SPC conditions clarified for combination drugs

Mayer Brown's **Sangeeta Puran** and **Daniel Gallagher** discuss the recent SPC ruling from the CJEU towards curtailing "evergreening" whilst still enabling extension of patent monopolies

The Court of Justice of the European Union (the CJEU) has clarified certain key conditions that patentees must satisfy to obtain a supplementary protection certificate (SPC) for medicinal products combining active ingredients. The CJEU's ruling[1] considered questions referred from the Court of Appeal of England and Wales in the proceedings *Medeva BV v Comptroller of Patents, Designs and Trade Marks*. This ruling has important implications for both patentees looking for patent term extension in key EU markets and their competitors looking to enter such markets.

The SPC Regulation and Articles 3(a) and 3(b)

Similar to the US Hatch-Waxman Act, Council Regulation (EC) No 469/2009 (the SPC Regulation) applies in each EU member state to effectively provide a system for patent term extension for medicinal products. The SPC Regulation recognises that a patentee loses significant periods of its 20-year term given the time it takes to reach achieving marketing authorisation (MA) for a new product and that an extension is justified to cover underlying R&D investment. The period of extension under an SPC can be up to five years, but is restricted to a product marketed under the underlying patent.

Article 3 of the SPC Regulation specifies the conditions for obtaining an SPC. The *Medeva* proceedings specifically considered the conditions under Articles 3(a) and 3(b), which provide that an SPC can only be granted if in the member state where the SPC application is made and at the date of the application:

- the product for which the SPC is sought is protected by a basic patent (Article 3(a)); and
- a valid authorisation to place the product on the market as a medicinal product has been granted (Article 3(b)).[2]

Whether an SPC application satisfies these two conditions requires identifying: (i) the product which is the subject of the application; (ii) the basic patent required by Article 3(a); and(iii) the product covered by the valid authorisation (ie, the MA) required by Article 3(b).

The relationship between the SPC product and the basic patent required under Article 3(a)

The *Medeva* proceedings arose out of five SPC applications submitted by Medeva BV. The relevant active ingredients of the SPC products (vaccines), the basic patent and the MAs are shown in Figure 1.

Figure 1: The active ingredients/substances of the SPC products, marketing authorisation and the basic patent in the *Medeva* proceedings

SPC 1 09/015

Basic patent:	A B
Marketing authorisation:	A B C D E F G H I
SPC Application:	A B C D E F G H I

SPC 2 09/016

Basic patent:	A B
Marketing authorisation:	A B C D E F G H I J K
SPC Application:	A B C D E F G H I

SPC 3 09/017

Basic patent:	A B
Marketing authorisation:	A B C D E F G H J
SPC Application:	A B C D E F G H J

SPC 4 09/018

Basic patent:	A B
Marketing authorisation:	A B C D E F G H I J K
SPC Application:	A B

SPC 5 09/019

Basic patent:	A B
Marketing authorisation:	A B C D E F G H
SPC Application:	A B C D E F G H

Key:
A = Pertactin
B = Filamentour Haemagglutinin
C = Diphtheria toxoid
D = Tetanus toxoid
E = Pertussis Toxoid
F = Inactivated poliovirus type 1
G = Inactivated poliovirus type 2
H = Inactivated poliovirus type 3
I = Haemophilus influenzae type b capsular polysaccharide
J = Pertussis Fimbrial Agglutinogens 2 and 3
K = Haemophilus influenza type B polyribosylribitol phosphate

With four of these applications, the SPC product includes but is not restricted to active ingredients claimed in the basic patent, being the patent in respect of which extension is sought. This mismatch led to the CJEU considering whether Article 3(a) precludes an SPC where the active ingredients specified in the application include active ingredients not mentioned in the claim(s) of the basic patent.

The CJEU held that an SPC confers the same rights as the basic patent and it follows that Article 3(a) precludes an SPC for active ingredients not specified in the wording of the claims of the patent. In other words, using an example, in the case of an SPC product consisting of a combination of active ingredients A and B, can such a product be said to be protected by a patent which claims only A? The answer is no.

The CJEU's ruling rejects the "infringement test". Supporters of the infringement test applying to Article 3(a) (namely, patentees)

Picture: Natalia Klenova / Shutterstock

argue that a patent for A alone still "protects" the combination of active ingredients A and B even though the patent does not expressly claim B. This is because the combination would infringe the patent by the presence of A. Arguably, the CJEU's position supports the counter argument that whilst the combination may infringe the patent for A, the patent only protects the A element of that combination and not any combination of product consisting of the patent with anything else in the world.

