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A Hat Trick of SPC Judgements from the CJEU - All Clear Now?

The last quarter of 2013 has seen a flurry of activity on Supplementary Protection Certificates (SPCs) with referrals from the national courts, opinions of the Advocate General, reasoned orders and judgements from the CJEU. The 12th December 2013 alone saw three important SPC judgements issued on the same day. We provide a brief summary of developments below and discuss the importance of the decisions for SPCs and applications.

Not necessary for a patent claim to specifically identify an active ingredient by a structural formula for an SPC? – *C-493/12 Eli Lilly and Co Ltd v Human Genome Sciences Inc*

Human Genome Science (HGS) is the holder of an EP (UK) Patent relating to the discovery of a new protein "Neutokine alpha" as well as to antibodies that bind specifically to that protein. The claims of the Patent had been found by the Supreme Court in the UK to be valid.

Lilly wished to market a pharmaceutical composition containing an antibody "tabalumab," that binds to HGS's Neutokine alpha, as an active ingredient. Lilly recognised although tabalumab was not specified in HGS's patent, their composition would, if marketed, infringe HGS's Patent.

Lilly brought an action before the UK Patents Court for a declaration that any SPC which relied on HGS's Patent and based on a Market Authorisation for a medicinal product containing Lilly's tabalumab antibody would be invalid. Lilly argued that their antibody was not covered by a "basic patent" within the meaning of Article 3 of the SPC Regulation. HGS contended that an SPC may be validly granted to it on the basis of its basic patent and any future MA obtained by Lilly for tabalumab. HGS also contended that it was standard practice for antibodies binding to previously unidentified proteins (such as Neutokine alpha) to be considered novel and inventive, and hence would be covered by their Patent. Functionally defined antibodies are usually accepted by the EPO and routinely used to support SPC applications.

The UK Patents Court stayed proceedings and referred 3 questions to the CJEU regarding (i) the criteria for deciding whether "the product is protected by a basic patent in force", (ii) was the same for combination products, and (iii) can antibodies be defined functionally?

The CJEU looked at the interpretation of the patents under the EPC and concluded that Article 3(a) of the SPC must be interpreted as meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, it is **not** necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula in the claims of a patent issued by the EPO, Article 3(a) does not, **in principle**, preclude the grant of a SPC for that active ingredient, **on condition** that it is possible to reach the conclusion on the basis of those claims, interpreted in the light of the description

of the invention, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question.

So, it is not necessary for a patent claim to specifically identify an active ingredient – however, the CJEU has left it to the national courts to decide if "the claims relate, implicitly but necessarily and specifically, to the active ingredient in question". That said the judgement provides some guidance to the courts and suggests that the objective of the SPC Regulation is to compensate the basic patent holder for the research which led to the specific approved medicinal product. If a patent holder does not sufficiently specify the product to be commercially exploited it may be appropriate to refuse an SPC. Undoubtedly the lack of clear guidelines from the CJEU will lead to divergent decisions from the national courts.

No second SPC if combination is not protected as such? *C-443/12 Actavis Group PTC EHF and Actavis UK Ltd v Sanofi, 12 December 2013*

Sanofi was the owner of an EP (UK) Patent relating to an anti- hypertensive drug "irbesartan". The Patent expired on 20 March 2011. Sanofi held an SPC for "Aprovel ™" (irbesartan optionally in the form of one of its salts), which expired on 14 August 2012. Sanofi also held a "combination" SPC for "CoAprovel ™" (irbesartan optionally in the form of one of its salts and hydrochlorothiazide) which would expire on 14 October 2013.

Actavis intended to market generic versions of both Aprovel ™ and CoAprovel ™. Both parties agreed that the generic version of CoAprovel™ would infringe the "combination" SPC. Actavis contended that the "combination" SPC was invalid as the combination was not protected by the basic patent within the meaning of Article 3 of the SPC Regulation. Furthermore, the "combination" SPC was invalid as it had already been the subject of the first "non-combination" SPC.

The Sanofi patent claimed irbesartan per se and also had as claim 20 a claim to irbesartan and a diuretic. However, hydrochlorothiazide was not specified in the claim.

Given diverging opinion amongst national courts on the grant of more than one SPC per patent, the UK Patents Court stayed proceedings and referred 2 questions to the CJEU. In brief, (i) What are the criteria for deciding whether "the product is protected by a basic patent in force" in Article 3 of the SPC Regulation and (ii) where multiple products are protected by a basic patent in force, does the SPC Regulation preclude the patentee from obtaining more than one SPC? Notably, the first question is the same as that asked in Lilly v HGS above.

