

***Supplementary Protection Certificates -
Problems in Practice***
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Supplementary Protection Certificates (SPCs) – Problems in Practice

- ▼ Problems with the mechanics of applying for an SPC
- ▼ Problems with the substantive law which determines
 - ▼ whether or not an SPC can be granted or,
 - ▼ if granted (especially in a non-SPC examining regime) whether it is valid
- ▼ Namely
 - ▼ What can constitute a “basic patent” for the purposes of the SPC Regulation?
 - ▼ What can constitute the first marketing authorisation in the EU for a “product” for the purposes of the SPC Regulation?
 - ▼ What marketing authorisations count for this purpose?
 - ▼ What constitutes a “product” and when is a product not a single active but a “combination of actives”?



Supplementary Protection Certificates – The statutory regime

- ▼ Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products
 - ▼ In force from 1993
 - ▼ Challenged in Case C-350/92 *Kingdom of Spain v Council*
 - ▼ Differing transitional provisions for different Member States, now spent
- ▼ Regulation (EC) No 1610/96 concerning the creation of a supplementary protection certificate for plant protection products
 - ▼ In force from 1997
 - ▼ Provides guidance as to the interpretation of Regulation 1768/92 without formally amending it (See Recital 17)
 - ▼ Transitional provisions now spent
- ▼ Both Regulations
 - ▼ New transitional provisions affecting the two most recent waves of EU accessions



Issues as to the mechanics of applying for a Supplementary Protection Certificate

- ▼ Choose basic patent
- ▼ File at national POs within six months of first Marketing Authorisation for that product having effect in that country
 - ▼ Unless patent not yet granted in which case file within 6 months of grant
 - ▼ Question as to date of grant of Marketing Authorisation and whether under national or EU law referred to ECJ from DE in C-452/07 *Health Research Inc*
 - ▼ Identify and file
 - ▼ Marketing Authorisation itself (Art 8(1)(b))
 - ▼ First Marketing Authorisation in EU (and EEA) (Art 8(1)(c))
- ▼ But some latitude if cannot get the actual Marketing Authorisations
 - ▼ Case 181/95 *Biogen v SKB Biologicals* relaxes Art 8(1)(b)
 - ▼ Plant Protection Products SPC (PPP SPC) Regulation relaxes Art 8(1)(c))



What can constitute a “basic patent”?

- ▼ Supplementary Protection Certificate (SPC) confers effective patent term extension (“within the limits of protection of the basic patent”), as to the product covered by the Marketing Authorisation and for any use of the product as a medicinal product authorised before expiry of the SPC, of the lesser of
 - ▼ 5 years from expiry of basic patent
 - ▼ or 15 years from first Marketing Authorisation in the EU for any medicinal product containing the product
- ▼ Article 1(c) of SPC Regulation 1768/92 defines “basic patent” as
 - ▼ “a patent which protects a product as defined in (b) as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;”
- ▼ Article 3(a) requires that at the date of application
 - ▼ “the product is protected by a basic patent in force”



What can constitute a “basic patent”?

- ▼ Case C-392/97 *Farmitalia Carlo Erba's SPC Application*
 - ▼ “29 ... in order to determine, in connection with the [SPC Regulation] whether a product is protected by a basic patent, reference must be made to the rules which govern that patent.”
- ▼ National courts do not equate “is protected by” with “would infringe”
 - ▼ *Takeda Chemical Industries Ltd's SPC Application (No. 3)* (English Patents Court) [2004] RPC 3 – patent with a product claim to lansoprazole was not a basic patent that protected the combination of lansoprazole + a specified antibiotic.
 - ▼ “In truth the combination is not protected by the basic patent in force - What is protected is only the [one component] element of the combination”
 - ▼ Followed by UKIPO in *Gilead Sciences, Inc's SPC Application* (10 January 2008)
 - ▼ Decision of the Spanish Supreme Court of 4 July 2007 as to Squibb's SPC application finding that a patent for a process to produce fosinopril was not a basic patent that protected the combination of fosinopril + hydrochlorothiazide



What can constitute the “first marketing authorisation in the Community” for a “product”?

- ▼ Supplementary Protection Certificate (SPC) confers effective patent term extension, as to the product covered by the Marketing Authorisation and for any use of the product as a medicinal product authorised before expiry of the SPC, of the lesser of
 - ▼ 5 years from expiry of basic patent
 - ▼ or 15 years from first Marketing Authorisation in the EU for [any medicinal product containing] the product
- ▼ Article 1(b) defines product as
 - ▼ “the active ingredient or combination of active ingredients of a medicinal product”
- ▼ Article 3(d) requires that the Marketing Authorisation on which the SPC application is based is the first to place the product on the market as a medicinal product (in that country)
- ▼ Two issues
 - ▼ What is a “first Marketing Authorisation [in the EU] / [in that country]”?
 - ▼ What is a “Product”?



What can constitute the “first marketing authorisation in the Community” for a “product”?

- ▼ Much SPC case law has concerned attempts to avoid the consequences of an early Marketing Authorisation in the EU for any “medicinal product” containing the “product” whether in the context of
 - ▼ the original transitional provisions for medicinal products already on the market on the coming into force of the SPC Regulation
 - ▼ which were keyed in different ways for different countries to when the first marketing authorisation in the EU had been or, these days
 - ▼ the availability of SPC protection, or if available its term
 - ▼ as this is also keyed to when the first marketing authorisation for the active ingredient or combination of active ingredients of a medicinal product in the EU had been



What can constitute the “first marketing authorisation in the Community”?

