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briefing

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Important New European Case Law

Three important new decisions have been issued recently by the Enlarged Board of Appeal of the EPO:

New Dosage Regime/ New Therapeutic Use

European law excludes the patenting of methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body, but explicitly permits the patenting of a substance or composition for use in such a method. It has been a long-standing practice of the EPO to allow patents not only for a first therapeutic indication of a substance or composition, but also for second and subsequent new and inventive therapeutic applications. Under an amendment of the EPC effective in December 2007, such “second therapeutic use” claims were explicitly acknowledged as allowable in new Art. 54(5) EPC.

In G0002/08, the Enlarged Board was asked to consider whether the new Art. 54(5) EPC allowed patenting of a new dosage regime, in which a medicament known for treatment of a particular illness was used in a different, new and inventive treatment of the same illness. The Enlarged Board held that such new dosage regimes are not

excluded from patentability by new Art. 54(5), even where the dosage regime is the only novel feature of the claim. An important additional conclusion of the Board was that second therapeutic use claims may no longer be in so-called “Swiss-type” form (“*Use of substance X in the manufacture of a medicament for use in the treatment of Y*”). The Enlarged Board recognises that there are many granted patents and pending applications including Swiss-type claims and explicitly states that its decision shall not have retroactive effect. It sets a three-month period from publication of their decision in the Official Journal (which has not yet taken place) for all future applications to comply with their finding. As previously, therefore, our advice is that, for Europe, you frame second therapeutic use claims in the form now permitted under Art 54(5) EPC (For example “*Substance X for use in the treatment of Y*”), and that where possible you take the opportunity to add such claims to pending applications relating to second therapeutic uses.

Method for Treatment by Surgery

In Enlarged Board decision G0001/07, further questions relating to excluded subject matter were considered. As mentioned above, European law excludes the patenting of methods for treatment

of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body (under Art. 53(c) EPC). The questions referred to the Enlarged Board related to diagnostic methods involving an invasive step (in the case in question injection of a contrast agent into the heart). The Board held that patentability is excluded by Art. 53(c) where the invasive step is one which represents a substantial physical intervention on the body which requires professional medical expertise and entails a substantial health risk even when carried out with the required professional care and expertise. The exclusion from patentability is not limited to curative surgery. In the case in question, the claims had covered both methods with the invasive step and methods without it. The Enlarged Board held that the exclusion from patentability can be avoided by disclaiming the embodiments affected or by omitting the pertinent step, provided that the claim was able to fulfil other requirements of the EPC, including those relating to disclaimers. Finally, the Board held that a claimed imaging method is not to be considered as being a treatment of the human or animal body by surgery merely because during a surgical intervention the data obtained immediately allow a surgeon to decide on the course of action to be taken during a surgical intervention. This decision serves to illustrate the difficulties that can be encountered

in Europe in patenting inventions relating directly or indirectly to surgical and/or diagnostic methods which involve an invasive step, and highlights the fact that the outcome will frequently depend upon the specific circumstances of the case in question. Drafting of patent specifications, especially the claims, with the case law in mind can improve the prospects of a successful outcome. If you would like further advice in this regard please ask your usual contact at Abel & Imray.

Language of the Proceedings

In decision G0004/08, the Enlarged Board of Appeal considered the question of whether, in a case where an International application had been filed and published in an official language of the EPO (i.e. English, French or German), the applicant can on entry to the European phase file a translation into another of the three official languages, thereby allowing a free choice of the language of the proceedings before the EPO irrespective of the language of the PCT application. The Enlarged Board ruled that such a change of language is not permissible under the EPC.

Reminder and Update - Changes to European Patent Office (EPO) Rules effective 1 April 2010

As noted in our July 2009 Briefing, a number of changes to the EPO rules will come into force on 1 April 2010. The rules themselves leave many questions unanswered, and while the EPO have issued further guidance many details are still unclear. If you have any concerns over the effect of the new rules on any of your applications, we strongly recommend that you contact the person who usually handles your work within Abel & Imray.

A summary of the key issues is as follows:

Deadline for filing divisional applications

The deadline for filing a divisional application will become two years from either:

- the first substantive communication from the Examining Division in respect of the earliest application for which a communication has been issued (so curtailing the filing of a "cascade" of divisional applications); or
- any communication from the Examining Division raising a lack of unity objection for the first time.

The rules will apply to applications for which a substantive communication has already been issued,

but under transitional provisions the deadline for filing a divisional application will be 1 October 2010 at the earliest. It will still be the case that a divisional application can only be filed from a pending application.

It is still unclear whether it will be possible to force the EPO to raise a unity objection, and if so whether the subject matter of any divisional applications filed in response would have to relate to that unity objection. Consequently, it would be unwise to rely on it being possible to extend the usual deadline of two years from the first substantive communication from the Examining Division.