The CJEU ruled that where, on the basis of a patent protecting an innovative active ingredient and a MA for a medicinal product containing that ingredient as the single active ingredient, the holder of that patent has already obtained an SPC for that active ingredient entitling him to oppose the use of that active ingredient, either alone or in combination with other active ingredients. As such Article 3(c) of the SPC Regulation must be interpreted as **precluding** that patent holder from obtaining a second

supplementary protection certificate on the basis of the same patent for a combination of that same active ingredient with another active ingredient **which is not protected as such** by the patent.

However, in the reasoning, the CJEU stated that if a combination consisting of an innovative active ingredient in respect of which an SPC has already been granted and another active ingredient, which is **not** protected as such by the patent in question, is the subject of a **new basic patent** within the meaning of Article 1(c) of the SPC Regulation, the new patent could, in so far as it covered a totally separate innovation, confer entitlement to an SPC for that new combination that is subsequently placed on the market.

The judgement therefore appears to turn on whether the product in question is protected as such by the patent in question.

Only one SPC per product per patent? *- C484/12 – Opinion of Advocate General in "Georgetown University", 14 November 2013 and Georgetown University v Octrooicentrium Nederland, Judgement of the Court, 12 December 2013*

Georgetown University owned a patent that protected four active substances – HPV6, HPV11, HPV16 and HPV18 and had been granted a marketing authorisation for the combination of these substances. Georgetown University sought a SPC for HPV16. SPCs in relation to this patent covering vaccines including a combination of HPV16 and HPV18 and a combination of HPV6, HPV11, HPV16 and HPV18 had already been obtained.

The Dutch Patent Office refused the application for a SPC for HPV16 on the basis that only one SPC could be granted per patent. Georgetown University subsequently appealed to the District Court in October 2012. The Patent Office stated that the application (for a SPC for HPV16) should be refused because two SPCs had already been granted based on the same basic patent, namely one for the combination of HPV16 and 18, and one for the combination of HPV6, 11, 16 and 18. This reasoning was based upon a comment in decision C322/10 "Medeva", where it was stated that… "Where the patent protects a product, in accordance with article 3(c) of Regulation No 469/2009, only one certificate may be granted for that basic patent."

The case was referred to the CJEU on the basis that the correct interpretation of article 3(c) of the Regulation was unclear. Five questions were asked in an attempt to clarify the situation on whether only one SPC may be granted per patent, and if so, could existing SPCs be surrendered to allow the grant of a new SPC?

The CJEU held that on the basis of a basic patent and a MA for a medicinal product consisting of a combination of several active ingredients, the patent holder has already obtained a SPC for that combination of active ingredients, protected by that patent within the meaning of Article 3(a) of the SPC Regulation. However, Article 3(c) of that regulation must be interpreted as not precluding the proprietor from also obtaining a supplementary protection certificate for one of those active

ingredients which, individually, is also protected as such by that patent. Therefore, more than one SPC per patent is possible.

The judgement at paragraph 33 carefully distinguishes over the Actavis judgement above because the individual components were protected by the patent.

The judgement also indicates at paragraph 38 that if the first SPC had been for HPV-16 it would not have been possible to obtain another SPC on the basis of the same patent relating to another product containing HPV-16.

Advocate General Opinion - The earlier Advocate General opinion did not respond on the issue of regarding the grant of one or more SPCs based on the same patent. However, it did recommend that, on the basis that only one SPC is allowed per patent the patentee should be able to surrender earlier SPCs in order to have a later one granted. However, such surrender would not have a retrospective effect, so must be made before the grant of a new SPC. Unfortunately the CJEU judgement did not address this aspect of the referral and so the effect of surrendering earlier SPCs remains unclear.

Vaccine + adjuvant does not give a new medicinal product for which an SPC can be granted - *C-210/13 Glaxosmithline Biologicals SA, Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma GmbH & Co. KG v Comptroller-General of Patents, Designs and Trade Marks, 14 November 2013*

Glaxosmithkline (GSK) applied to the UKIPO for two SPCs, for an adjuvant and for an influenza vaccine including the adjuvant, based on a European marketing authorisation for a form of the vaccine. The UKIPO refused the application on the basis that the adjuvant was not an “active ingredient” under the definition of protected "products" in Article 1(b) of the SPC Regulation.

