D YOUNG & CO PATENT NEWSLETTER no.16

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D Young & Co Rebrands

Introducing our new brand identity, including a highly developed website and online intellectual property 'knowledge bank' resource

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Editorial

As we publish this edition of our patent newsletter, we are pleased to announce our new brand identity and logo, launched on 1 April.

We are committed to providing regular and reliable IP news and updates and an important element in our rebrand has been the extensive development of the resources area of our website, which has culminated in the launch of our IP knowledge bank. The online knowledge bank is an ever growing library of IP related commentary, reviews and analysis, now also available as audio downloads and via RSS feed.

We would like to thank our design team at Mytton Williams and web build team at Positive New Media for their commitment and effort in bringing this rebrand project to launch. We welcome your feedback and the opportunity to improve the information that we publish, so if you have any suggestions please let us know. We encourage you to contact our Business Development Manager, Rachel Daniels (rjd@dyoung.co.uk), or your usual D Young & Co patent attorney with any comments.

Our new look aside, readers will no doubt note that the European Patent Office appears to have been focused on the life sciences of late, issuing decisions regarding the industrial applicability of gene sequences, the patentability of dosage regimes and the interpretation of the method for treatment for surgery. Our Biotechnology, Chemistry & Pharmaceuticals Group attorneys therefore steal the lion's share of this month's newslettter. Rest assured, those of us in the Electronics, Engineering & IT Group are eager to win back some column space in June.

Editor:
Ian Harris

Article 01

Industrial Applicability of Gene Sequences
UK Court of Appeal v EPO Board of Appeal (Human Genome Sciences v Eli Lilly)

In October 2009 the European Patent Office Court of Appeal found Human Genome Science's gene-sequence patent to meet the requirements of Article 57 EPC. Contrary to this decision, in December 2009 the UK Court of Appeal upheld an earlier UK decision invalidating the patent under grounds of lack of industrial applicability.

Legislation

An invention is only patentable if it is "susceptible of industrial application". Article 57 EPC states: "An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture."

The EU Biotech Directive (99/44EC) provides:

1. "The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application."

Background

EP 0939804B to Human Genome Sciences (HGS) is directed to neutrokine-α. HGS had identified neutrokine-α as being a member of the TNF protein super-family using bioinformatics. HGS and GSK are jointly developing an antibody to neutrokine-α as a treatment for the autoimmune disease lupus.

In the application as filed, HGS listed possible uses for neutrokine-α based on known uses of other members of the super-family. The treatment of a large number of diseases was proposed, either using neutrokine-α or an antibody to it, for example in the treatment of cancer, infection, diabetes. Some of the proposed effects were contradictory.

Eli Lilly sought to revoke the patent in the UK and filed an opposition at the European Patent Office (EPO).

EPO Board of Appeal

On 21 October 2009 the EPO's Board of Appeal ruled that the requirements of Article 57 EPC were met for the patent.

In coming to its decision, the EPO noted that all members of the TNF super-family were known to participate in the regulation of immune cell proliferation, activation and differentiation, and are involved in various medical conditions. It was their view that given the assignment of neutrokine-α to this family, the skilled person would expect it to display common features such as expression on activated T-cells and the ability to co-stimulate T-cell proliferation. They did not find anything in the patent specification which contradicted this expectation. Regarding alleged contradictory statements, the Board of Appeal felt that the skilled person, when reading the patent specification, would distinguish between the positive technical information known from his common general knowledge from other allegedly contradictory statements.

The Board of Appeal found therefore that the patent provided a concrete technical basis for the skilled person to recognise a practical exploitation of the claimed invention in industry. Thus the requirements of Article 57 EPC were found to be fulfilled.

UK's Court of Appeal

In direct contrast, following a hearing in December 2009, the UK Court of Appeal upheld an earlier UK decision invalidating the patent under grounds of lack of industrial applicability. In doing so it sought to distinguish itself on the facts, rather than legal principles,

EP 0939804B Abstract

"The present invention relates to a novel Neutrokine-α protein which is a member of the TNF protein family. In particular, isolated nucleic acid molecules are provided encoding the human Neutrokine-α protein including soluble forms of the extracellular domain. Neutrokine -α polypeptides are also provided as are vectors, host cells and recombinant methods for producing the same. The invention further relates to screening methods for identifying agonists and antagonists of Neutrokine-α activity. Also provided are diagnostic methods for detecting immune system-related disorders and therapeutic methods for treating immune system-related disorders."

