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Supplementary protection for pharmaceutical products in the EU

Supplementary protection certificates

Patent protection in Europe can last up to 20 years from the date of filing. However, pharmaceutical innovators find that much of this term of protection is lost due to the lengthy regulatory processes required to obtain a marketing authorisation (MA) to place a new product onto the market.

In order to compensate for this, the EU introduced supplementary protection certificates (SPCs) designed to allow innovators an extension of protection equal to the period from patent filing to MA grant, less five years (subject to a maximum extension of five years).

However, recent court decisions have highlighted problems with the SPC framework and raise questions as to whether the system is even fit-for-purpose. Following inconsistent decisions of courts across Europe, several cases have been referred to the Court of Justice of the EU (ECJ). In order to steer the right path through the unclear landscape, innovators need commercially aware advice covering both pharmaceutical regulation and intellectual property.

Conditions of grant

Four conditions need to be satisfied in order to obtain an SPC: the product is protected by a "basic patent" in force; a valid MA has been granted; the product has not already been the subject of an SPC; and the MA is the first authorisation to market the product as a medicinal product.

Particular problems arise when considering products containing combinations of active ingredients. These products have been treated differently in different EU countries, leading to a confused state of affairs.

Key problem areas

"Product protected by a basic patent" and "valid authorisation"

The question of what is "protected" by a basic patent is not harmonised at European level. The ECJ has held that this is a matter for national law. Courts in different countries have adopted different tests.

There are essentially two approaches: the 'infringement' test - would the product infringe the basic patent (for instance, where the patent covers one part of a combination product); and the narrower 'express disclosure' test - does a claim of the basic patent, properly construed, disclose the entire product. It is the latter test that has been adopted by the English courts, while, eg, the German courts adopt the 'infringement' test.

Where the product authorised under the MA is broader than that disclosed in the patent, the 'express disclosure' test cannot be circumvented by applying for an SPC that is limited to the scope of the basic patent because the SPC must also have the same scope as the MA. The table below summarises the differences in approach under the two tests.

Combination products summary

Basic patent claim	MA	SPC application	SPC granted?	
			Infringement test	Express disclosure test
A	A+B	A	No	No
A	A+B	A+B	Yes	No
Product 'comprising' A	A+B	A+B	Yes	No
A+B	A	A	Yes (only if indirect infringement is accepted)	No
A+B	A+B	A+B	Yes	Yes
A plus optionally any other (unidentified) therapeutic agent	A+B (a therapeutic agent)	A+B (a therapeutic agent)	Yes	Yes

Several cases have been referred to the ECJ for preliminary rulings as to which tests are correct. The eventual decisions will have huge consequences for innovative pharma.

Second medical uses

The "product" is defined as "the active ingredient or combination of active ingredients". The ECJ has taken a very narrow interpretation of the "product", denying SPC protection for reformulations of existing active ingredients. Similar issues arise for second medical use patents.

The English Court of Appeal has recently expressed concern that a blanket denial of SPC protection for second medical use patents would be "unfortunate". A reference to the ECJ has been made in a case that concerns a medicinal product for the treatment of insomnia in humans that was denied SPC protection due to the active ingredient having previously been approved for use in improving the reproductive performance of sheep.

Paediatric extensions

In order to encourage pharmaceutical companies to test their products for safety in children, the EU provides for a six-month paediatric extension (PE) to the SPC term provided certain conditions are satisfied. However, without an SPC there can be no PE.

This has become an issue where an MA is granted four and a half to five years after patent filing, where an SPC itself would not provide any benefit. The UK courts (unlike, eg, those in Germany) allow the grant of 'negative-term' SPCs, which may be pushed into positive territory by the addition of the six-month PE. The ECJ is currently considering the legality of this approach: indications are that the UK approach will be approved, providing a boost for innovative pharma.

In summary

Given the identified problem areas and pending ECJ references, the SPC landscape remains blurred. The key for pharmaceutical innovators is to manage the uncertainty by considering SPC availability during patent drafting and prosecution and ensuring close co-operation between IP and regulatory functions. Foreseeing and avoiding the problem areas is the best way to ensure full protection for the blockbuster drugs of the future. Taking advice on the best and worst case scenarios is particularly necessary in uncertain times.

Arnold & Porter's London practice includes innovative work in the intellectual property and life sciences areas. We count some of the world's largest global pharmaceutical and medical device companies among our clients, and our practice is recognised for its leadership in this arena. The firm's life sciences regulatory practice was described by Chambers UK 2011 as "second to none".