Given a number of inconsistencies in the relevant case law, the UK Court referred two questions to the CJEU. Specifically, whether an adjuvant which has no therapeutic effect on its own, but which enhances the therapeutic effect of an antigen when combined with that antigen in a vaccine, can be considered an ‘active ingredient’ within the meaning of SPC regulation, and if not, whether the combination of such an adjuvant with an antigen nevertheless be regarded as a ‘combination of active ingredients’.

The response from the CJEU was that Article 1(b) of the SPC Regulation “...must be interpreted as meaning that, just as an adjuvant does not fall within the definition of 'active ingredient' within the meaning of that provision, so a combination of two substances, namely an active ingredient having therapeutic effects on its own, and an adjuvant which, while enhancing those therapeutic effects, has no therapeutic effect on its own, does not fall within the definition of 'combination of active ingredients' within the meaning of that provision".

This is another important decision from the CJEU with respect to clarifying the SPC regulations. It confirms that adjuvants in vaccines are not in themselves "active" and as such a vaccine + adjuvant does not give a new medicinal product for which an SPC can be granted.

Change in UKIPO Practice for the calculation of the duration of certain SPCs - *BL O/418/13 Genzyme Corporation, 22 October 2013*

Genzyme applied to the UKIPO for a six month extension to an existing SPC. As part of their application, they requested that the term for the original SPC be corrected because the SPC expiry date should have been calculated from the date of notification of the relevant marketing authorisation. Not, as it was, from the date of grant of such authorisation. The basis for their argument was that the holder of the marketing authorisation does not know marketing authorisation has been granted and has valid legal effect until notification is received. The OJEU records the date of the Commission decision and the date on which the decision is delivered to the holder by a nominated courier (the notification date). The notification date is generally a few days after the Commission decision.

The UKIPO hearing concluded that the calculation of the duration of an SPC based upon a European marketing authorisation should take account of the date of notification of the decision by the European Commission to grant the relevant marketing authorisation and not the date of the decision itself. In this specific case, this afforded 2 additional days of SPC protection for the Genzyme product.

This has resulted in a change in practice of the UKIPO regarding the calculation of the duration of a SPC where the first authorisation in the European Community is one granted by a decision of the European Commission. The decision currently only applies to marketing authorisations granted under the centralised procedure and any additional term cannot exceed the 5 year cap on SPC term. It remains to be seen if other national patent offices will adopt the same practice.

SPC holders may therefore benefit from extra days of SPC protection. HGF can advise on the procedure to amend applications for SPCs, granted SPCs and paediatric extensions to SPCs following this decision.

The meaning of the "first market authorisation" - *Case C-617/12 AstraZeneca AB v Comptroller-General of Patents, 14 November 2013*

The referral to the CJEU was made by the UK Patents Court in October 2013 asking for clarification on what constitutes the first authorisation to place a product on the market in the Community. The case specifically concerned a Swiss marketing authorisation, which at the time was automatically valid in Lichtenstein and so valid in the EEA. The Swiss authorisation was however considered by the European Medicines Agency (EMA) not to satisfy the conditions for grant of a European marketing authorisation and subsequently the Swiss marketing authorisation was suspended. AstraZeneca carried out further clinical trials on its product and some years later the EMA granted a new marketing authorisation for the product. AstraZeneca argued that the date of the new authorisation should be used to calculate the SPC term.

The CJEU concluded that the SPC Regulation "must be interpreted as meaning that an administrative authorisation issued for a medicinal product by the Swiss Institute for Medicinal Products (SwissMedic), which is automatically recognised in Liechtenstein, must be regarded as the first authorisation to place that medicinal product on the market… where that authorisation predates marketing authorisations issued for the same medicinal product, either by the European Medicines Agency (EMA), or by the competent authorities of European Union Member States…" The fact that, on the basis of similar clinical data, the European Medicines Agency, unlike the Swiss authority, refused to grant a marketing authorisation for that medicinal product at the conclusion of its examination of those data, or the fact that the Swiss authorisation to place the product on the market was suspended by the Swiss Institute for Medicinal Products and subsequently reinstated by the latter only when the holder of the authorisation submitted additional data to it was said to be irrelevant.

This decision relates to a very specific set of circumstances which are unlikely to affect other SPCs. However it confirms the strict interpretation of the "first authorisation" requirements of the SPC Regulation 469/2009/EC.

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If you would like further advice on this or any other Patent matter, please contact Mike Nelson or your usual HGF representative or visit our Contact Page to get in touch with your nearest HGF office.