UK Court of Appeal v EPO Board of Appeal: Industrial Application of Gene Sequences

indicating that whilst the patent did convey enough information to make it plausible that neutrokine-α is a member of the TNF super-family, this was not good enough for in its view the biological effects and activities of that family were so poorly understood that any actual use should be regarded as purely speculative.

Conclusion

On the face of it, the UK Courts are using a harsher test than the EPO for industrial application. The UK Court justified its decision by indicating that it had the "benefit" of hearing witnesses, which is limited at the EPO. Nevertheless, the current situation presents a difficult dilemma for the applicant wishing to file his application at the optimum time. Careful consideration of the facts of your case at an early stage with your usual representative is paramount.

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Useful links:

- www.hgsi.com
- www.gsk.com
- www.lilly.co.uk

Article 02

Oral Proceedings
Preparing for Oral Proceedings Before the EPO Examining Division

The European Patent Office (EPO) can summon a patent applicant to oral proceedings during examination of a patent application to draw examination to a conclusion. The summons may follow a precautionary request for oral proceedings made by the applicant to ensure a last opportunity to defend the application and avoid an unexpected written refusal.

How should your representative respond when a summons to attend oral proceedings is received? Preparing for and attending oral proceedings is potentially time-consuming and costly, so careful consideration is advisable. This article aims to explain the options available.

The summons gives the scheduled date of the oral hearing and an analysis of the examiner's objections. A deadline for the applicant to file written submissions is also given; this is typically one month before the hearing date.

Sometimes the way ahead will be obvious. For an important application where all efforts are to be made to obtain grant, preparing for and attending the oral proceedings is probably appropriate. Conversely, if the application is no longer of interest, it may be appropriate to write to the EPO to withdraw the application prior to the oral proceeding to avoid a negative decision issuing. However, in other cases, the approach to be taken may not be so clear at the outset.

It is useful to bear in mind that the oral proceedings process has two-stages: the filing of the written submissions; and then attending the oral proceedings. If the written submissions stage is well-managed, it can become clearer whether it is worthwhile attending the oral proceedings. It can be strategically beneficial to embark on the written submissions stage, and to postpone the decision about attending the oral proceedings until the reaction of the Examining Division to the written submissions has been assessed.

The written submissions should address all the objections raised in the summons. Usefully, you can include more than one option for addressing the objections. Each of these options is called a request, with your preferred option typically being labelled as the primary, or main request, and less preferred options as first auxiliary request, second auxiliary request, etc. Each request typically comprises a set of claims with supporting arguments showing the allowability of those claims. If desired, one request can be the claims pending when the summons was issued. Also, claims previously considered during examination may be included. It is advisable not to burden the Examining Division with too many requests. The Examining Division will consider the requests in the order in which they are presented, stopping if they find a request which they believe overcomes the objections. Hence it is important to order the requests carefully. Often, this will be in order of increasing narrowness of the claims, but it is also acceptable to have requests directed to different aspects.

After sending the written submissions, it is advisable to contact the primary examiner, for example by telephone, to see how the requests have been received. This is valuable information for deciding how to proceed further. If the Examining Division finds a request allowable, it may decide to cancel the oral proceedings. Alternatively, the primary examiner may advise that a request would be allowable if amended in a particular way. If you can agree an amendment with the primary examiner, it may be possible to avoid the need for the oral proceedings by submitting the agreed amendment. Less positively, the primary examiner may indicate that none of your requests are allowable, and that there are no other amendments that would be acceptable. This is still useful, however, because it allows you to make a reasoned decision as to whether it is worth attending the oral proceedings based on the reaction of the Examining Division.

In a case where it looks like you would be unable to convince the Examining Division to change from a negative stance by oral presentation after the filing of the written submissions, it may well be more cost-effective to request that a written decision is issued by the Examining Division without attending the oral proceedings. The cost of attending can then be invested instead in the filing of an appeal. As the appeal is dealt with by an Appeal Board, rather than an Examining Division, it is often the case that the chance of reaching a favourable outcome is increased, especially where the position of the Examining Division is unreasonable or unjustified.

