Client Alert

December 2013

Less Uncertainty in the SPC World - More Clarity Still Needed

On 22 November 2011, the Court of Justice of the European Union (CJEU) rendered two very important rulings in the *Medeva* (C-322/10) and *Georgetown* (C-422/10) cases. Those rulings however raised new issues that national patent courts quickly referred back to the Court. Yesterday, the CJEU decided on three *Medeva* follow-up cases. The new rulings brought more clarity about the conditions under which an SPC may be granted. So,

(i) An active ingredient is "specified in the wording of the claims" if it is defined structurally or functionally therein. Where the active ingredient is covered by a functional definition or formula in the claims of a patent issued by the European Patents Office, an SPC may, in principle, be granted for that active ingredient, provided that the claims, interpreted inter alia in light of the description of the invention, allow to conclude that they relate, implicitly but necessarily and specifically, to the active ingredient; such conclusion has to be reached by the national court.

(ii) An SPC for a combination of active ingredients does not preclude SPCs for the individual active ingredients, even on the basis of a same basic patent. On the other hand, an SPC for an active ingredient precludes an SPC for a combination of that active ingredient and another ingredient where the latter is not protected as such by the basic patent.

Questions of course remain, especially as regard the identification of the active ingredient in the patent claims. More generally, the CJEU used terms that undermine the general scope of its rulings or made comments that cast doubt about established principles, such as the granting of an SPC on the basis of a marketing authorization (MA) held by an independent third party.

When is an active ingredient specified in the wording of the claims of the basic patent?

In the *Medeva* and *Georgetown* cases, the CJEU first ruled that an SPC may not be granted for active ingredients that are not specified in the wording of the claims of the basic patent relied upon for the SPC application. That ruling was confirmed the day after in three other cases.

National patent offices and courts struggled to apply a criterion as vague as "specified in the wording of the claims of the basic patent", so follow-up questions were referred to the CJEU.

In the *Actavis v. Sanofi* case (C-443/12), the UK High Court of Justice asked the European Court about the criteria for deciding whether "the product is protected by a basic patent in force" under Article 3(a) of Regulation 469/2009. The case concerned a combination of an active ingredient (irbesartan) and a diuretic. Sanofi was granted an SPC for irbesartan on the basis of a marketing authorization (MA) for Aprovel, a medicinal product containing that active ingredient only. Sanofi then applied for an SPC for the combination on the basis of a second MA, a MA for CoAprovel, a medicinal product containing the combination. The patent claimed irbesartan as well as irbesartan in association with a diuretic but no specific diuretic was mentioned in the claims or the description of the invention. The question on the identification of the diuretic in the basic patent however was not answered by the Court as it first decided that an SPC may not be granted for the combination (see below).

The UK High Court asked a same question in the *Eli Lilly v. Human Genome Science* case (C-493/12) but this time the question concerned antibodies (in the case of a claim to an antibody or a class of antibodies, is it sufficient that the antibody or antibodies are defined in terms of their binding characteristics to a target protein, or is it necessary to provide a structural definition for the antibody or antibodies, and if so, how much?). The *Lilly* case was complex. Human Genome Science holds a patent that relates to a new proteine and to antibodies which bind specifically to that protein. Eli Lilly filed a request to prevent Human Genome Science from obtaining an SPC on the basis of the MA for which Eli Lilly intends to apply for a medicinal product containing an antibody (tabalumab). The basic patent defines the antibodies functionally rather than structurally and thus covers numerous unspecified antibodies. Moreover, the patent specification contains neither an example of an antibody being made or tested, nor a structural description of antibodies that could have therapeutic effect. Tabalumab is not expressly named in the claims and is not otherwise specified in the descriptions or specifications of the patent. The CJEU first recalled that an active ingredient is only protected by the patent if it is identified in the patent claims by means of a structural or a functional definition. The Court then decided that it is not necessary for the active ingredient to be identified in a structural definition or formula. Where the active ingredient is covered by a functional definition or formula in the claims of a patent issued by the European Patents Office, an SPC may, in principle, be granted for that active ingredient, provided that the claims, interpreted inter alia in light of the description of the invention, allow to conclude that they relate, implicitly but necessarily and specifically, to the active ingredient. This conclusion however has to be reached by the national court.

Can several SPCs be granted on the basis of a same basic patent?

In the *Medeva* and *Georgetown* cases, the Court also ruled that an SPC for a combination of two active ingredients may be granted where the medicinal product for which the MA is submitted in support of the SPC application contains not only that combination of the two active ingredients but also other active ingredients. The Court specified that (i) only the authorisation in respect of the first medicinal product placed on the EU market comprising, among its active ingredients, the combination of the two active ingredients, may be regarded as the first MA for that 'product'; and (ii) where a patent protects a product, only one SPC may be granted for that basic patent.

This last specification casts doubt among the patent offices about the possibility to grant several SPCs on the basis of a same basic patent.

In the *Georgetown II* case (C-484/12), the Dutch court asked the CJEU whether, in a situation where a basic patent protects several products, the patent holder may be granted an SPC for each of the protected products. The Court ruled that the granting of an SPC for a combination of active ingredients does not prevent the granting of SPCs for the individual active ingredients, even on the basis of a same basic patent.

