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Three SPC Judgements - are things any clearer?

The end of 2013 saw a flurry of activity in the SPC world as the CJEU handed down its judgements in cases **C-484/12** *(Georgetown University v Octrooicentrum Nederland)*, **C-443/12** (*Actavis Group v Sanofi*) and **C-493/12** (*Eli Lilly v HGS*). These decisions have been eagerly awaited, because the referrals to the court addressed two key issues: (I) can a Patentee obtain more than one SPC per patent and (II) what is a "product protected by a basic patent in force" under Article 3(a) of Regulation No. 469/2009 (the SPC Regulation).

Regarding the first issue, it has been made clear by the decision in C-484/12 that it is possible to obtain several SPCs on the basis of a patent which protects several different products, provided that each of those products is 'protected as such' by that basic patent. However, in C-443/12, it was held that Sanofi was not entitled to two SPCs based on their patent covering the active ingredient "irbesartan". More specifically, it was held that the first SPC covering irbesartan and the second SPC, which was based on a later marketing authorisation for irbesartan in combination with a specific diuretic not explicitly identified in the claims of the patent, were connected with the *same product*. Although the claims of Sanofi's Patent did cover irbesartan in combination with a general "diuretic", the court did not consider it necessary to address directly the fundamental issue of what constitutes a "product protected by a basic patent". However, this second key issue was at the heart of C-493/12, in which it was confirmed that in principle an SPC could be granted for a product functionally defined in the claims. It was noted that this would be acceptable only where the claims related "*implicitly but necessarily and specifically to the active ingredient in question*". In reaching these decisions, it would seem that the CJEU has once again put the interpretation of Article 3(a) of the SPC Regulation back into the hands of the national courts and therefore divergent practices may well continue. But have we learnt anything from these cases?

In all three Judgements, it was emphasised that the purpose of the SPC is to encourage research and to ensure that investments into research are adequately rewarded. This overarching goal seems to underpin all three decisions. It follows therefore, that in situations such as C-484/12, where a basic patent clearly covers more than one well-defined active ingredient, multiple SPCs should be allowable. However, attempts by Patentees to evergreen SPCs based on subsequent marketing authorisations for combinations of an innovative active ingredient protected by a basic patent with other active ingredients identified only in general terms may well be unsuccessful. It would also appear that attempts by Patentees to seek reward beyond the intended purpose of the SPC system will be viewed negatively. That said, how the authorities responsible for the grant of SPCs will reconcile these principles with day-to-day SPC practice remains to be seen.

For more information about the referrals and the CJEU Judgements, see our previous bulletins **here** and **here**.

WINTER ISSUE

News from the EPO and beyond

> The EPO has published a **notice** advising that all first instance cases where the decision depends entirely on the outcome of the Enlarged Board of Appeal's decisions in G2/12 and G2/13 will be stayed. As reported in our previous **bulletin**, these referrals seek to clarify in particular whether the exclusion of essentially biological processes for the production of plants may affect the allowability of product claims directed to plants or plant material. For more details, see **here**.

> In November, the UK Intellectual Property Office published a Practice **notice** reporting a change to SPC practice. In situations where an SPC is to be granted on the basis of a European Commission Marketing Authorisation (MA), the date for the purposes of calculating the SPC practice term is the date of *notification*, rather than the date of grant of the MA.

> SPC-type protection is to be introduced into Canadian law as a result of the *Comprehensive Economic and Trade Agreement between Canada and the European Union*. Canada will implement an up to two-year "patent term restoration", which will be intended to compensate Patentees in the pharmaceutical sector.

> In case C-109/12, the CJ-EU confirmed that a product classified as a "medical device" in certain member states of the EU could still be regarded as a "medicinal product" in other states. For more information on this decision, read our **bulletin**.

The Bolar Exemption and third party supply

The Bolar Exemption allows generic pharmaceutical companies to manufacture and use a patented product in the clinical trials required to obtain marketing authorisation. However, whether third parties are able to manufacture and supply the product to generics for the purposes of clinical trials under this exemption remains unclear.

The Düsseldorf Court of Appeal has recently referred questions on this matter to the Court of Justice of the European Union (CJEU). The questions include: whether third party suppliers also benefit from the exclusion; whether this benefit depends on whether the product is actually used in exempted clinical trials; and whether the third party supplier must take precautions to ensure that the patented product will only be used in exempted trials.

A translation of the referral by the Düsseldorf Court of Appeal can be found **here**.

Australian High Court finds non-infringement of a second medical use claim

In a landmark ruling in the case of Apotex Pty Ltd ("Apotex") v. Sanofi-Aventis Australia Pty Ltd ("Sanofi"), the High Court of Australia has confirmed that methods of medical treatment are patentable in Australia. The High Court also decided that the generics manufacturer, Apotex, did not infringe Sanofi's second medical use Patent, on the basis of the "skinny labelling" used by Apotex for their generic product.

This is one of the first cases to address the issue of infringement of second medical use claims, and in particular, the issue of infringement where a generics company sought to carve out the patented therapeutic indication from their generic product prescribing information. This issue is yet to be tackled in Europe where a great deal of uncertainty still remains as to the impact of second medical use Patents on the generics industry.

For more information on this Judgement, see our full article **here**.

AIPPI observations on "Broccoli II"

In response to the invitation for observations on the "Broccoli II" referral to the Enlarged Board of Appeal at the EPO (discussed **here** in "Essentially Biological Products? – "Broccoli II""), a number of parties have submitted comments on the patentability of products produced by essentially biological processes, including AIPPI.

AIPPI is an international organisation with the objective of improving and promoting the protection of intellectual property worldwide. **Claire Baldock**, Chair of the AIPPI Biotechnology Committee and Head of Biotechnology at Boult Wade Tennant, oversaw the preparation of the AIPPI submissions; these set out in detail why the AIPPI consider that the exclusion from patentability of essentially biological processes should not limit the patentability of plant products. The full submissions can be found **here** on the EPO website.

We've listened to what our clients told us. Now we're acting on it

We know that it makes business sense to get to know our customers and to build our services around their needs. For us, our service is about people, not just IP. That means responding to our clients with commercial understanding as well as technical and legal expertise if we are to guide them to the best solution for their needs. We want people to choose Boult Wade Tennant and stay with us because they know we will work with them, not just for them.

To strengthen our understanding of what excellent service means to our clients and to ensure we are well placed to respond to changing client needs, we have invested in a programme of client research, conducted by an independent agency. This research has measured our service against those indicators that really matter to our clients and has, for the first time, allowed us to accurately benchmark ourselves against competitors in our sector. You're invited to read our **Client Feedback Report**.

> Missed the last edition of boult.bites Biotech? Catch up by clicking **here**

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We aim to work with our clients, not just for them

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