Preparing for oral proceedings can be time-consuming and costly

In summary, it is beneficial to consider each case individually when deciding how to proceed on receipt of a summons to oral proceedings. A policy of always attending oral proceedings could prove wasteful when time and money is spent on attending oral proceedings which could have been assessed in advance as being unlikely succeed. The opposite policy of never engaging in the oral proceedings process, and instead filing appeals for those cases of most interest, might also be detrimental. Examiners may be quicker to call oral proceedings for applicants who have a reputation for not attending as a way of disposing of applications rapidly, which could result in more of your applications being refused. A balanced approach in which each case is considered on its merits is therefore recommended. Where funds allow, take advantage of the written submissions stage before making a final decision about attending the oral hearing.

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> *EPO Decisions*
> *http://www.epo.org/patents/appeals/eba-decisions.html*

> *EPC (13th Edition)*
> *http://www.epo.org/patents/law/legal-texts/epc.html*

Dosage Regimes Patentable
Enlarged Board of Appeal Liberalises Law on Second Medical Use Claims

In its recent decision G 2/08, the European Patent Office's Enlarged Board of Appeal has clarified the law on second medical use claims. The Enlarged Board has decided that, when it is already known to use a medicament to treat a particular illness, Article 54(5) of the European Patent Convention does not exclude from patentability this medicament for use in a different treatment of the same illness. This decision is expected to liberalise the law on second medical uses, as the Enlarged Board has confirmed that it is not necessary for the treatment to be directed to a different illness to confer novelty on the second medical use claim.

In particular, the Enlarged Board has decided that this ruling also applies to second medical use claims where the only novel feature relates to a dosage regime. This confirms that claims to dosage regimes are allowable before the EPO.

Examples of dosage regime claims include the following:

> *"Substance X for use in the treatment of disease Y, wherein substance X is administered every morning for a 10 day period."*

> *"Substance X for use in the treatment of disease Y, wherein substance X is administered at a dosage of 50 to 100 mg/day."*

Article 53(c) EPC 2000 excludes from patentability methods of surgery, therapy or diagnosis carried out on the human or animal body. However, this does not apply to products for use in such methods.

In its first ever decision (G 5/83) the Enlarged Board decided that claims to further medical uses of known products were not covered by the methods of treatment exclusion, provided the claims were worded in the Swiss format - "Use of substance X in the manufacture of a medicament for the treatment of disease Y".

Article 54(5) EPC 2000 enshrined this decision and permitted second medical use claims to be worded in the format "Substance X for use in the treatment of disease Y".

The subsequent case law allowed second medical use claims directed to new treatments of a disease where the use of the substance to treat this disease was already known in general terms. Examples include those relating to a novel group of subjects to be treated (T 19/86) and those relating to a mode of administration (T 51/93). However, different Boards issued conflicting decisions regarding dosage regime claims.

The Enlarged Board confirmed that the introduction of new Article 54(5) was simply to enshrine G5/83 in the Convention and that the existing case law in this area should be followed. Based on this earlier case law, the Enlarged Board confirmed that it is not necessary for a treatment to be directed to a different illness to make a second medical use claim directed to this treatment novel.

In particular, the Enlarged Board ruled that dosage regime claims of the type described above were allowable even if substance X is already known in general terms for treating of disease Y. However, as such claims would be considered a selection invention over this general disclosure, the Enlarged Board has indicated that these claims must comply with the existing requirements of Boards of Appeal case law for selection inventions. In particular, it will be necessary for the dosage regime defined in the claim to provide a technical effect (such as an improvement or advantage) over the general disclosure to meet the requirements of novelty and inventive step.

Finally, the Enlarged Board indicated that the Swiss-form claim will no longer be acceptable for second medical use claims before the EPO. They reasoned that, as the new format is now specifically permitted by the EPC, there was no longer any need for the Swiss claim. The Enlarged Board has set a 3-month time limit from publication of the decision for applicants to comply with this ruling: for applications filed after this time, second medical use claims will be required to use the new format introduced by EPC2000. However, this decision does not have retroactive effect, so Swiss-form claims will continue to be acceptable for applications filed before this time period expires.

Enlarged Board of Appeal Decision G2/08

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Useful links:

www.epo.org

EPO Enlarged Board of Appeal Decision in Case G 1/07
Interpretation of "Method for Treatment by Surgery"

Case G1/07 Interpretation of "Method for Treatment by Surgery"

The European Patent Convention contains a specific exclusion from patentability of methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.

