

## Newsletter - Edition May 2010



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## I. The firm

**De Clercq & Partners** is a firm of European patent attorneys and lawyers that provides a full range of Intellectual Property (IP) and legal services. The main office is in Sint-Martens-Latem (Belgium), close to Ghent, with a second office in Leuven (Belgium) as a result of the further expansion of the firm.

Our firm offers a range of services covering all aspects of intellectual property (IP), such as carrying out filing and prosecution of patent applications, evaluating intellectual property rights, conducting searches, acting on oppositions and revocation actions, advising and acting on supplementary protection certificates (SPCs), advising on IP protection optimization strategies, portfolio management and strategic advice, legal opinions such as freedom-to-operate or validity opinions, due diligence, and advising on licensing and infringement matters. Our firm also provides renewal and translation services.

The firm offers services in biotechnology, chemistry, pharmaceuticals, food industry, mechanics and engineering, benefiting from a highly specialized and experienced staff. Historically, our firm has an emphasis on life sciences. The technical and legal specialization of our professionals and their experience enables the firm to provide a high quality service in all aspects of patent practice. That applies not only to drafting and prosecuting national, European and International patent applications before the Belgian, Dutch and European Patent Offices but also to representing clients in EPO Oppositions and Appeals, be it for the Patentee or for an Opponent. Thanks to the national diversity of our professionals, we can offer our services in at least 5 different languages.



## 2. De Clercq & Partners will be present on numerous events

De Clercq & Partners will be present on the following events:

- **BIO 2010 Chicago** (<http://convention.bio.org>): The BIO International Convention is the largest global event for the biotechnology industry and attracts the biggest names in biotech and provides insights on the major trends affecting the industry. The event features keynotes and sessions from key policymakers, scientists, CEOs, and celebrities. Come visit Dr. Ann De Clercq and Dr. Liesbet Paemen at the Belgian Pavilion at booth 4805.
- **Knowledge for Growth** (<http://knowledgeforgrowth.be>): this is the sixth edition of the Flanders Bio annual life sciences convention. It is one of the most important events of Belgian Biotech. We are looking forward to seeing you there, at booth 38.





### 3.G 1/07: Surgical methods

On February 15, 2010, the Enlarged Board of Appeal (EBA) rendered its long awaited decision in a referral from the Technical Board of Appeal in the T 0992/03 case pertaining to the border area between diagnostic and surgical methods. As there is a growing number of cases where an invasive step is applied on the human body for diagnostic or surgical purposes, the importance of this decision could not be overestimated. Article 52(4) EPC1973 (Article 53(c) EPC2000) excludes that patents are granted for methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.

The questions asked by the referring Board were the following:

1. Is a claimed imaging method for a diagnostic purpose (examination phase within the meaning given in G 1/04), 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" pursuant to Article 52(4) EPC if such step does not per se aim at maintaining life and health?
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 (examination phase within the meaning given in G 1/04) to be considered as being a constitutive step of a "treatment of the human or animal body by surgery" pursuant to Article 52(4) EPC 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?

Summarising the underlying facts of the case, it could be said that the independent claims of European patent application EP 1 066 537 all encompassed an imaging method encompassing a step of "delivering polarized 129Xe to the subject", not specifying the delivery method or means. In a preferred embodiment of the application, the delivery step was preferably done by inhalation (claimed) or by injecting the 129Xe directly into the heart (not explicitly claimed, but described in the description as a particularly preferred embodiment). The delivery step was hence seen to encompass a "method of treatment of the human or animal body by surgery", which is excluded from patentability under Article 54(4) EPC1973 (Article 53(c) EPC2000).

The EBA extensively dealt with the two approaches cited in the case law of the EPO in connection with surgical methods. Summarising these approaches, the cited jurisprudence identifies two aspects in the definition of surgery, namely in a first approach emphasizing on the nature of the physical intervention on the one hand (first approach) and in a second approach on its purpose on the other hand (second approach). The EBA decided not to follow any of these approaches literally, but considered that the second approach was not tenable from a legal point of view, also providing very little legal certainty, as it would necessitate making complex analyses as to whether in a specific case the surgical intervention had a therapeutic purpose or not.

#### ***One feature constituting a method of surgery suffices to make that method fall within exclusionary provision***

A first fundamental layer of the reasoning of the EBA in the G 1/07 case states that one feature constituting a method of surgery suffices to make that method fall within exclusionary provision. According to the EBA, "The Enlarged Board thereby endorsed the principle developed in the jurisprudence of the boards of appeal that a method claim falls under the prohibition of Article 52(4) EPC 1973 (or Article 53(c) EPC2000 for that matter) if it includes at least one feature defining a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy."

