFERENCES

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