Much case law from the Technical Boards of Appeal has been delivered which attempts to define the terms of this exclusion and how far they should be extended. The breadth of the exclusion concerning diagnostic methods has been clarified in decision G 1/04 of the Enlarged Board of Appeal. Until now, however, somewhat less consistent guidance was available in relation to methods for treatment by surgery.

Previously, the Technical Boards of Appeal had produced divergent case law as to the breadth of the surgical exclusion. In particular, whilst some decisions have considered that it is the nature of the physical intervention that is decisive, e.g. an injection, others have considered that it is the purpose of the surgery that is decisive, e.g. that the surgery should aim to maintain or improve health, as opposed to some other non-health related goal, such as cosmetic surgery.

G 1/07 provides a ruling as to which approach should be taken, as well as to setting out other indications of when a method can be considered to be a "method for treatment by surgery".

The background to the case in questions concerned magnetic resonance methods for imaging the pulmonary and/or cardiac vasculature and evaluating blood flow using dissolved polarized 129Xe.

When considering whether the claimed methods in relation to this subject matter were to be excluded from patentability, the following questions were referred to the Enlarged Board of Appeal:

1. *Is a claimed imaging method for a diagnostic purpose, which comprises or encompasses a step consisting in a physical intervention practised on the human or animal body (in the present case, an injection of a contrast agent into the heart), to be excluded from patent protection as a "method for treatment of the human or animal body by surgery" if such a step does not per se aim at maintaining health and life?*

2. *If the answer to question 1 is in the affirmative, could the exclusion from patent protection be avoided by amending the wording of the claim so as to omit the step at issue, or disclaim it, or let the claim encompass it without being limited to it?*

3. *Is a claimed imaging method for a diagnostic purpose to be considered as being a constitutive step of "method for treatment of the human or animal body by surgery" if the data obtained by the method immediately allow a surgeon to decide on the course of action to be taken during a surgical intervention?*

In answering question 1), the Enlarged Board was careful in stressing that the answer applied to the specific situation of the imaging method of the present case. However, in coming to the conclusion, the Enlarged Board set out that,

> *"treatment by surgery is not to be interpreted as being confined to surgical methods pursuing a therapeutic purpose."*

Thus, the Enlarged Board have decided that just because a surgical method is not aimed at maintaining, restoring or improving health, does not mean that it is not "treatment by surgery".

This outcome can be seen as negative for many applicants in the field of medical method and device research Previously, it may have been arguable that where some methods of

> *Related Articles*
> *"New Referral to the Enlarged Board of Appeal of the European Patent Office in Relation to "Surgical Methods" (G1/07)" August 2007. Full article (pdf/audio/html) at www.dyoung.com/articles*

> *EPO Decisions*
> *http://www.epo.org/patents/appeals/eba-decisions.html*

surgery did not aim to maintain or improve health, but instead had only had an industrial or cosmetic goal, they would not be methods of "treatment by surgery". This, however, no longer appears to be the case.

Although this apparent broadening of the exclusion can be seen as negative for applicants, in an attempt to provide a ruling which can adapt as technology advances, it may be that the Enlarged Board have left open a window for pursuing certain types of method claims.

The Enlarged Board have noted that,

> *"[the] broad view of what should be regarded as surgical activities excluded from patentability has in the Enlarged Board's view… become overly broad when considering today's technical reality. The advances in safety and the now routine character of certain, albeit invasive techniques, at least when performed on uncritical parts of the body, have entailed that many such techniques are nowadays generally carried out in a non-medical, commercial environment like in cosmetic salons and in beauty parlours and it appears, hence, hardly still justified to excluded such methods from patentability. This applies as a rule to treatments such as tattooing, piercing, hair removal by optical radiation, micro abrasion of the skin."*

Thus, whereas the Enlarged Board have broadened what can be considered to be "treatment by surgery", it seems that they have also narrowed what is to be considered "surgery".

Although still limited to the specifics of the present case, the Enlarged Board indicated that when judging whether a method is a "method for treatment by surgery" what will be assessed is whether the method includes an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a health risk even when carried out with the required professional care and expertise.

Clearly, this "test" contains many relative terms and how far it reaches will no doubt be the subject of further case law. However, it may be that certain other uncritical methods involving only a minor intervention and no substantial health risks, when carried out with the required skill and care, are not excluded from patentability.