### ***One feature constituting a method of surgery suffices to make that method fall within exclusionary provision***

A first fundamental layer of the reasoning of the EBA in the G 1/07 case states that one feature constituting a method of surgery suffices to make that method fall within exclusionary provision. According to the EBA, "The Enlarged Board thereby endorsed the principle developed in the jurisprudence of the boards of appeal that a method claim falls under the prohibition of Article 52(4) EPC 1973 (or Article 53(c) EPC2000 for that matter) if it includes at least one feature defining a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy."

### ***No reason to limit the exclusion to these surgical methods which are of a therapeutic nature or which serve a therapeutic purpose only***

In a second layer of the reasoning, the EBA held that there is no reason to limit the exclusion to these surgical methods which are of a therapeutic nature or which serve a therapeutic purpose only. In the view of the Board, in today's medical and legal linguistic usage the term "treatment" is not restricted to a treatment serving a curative purpose but may also include treatments for other, non-curative purposes such as cosmetic treatment, the termination of pregnancy, castration, sterilisation, artificial insemination, embryo transplants, treatments for experimental and research purposes and the removal of organs, skin or bone marrow from a living donor. When carried out by surgery, these treatments are regarded as surgical treatments. Undermining the second approach used in the past in case law of the Boards of Appeal, the EBA held that "in particular as regards serious and risky surgical interventions, e.g. in cosmetic surgery, organ transplantation, embryo transfer, sex change operations, sterilisation and castration, i.e. surgical methods which require considerable professional medical expertise to be carried out and involve serious health risks even when carried out with the required professional care and expertise, the ratio legis of the exclusion, i.e. to free practitioners from being potentially hampered by patents in the application of the best possible treatment on their patients, does apply, is important and calls for their exclusion from patentability."

### ***Which intervention is considered to be a "treatment by surgery".***

In a third and final layer, also constituting the closing end of the reasoning, it is to be determined which intervention is considered to be a "treatment by surgery". In a broad construction, it could cover any non-insignificant intervention performed on the structure of an organism by conservative ("closed, non-invasive") procedures such as repositioning or by operative (invasive) procedures using instruments including endoscopy, puncture, injection, excision, opening of the bodily cavities and catheterisation. According to the EBA, this approach has rightly been criticised. 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 exclude 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. In the view of the EBA, the exclusion serves the purpose of, in the interests of public health and of patients, specifically freeing the medical profession from constraints which would be imposed on them by patents granted on methods for surgical or therapeutic treatment, thus any definition of the term "treatment by surgery" must cover the kind of interventions which represent the core of the medical profession's activities, i.e. the kind of interventions for which their members are specifically trained and for which they assume a particular responsibility. These are the physical interventions on the body which require professional medical skills to be carried out and which involve health risks even when carried out with the required medical professional care and expertise. It is in this area that the ratio legis of the provision to free the medical profession from constraints by patents comes into play. health risk is associated with the mode of administration, and not solely with the agent as such. The EBA further clarified in this respect that in cases where the administration of agents causes negative effects, there is an exclusion from patentability only if the health risk is associated with the mode of administration, and not solely with the agent as such.



### ***New standard***

Even though this final layer of the reasoning is not very clear and determinate, something which was even admitted by the EBA, it has meant to exclude from patentability those physical interventions on the body which require professional medical skills to be carried out and which involve health risks even when carried out with the required medical professional care and expertise.

### ***Disclaimer possible***

In conformity with case law of the EBA, the exclusion from patentability under Article 53(c) EPC can be avoided by disclaiming the embodiment, it being understood that in order to be patentable the claim including the disclaimer must fulfil all the requirements of the EPC and, where applicable, the requirements for a disclaimer to be allowable as defined in decisions G1/03 and G2/03 of the EBA.

### ***Omission of the surgical step***

In conformity with what was held in G 1/04, it was held by the EBA in the present case that Article 84 in conjunction with Rule 43 EPC requires that the claims shall define the matter for which protection is sought, which implies that the claim should explicitly specify all of the essential features needed to define the invention. That will not always allow omitting a surgical step. The EBA, however, specifies that methods which are merely directed to the operating of a device without themselves providing any functional interaction with the effects produced by the device on the body are teachings in which the performance of a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy is not required in order for the teaching of the claimed invention to be complete. Even if in such a case the use of the device itself requires the application of a surgical step to the body or is for therapeutic treatment the same does not apply to the claimed method for operating the device. The EBA concludes then also that such claims are not excluded under Article 53(c) EPC2000 or Article 52(4) EPC1973 for that matter.

### ***Conclusion***

The EBA has with G 1/07 rendered a decision which is logical from a legal point of view, but which leaves quite some room for interpretation by the examiners and users of the patent system. It can be expected that this decision will not immediately lead to a uniform practice in this area of technology, which is always regrettable. The criterion that only those physical interventions on the body which require professional medical skills to be carried out and which involve health risks even when carried out with the required medical professional care and expertise are to be excluded from patentability, leaves considerable room for manoeuvre and hence discussion. The EBA is nevertheless to be lauded for the clear stand it has taken in that the approach focussing on the purpose of the intervention to determine whether or not such method is excluded from patentability, provides insufficient legal certainty to be acceptable.