- ▼ Marketing Authorisation in Switzerland counts because under the EEA Agreement “Community” means EEA and by virtue of Liechtenstein linkage this includes Switzerland for this purpose
 - ▼ Cases C-207/03 *Novartis* and C-252/03 *Millenium*
- ▼ Marketing Authorisation still counts even where product could not be sold before reimbursement authorization secured
 - ▼ Case C-127/00 *Hassle v Ratiopharm*
- ▼ Marketing Authorisation counts as against an SPC on a human medicinal product even where it was for a veterinary medicinal product
 - ▼ Case C-31/03 *Pharmacia Italia*
- ▼ What is the status of a pre-Community accession Marketing Authorisation?
 - ▼ BE – *Almirall's SPC* (CFI Brussels, Under Appeal) – pre accession PT authorisation counts
 - ▼ DE – 3 Ni 2/06 (BPatG) – similar view, not following an earlier BPatG decision
 - ▼ DE – 3 Ni 59/05 – *Memantine* (BPatG) – pre Directive 65/65 DE authorisation counts



What can constitute the first marketing authorisation in the Community for a “product”?

- ▼ Marketing Authorisation can have been for impure active
 - ▼ C-258/09 - *BASF* – (Plant Protection Product SPC Regulation)
 - ▼ What then is the status of an enantiomer the racemate of which was the subject of an earlier marketing authorisation?
- ▼ Marketing Authorisation can have been
 - ▼ for a wholly different formulation of an active
 - ▼ *AB Draco's SPC Application* (English Patents Court) [1996] RPC 417
 - ▼ C-431/04 *MIT* ...
 - ▼ for use of an active in a product for a wholly different indication
 - ▼ C-202/05 - *Yissum* ...
 - ▼ DE – 3 Ni 59/05 – *Memantine* (BPatG)



ECJ Case C-431/04 - *Massachusetts Institute of Technology*

- ▼ Basic patent was for
 - ▼ The combination of (1) polifeprosan, a polymeric, biodegradable excipient and (2) carmustine, an active ingredient which had long been used in intravenous chemotherapy
 - ▼ The combination reduced the toxicity of carmustine
- ▼ Marketing Authorisation granted for the combination used in the treatment of brain tumours, sold as Gliadel®
- ▼ MIT's SPC application in Germany for the combination was rejected
 - ▼ Polifeprosan could not be considered to be an active ingredient within the meaning of Article 1(b) and Article 3 of Regulation No 1768/92.
 - ▼ No SPC could be granted for carmustine alone because it had already long been covered by an MA



ECJ Case C-431/04 - *Massachusetts Institute of Technology*

- ▼ Advocate General recommended that the ECJ render a decision which would have allowed the SPC
- ▼ The ECJ disagreed, holding that
 - ▼ “A substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of ‘active ingredient’, which in turn is used to define the term ‘product’”
 - ▼ “The fact that the substance without any therapeutic effect of its own renders possible a pharmaceutical form of the medicinal product necessary for the therapeutic efficacy of the substance which does have therapeutic effects cannot invalidate that interpretation”
- ▼ Therefore not a combination of actives
- ▼ Thus an old marketing authorisation for the real active precluded SPC grant



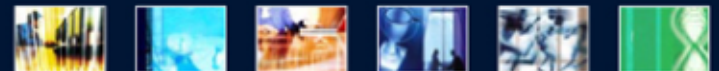
ECJ Case C-202/05 - *Yissum R&D Company of the Hebrew University of Jerusalem*

- ▼ Basic patent for second use
- ▼ Marketing authorisation for reformulated active granted
- ▼ SPC sought for
 - ▼ Combination of active and excipient
 - ▼ Active on basis that new use of active meant this was a new “product” under the SPC Regulation
- ▼ First question dropped per *MIT* but second question proceeded
- ▼ ECJ held that:
 - ▼ “[The SPC Regulation] is to be interpreted as meaning that in a case where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product.”



Combinations of Actives

- ▼ From a regulatory perspective, a new fixed combination of actives is regarded as a new product.
- ▼ The same applies in the SPC system.
- ▼ Case law
 - ▼ ECJ Case C-431/04 - *Massachusetts Institute of Technology*
 - ▼ *Takeda Chemical Industries SPC Application (No. 3)* [2004] RPC 3
 - ▼ “In truth the combination is not protected by the basic patent in force - What is protected is only the [one component] element of the combination”
 - ▼ *Centocor’s SPC Application* [1996] RPC 118
 - ▼ Patent for combination cannot be basic patent for a product that is one element only of the combination, even if commonly administered along with other product
- ▼ Does not provide a mechanism for protecting two products with different actives administered at the same time but not combined together in the one product



Conclusions

- ▼ In determining whether a patent can constitute a basic patent for a product
 - ▼ “is protected by” is, under national case law, a narrower concept than “infringes”
- ▼ There is no scope for SPC protection for an old single active (ie “product”) unless as part of a new combination of real actives (ie combination “product”)
 - ▼ Little prospect of legislative change
- ▼ In general the case law is leaning towards a broad view of what constitutes a first marketing authorisation for a product
- ▼ The combinations provisions of SPC Regulation are of narrow scope
 - ▼ Actives must be compounded together in the same medicinal product
 - ▼ Does not provide a mechanism for protecting two medicinal products with different actives administered at the same time but not combined together in the one product