Whether this turns out to be the case will of course depend on the interpretation of this decision by the departments of first and second instance of the EPO (Examining Divisions/ Opposition Divisions/ Technical Boards of Appeal).

The answers to the questions 2) and 3) were relatively straight forward. With particular reference to question 2), the Enlarged Board confirmed that a claim which encompasses a step which encompasses a "method of treatment of the human or animal body by surgery" cannot be left to encompass that embodiment. Instead, it was possible to use a disclaimer to such a step, or to amend the claim so as that to ensure that the step no longer formed part of the claim. In both instances the disclaimer and the amendment must meet the other requirements of the EPC and case law, and will of course be assessed on a case by case basis.

In summary, whilst the Enlarged Board have broadened the interpretation of what can be considered to be "treatment by surgery" and thus has been largely unhelpful to applicants, they have acknowledged that as surgical research advances, some uncritical methods involving minor interventions may "come through the other side" so as to potentially be patentable.

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Useful links:

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Case C-34/10 Update

Further to our report in the February 2010 edition of this newsletter, we note that according to the UKIPO website, the final version of the questions referred to the European Court of Justice in Case C- 34/10 Oliver Brüstle v Greenpeace e.V. is as follows:

"1. What is meant by the term 'human embryos' in Article 6(2)(c) of Directive 98/44/EC [on the Legal Protection of Biotechnological Inventions]?

(a) Does it include all stages of the development of human life, beginning with the fertilisation of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied?

(b) Are the following organisms also included:

(i) unfertilised human ova into which a cell nucleus from a mature human cell has been transplanted;

(ii) unfertilised human ova whose division and further development have been stimulated by parthenogenesis?

(c) Are stem cells obtained from human embryos at the blastocyst stage also included?

2. What is meant by the expression 'uses of human embryos for industrial or commercial purposes'? Does it include any commercial exploitation within the meaning of Article 6(1) of the Directive, especially use for the purposes of scientific research?

3. Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching:

(a) because the patent concerns a product whose production necessitates the prior destruction of human embryos,

(b) or because the patent concerns a process for which such a product is needed as base material?"

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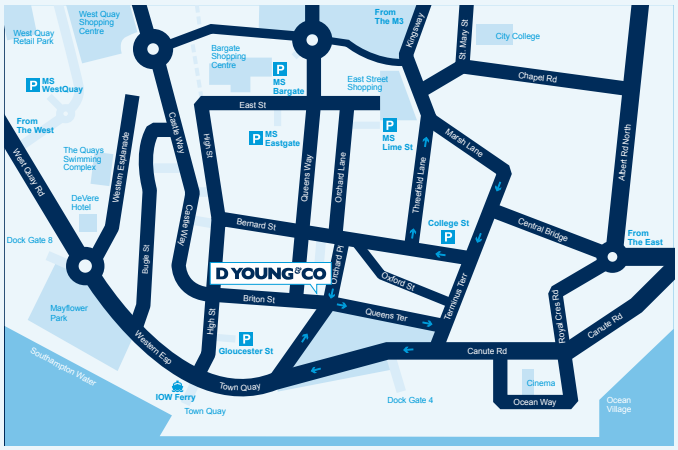

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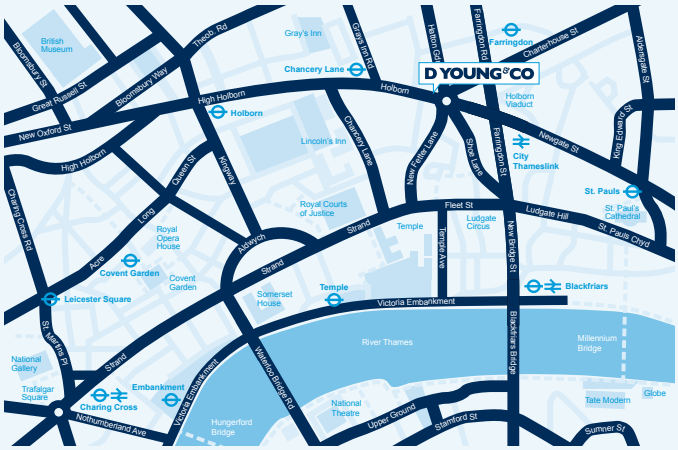

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