The CJEU's position is also the simpler, as the infringement test warrants a European concept of infringement separate from its meaning under any national law.

The relationship between the SPC product and the MA required under Article 3(b)

In another application, the MA relied on to satisfy Article 3(b) includes active ingredients in addition to those in the SPC product. This mismatch between the active ingredients of the MA and the SPC product led to the CJEU considering whether Article 3(b) precludes an SPC for a combination of active ingredients, where the MA submitted in support of the application contains not only that combination of active ingredients but also other active ingredients.

The CJEU held that Article 3(b) does not, provided the other requirements laid down in Article 3 are also met, preclude an SPC for active ingredients where the designated MA contains not only the combination of those active ingredients but also other active ingredients. This ruling differed from the earlier national rulings, where the approach was that the MA must be for a product the same as the SPC product. The CJEU instead held that the requirement in Article 3(b) that the "product" must be covered by a MA does not in itself rule out the possibility that the MA may cover other active ingredients in such a product. To hold otherwise, the CJEU thought, would be incompatible with the fundamental objectives of the SPC Regulation.

Good news for both patentees and their competitors?

Prior to the CJEU's rulings, much of the discussion about the SPC Regulation focused on what should be the appropriate test for determining the basic patent for the purposes of Article 3(a). If the appropriate test was held not to be the infringement test, the general view was that this could lead to harsh results for patentees whose patented active ingredients had only been marketed in combination with other active ingredients. Such patentees, notwithstanding investing and innovating, would miss out on patent term extension through the SPC Regulation.

Yet, even though the CJEU rejected the infringement test, industry bodies representing the interests of pharmaceutical innovators have welcomed its rulings. This is because by permitting a degree of mismatch between the SPC product and the designated MA in connection with Article 3(b), the CJEU specifically avoided the harsh result described for patentees.

The patentee's objectives are twofold. First, a patentee whose patented active ingredients have only been marketed in combination with other active ingredients does not wish to be deprived of an SPC. Secondly, the patentee will wish to use its SPC to protect its market.

On the first objective, the patentee does not need to nominate as its SPC product the commercial combination product it is seeking to protect. In fact, depending on the active ingredients claimed by the underlying patent, the patentee may not be able to nominate the commercial version as its SPC product.

The reason for a patentee nominating the combination product as the SPC product would be to gain a monopoly for the whole combination of active ingredients (ie, a different monopoly). This, however, is inconsistent with the purpose of the SPC system, which is to provide supplementary protection to that provided by the underlying patent.

Therefore, the CJEU's overall interpretation of Articles 3(a) and 3(b) is good news for patentees to the extent it clarifies that SPCs are not deprived solely because a patentee for a new drug has marketed it only in combination with active ingredients not claimed in the underlying patent. Without this clarification, such patentees could be facing either selling a drug containing only their patented ingredients for which there is no current market but an opportunity for patent term extension or selling a combination product in the interests of patients and national public health authorities, but without the same opportunity for patent term extension.

As to the position of a patentee in respect of the second objective, an SPC covering only part of the active ingredients of a product should operate against infringers in the same way as the underlying patent. If during the period in which such patent was valid, the patentee could not prevent use of a competitor product, then an SPC should not (and will not) give the patentee any greater rights to do so.

So, generic manufacturers and other competitors can also welcome the CJEU's interpretation clarifying that patentees cannot use the SPC system to expand their monopoly. The CJEU reiterated that only one SPC can be granted for a patent, meaning that the same patent cannot be extended multiple times, as was attempted in the Medeva applications, by a patentee tagging different SPC products to the one patent. This limits the patentee's use of the SPC system to implement "evergreening" by reference to that patent. It remains to be seen whether the SPC system will play a role in curtailing evergreening by restricting the number of extensions for medicinal products falling within a particular patent and product family.

Footnotes

1. Delivered on 24 November 2011
2. The other conditions are that the product has not already been the subject of an SPC and the authorisation referred to in Article 3(b) is the first authorisation to place the product on the market as a medicinal product.

Authors

Sangeeta Puran is a partner in the intellectual property practice of the London office of Mayer Brown International LLP. She is a member of the firm's global healthcare group and advises on commercial arrangements covering research, development and commercialisation in the healthcare sector.

Daniel Gallagher is a trainee solicitor in the intellectual property practice of the London office of Mayer Brown International LLP. He has worked on IP-related matters across a number of industry sectors including healthcare.