Because 1 October 2010 is the inextensible deadline for all pending applications in which the first substantive communication was issued earlier than 1 October 2008 either on the application itself or, if it is a divisional application, from the earliest filed parent application, it is expected that there will be many applications filed by that deadline. We strongly recommend that you instruct filing of any necessary divisional applications on your cases in good time, and preferably at least three months before the deadline.

Compulsory response to extended European search report

Currently the EPO issues a search opinion with the European search report, setting out any objections they have to the application. If no response is made to the search opinion, the first substantive examination report merely refers to the search opinion. Under the new rules, a response to the search opinion will be compulsory. The deadlines for filing the response for the various possible cases are as follows:

- For direct European applications, the deadline will be six months from the publication of the search report (so coinciding with the deadline for requesting examination and paying the designation fee).
- For ex-PCT applications where the EPO did not perform the International search, a supplementary European search report with search opinion will be issued after entry to the European phase. The deadline for responding to the search opinion will typically be two months from a subsequent communication asking the applicant to confirm that they wish to proceed with the application.

- For ex-PCT applications where the EPO performed the International search, a search opinion will have been issued with the International Search Report. The deadline for responding to the search opinion will be one month from a communication issued shortly after entry to the European phase.

The deadline indicated in each case above will be the last opportunity for filing voluntary amendments to the application.

Multiple independent claims

Apart from in exceptional cases, a European application cannot have multiple independent claims in the same category (e.g. apparatus, method, use). Under the new rules, the EPO will raise this objection before performing the search, setting a two month deadline in which to indicate the claims to be searched. It is still unclear whether this will mean that the EPO will in certain cases be able to avoid raising a unity objection, removing the opportunity to request further searches.

Incomplete search

If the EPO considers that no meaningful search can be performed, it shall set a two month deadline in which to indicate the subject matter of the application which should be the subject of the search. (Currently the EPO issues a reasoned declaration that no search is possible, or, as far as is practicable, draws up a partial search report.)

Improved Patent Prosecution Highway Arrangements

The original Patent Prosecution Highway (PPH) scheme was initiated by the US and Japanese patent offices and enabled an applicant who had allowable claims in one country to have the corresponding application in the other country examined early and with reference to the examination ("work products") in the first country. It was intended to make examination quicker and cheaper, both for the applicant and the patent offices involved.

The PPH scheme has since grown to include 14 national/regional offices, most notably including the European Patent Office, with differing bilateral agreements between the various offices.

However, the scheme has been fairly limited, with only certain applications meeting the various requirements. In particular, one major drawback of the scheme was that it could not generally be applied to PCT applications.

But that is now set to change after the EPO, USPTO and JPO have agreed to use PCT work products in the PPH scheme. On 29 January 2010, they launched a pilot PPH scheme, allowing a PPH request to be based on a positive written opinion and/or IPER of a PCT application. Therefore, if PCT claims are determined to be patentable by the EPO, USPTO or JPO as ISA or IPEA, then on entering the US, JP or EP national/regional phases, accelerated examination of the national/regional phase applications can now be requested. One point to note is that the offices can still insist on certain formal requirements, for example, the EPO may still require the two-part claim format. Therefore, in order to minimise the chances of receiving and having to respond to an examination report, the claims should be amended on national/regional phase entry with this in mind.

This should open up the PPH scheme to many more applications and enable a greater number of applicants to enjoy faster and more economical prosecution in three of the major patent territories. It may also pave the way for other patent offices

agreeing to use PCT work products in the PPH scheme. However, it does require applicants to limit to the scope of claims that were indicated as allowable. Hence, it may not be appropriate where only dependent claims have been considered patentable or where the application relates to a high-value product.

If you have any queries about the PPH scheme or would like advice about whether it could be used for any of your cases, please get in touch with your usual contact at Abel & Imray.

New route for obtaining patent protection in Montenegro via the EPO

With effect from 1 March 2010, patent protection is obtainable in Montenegro via a European Patent Application under a new "extension agreement" between the EPO and Montenegro. The extension agreement allows for the protection conferred under a European patent to be extended to Montenegro, providing in that state essentially the same protection as that granted for designated full member states of the European Patent Organisation. Extension is at the request of the applicant, but will be deemed requested for all European patent applications and PCT applications

filed on or after 1 March 2010. Extension to Montenegro under the new extension agreement is not available retroactively but, for some applications filed since 2004, comparable effects may be available under the previously operating co-operation and extension agreement between the former Federal Republic of Yugoslavia and the European Patent Organisation. Other currently available extension states are Albania, Serbia, and the state of Bosnia and Herzegovina. Albania and Serbia have been invited to accede to the EPC and can therefore be expected to become full member states in due course. Extension is subject to an extension fee payable to the EPO at the same time as the designation fee, and to compliance with national requirements on grant which usually include provision of a translation.

If you have any questions regarding any of the above changes, or any other aspects of European patent law, please do not hesitate to email your usual contact at Abel & Imray or email us at ai@patentable.co.uk with "Patent law briefing" in the subject line.