A same question had been asked by the UK High Court in the *Actavis v. Sanofi* case (C-443/12). The factual situation however was different from this in the *Georgetown II* case as the second SPC (for the combination) was requested on the basis of a different, subsequent MA. Could an SPC be granted for the combination even though a first SPC had been granted for irbesartan on the basis of a same patent but a different MA? The CJEU decided that such an SPC may not be granted, regardless of whether the combination is protected as such by the basic patent. The Court noted that an SPC had been granted for irbesartan, that the diuretic was not protected as such by the patent and, that an SPC for an active ingredient protects against medicinal products containing that active substance (i.e. the combination had already benefited from the SPC protection through the SPC for irbesartan). Interestingly, the Court stressed that the objective of Regulation No 469/2009 is to compensate for the delay to the marketing of the core inventive advance that is the subject of the basic patent, i.e. irbesartan. The balance between the interests of the pharmaceutical industry and those of public health would be upset if all subsequent marketing of that active ingredient in conjunction with an unlimited number of other active ingredients, not protected as such by the basic patent but simply referred to in the wording of the claims of the patent in

general terms (such as 'beta-blocking compound', 'calcium antagonist', 'diuretic', 'non-steroidal anti-inflammatory' or 'tranquilizer'), were to entitle to multiple SPCs.

How can a company remedy the situation where it holds an SPC that covers an active ingredient that is not specified in the wording of the patent claims or that affords less protection than another possible SPC?

On the one hand, an SPC that has been granted for an active ingredient which is not specified in the wording of the patent claims is invalid. On another hand, an SPC that has been granted for a combination of active ingredients affords less protection than an SPC that would have been granted for an individual active ingredient contained in that combination; indeed, an SPC for an individual active ingredient protects against medicinal products which contain that active ingredient, alone or in combination with other active ingredients (see *Novartis v. Actavis,* C-442/11). How can companies address such situations?

Companies may want to file a new SPC application that covers, respectively, an active ingredient which is specified in the wording of the patent claims or an individual active ingredient. To the extent that only one SPC may be granted per active ingredient, this remedy presupposes that the company surrenders the SPC which has already been granted. This was Georgetown' s proposal to the Dutch patent office.

In the *Georgetown II* case, the Dutch court asked the CJEU whether, if the patent holder were to surrender the granted SPC in order to file an SPC application for another active ingredient, the surrender of the SPC would be governed by Regulation 469/2009 or by national law and would apply retrospectively. The CJEU did not address those issues as it first decided that SPCs may be granted for individual active ingredients even if an SPC has already been granted for a combination of active ingredients. However, the Advocate General had considered that surrenders of SPCs are governed by Article 14 of Regulation 469/2009 and that they do not apply retrospectively.

Where do we stand now?

The new rulings of the CJEU clarify the following:

- An SPC for a combination of active ingredients does not preclude an SPC for each individual active ingredient on the basis of a same basic patent.

- An SPC for an active ingredient precludes an SPC for a combination of that active ingredient and another ingredient which is not protected as such by the basic patent. In the *Actavis v. Boehringer* case (C-577/13), which is still pending, the Court is asked whether an SPC may be granted to a combination of active ingredients despite an SPC having been granted to one of the active ingredients of that combination. This question is still relevant if both active ingredients are protected as such by the basic patent.

- An active ingredient may be identified in the patent claims by means of a structural or a functional definition or formula. A structural definition is not required, but, where the definition is functional, the claims, interpreted in the light of the description of the invention, must allow to conclude that they relate, implicitly but necessarily and specifically, to the active ingredient. In its ruling, the Court used the expression "in principle" and expressly referred to a patent granted by the European Patent Office; both could justify a different outcome in other factual cases, for example, in cases where the patent would be national.

In the *Eli Lilly v. Human Genome Science* case, the CJEU stressed that, in light of the objective of Regulation No 469/2009, the refusal of an SPC application for an active ingredient which is not specified in a patent issued by the EPO may be justified "where the holder of the patent in question has failed to take any steps to carry out more in-depth research and identify his invention specifically, making it

possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients". If an SPC were granted to the patent holder, even though he did not invest in research relating to the pharmaceutical aspect of his original invention (since he was not the MA holder for the medicinal product), the objective of Regulation No 469/2009 would be undermined (43). This comment is important for the current debate about the possibility to claim an SPC on the basis of a MA held by an independent third party. Eli Lilly had asked that this question be referred to the CJEU as well, but the UK court refused on the ground that the answer was clear in light of the Court's ruling in the *Biogen* case (C-181/95). Not that clear after all, as the CJEU's comment suggests that an SPC based on a MA held by an independent third party could be refused if the patent holder did not invest at all in the determination of the active ingredient that may be commercially exploited in a medicinal product.

Finally, surrendering an SPC in order to file a new SPC application for a "better" SPC may not be a sound option. The surrender having no retrospective effect (according to the Advocate General), the patent holder would be requesting a second SPC for the same active ingredient, what is not in line with Regulation 469/2009. The *Actavis v. Boehringer* case (C-577/13) tests another remedy with the CJEU, i.e. amending the patent. Indeed, the Court is asked whether the patent may be amended after grant to specify a product, if so until when, and whether the SPC procedure may be suspended in the meantime.

Contacts

Geneviève Michaux
gmichaux@hunton.com

Gary C. Messplay
gmessplay@hunton.com

Prof. Lucas Bergkamp
lbergkamp@hunton.com