## **4. Dosage regime patent claims are allowable: G 2/08**

Another long awaited decision was rendered on February 19, 2010 in the G 2/08 case pertaining to further medical indication claims, more in particular pertaining to dosage regimens.

According to Article 53(c) EPC2000 (Article 52(4) EPC1973), no patents shall be granted for methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body, but this provision shall not apply to products, in particular substances or compositions, for use in any of these methods. According to Article 54(5) EPC2000, patents can be granted for any substance or composition which is already known in the art for the first use in a medical treatment method falling within the scope of Article 53(c) EPC2000, for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.

The referring Board in the T 1319/04 decision had the following questions:

1. Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC 2000 for use in a different, new and inventive treatment by therapy of the same illness ?
2. If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime ?
3. Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC2000?

The European patent application in issue EP 0 643 965 pertained to the use of nicotinic acid or a compound metabolized to nicotinic acid by the body selected from a group consisting of d-lucitol hexanicotinate, aluminium nicotinate, niceritrol, d,1-alpha-tocopheryl nicotinate and nicotinyl alcohol tartrate, for the manufacture of a sustained release medicament for use in the treatment by oral administration once per day prior to sleep, of hyperlipidaemia, under certain further parameters.

#### **Article 54(5) EPC2000 versus Article 54(5) EPC1973**

The EBA started by clarifying that Article 54(5) EPC2000 now expressly provides for a possibility to claim further patent protection of substances or compositions already known as medicines provided their use in a medical treatment method under Article 53(c) EPC2000 be specific and not comprised in the state of the art, in contrast to former Article 54(5) EPC1973 (now corresponding to Article 54(4) EPC2000) which covered literally the first medical application of a product not yet known for the use in a method under Article 52(4) EPC1973, but the scope of which was expanded under case G 5/83 to cover by means of so-called 'Swiss claims' also further medical indications.

#### **Article 53(c) EPC2000 versus Article 54(5) EPC2000**

The EBA was very firm on the relationship between the exclusion from patentability of medical treatment methods under Article 53(c) EPC2000 and the allowability of products used in these methods. It was held in that respect that the provisions of Article 53(c) EPC2000 are clear and unambiguous, drawing a borderline between unallowable method claims directed to a therapeutic treatment on the one hand and allowable claims to products for use in such methods on the other hand.

#### **Article 54(5) EPC2000 not confined to a new disease**

The EBA basically identified two possible ways of interpreting Article 54(5) EPC2000. One would be to merely contrast this provision to the generic broad protection conferred by Article 54(4) EPC for the first therapeutic application of a known substance or composition, which is then in principle not confined to any particular indication, in which case the second or further claimed use need not necessarily consist in the treatment of a different disease. Any further medical indication, such as a new mode of administration, would under such an interpretation be acceptable.

A second way of interpreting Article 54(5) EPC2000 is to treat Article 53(c) EPC as the general prohibition on patenting medical treatment methods and giving the provisions of Article 54(5) EPC only the status of a *lex specialis* and interpreting this provision narrowly in the sense that only a disease not yet treated by the known substance or composition can constitute a specific use within the meaning of that article.

The EBA rejected the second interpretation, as Article 54(5) EPC does not define the nature of the further therapeutic use of a substance or composition already known as a medicine deserving protection under Article 54(4) EPC further than by saying that it must be specific. In particular, it does not define any degree of distinctiveness required for the new use in order to qualify as a specific use within the meaning of that article.





The EBA rejected the second interpretation, as Article 54(5) EPC does not define the nature of the further therapeutic use of a substance or composition already known as a medicine deserving protection under Article 54(4) EPC further than by saying that it must be specific. In particular, it does not define any degree of distinctiveness required for the new use in order to qualify as a specific use within the meaning of that article.

The EBA comes to the conclusion that there can be only one sensible way of construing the requirement underlying the specificity of the use, namely merely by contrast to the generic broad protection conferred by the first claimed medical application of a substance or composition, which is in principle not confined to a particular indication. Thus, the new use within the meaning of Article 54(5) EPC need not be the treatment of another disease. Such use can be either a new indication *stricto sensu* (in the sense of a disease not yet treated by the claimed substance or composition), or one or more steps pertaining by their nature to a therapeutic method which may not be claimed as such. This at the same time answers question 1, i.e. where it is already known to use a particular medicament to treat a particular illness, this known medicament can be patented for use in a different, new and inventive treatment by therapy of the same illness.

#### ***Dosage regimen is perfectly allowed under Article 54(5) EPC2000***

Having regard to the answer given to question 1, and considering in particular that, since Article 54(5) EPC may be used in cases of the treatment of the same illness, the "specific use" in the sense of that provision may reside in something else than the treatment of a different illness, the Enlarged Board of Appeal holds that there is no reason to give to a feature consisting in a new dosage regime of a known medicament a different treatment than the one given to any other specific use acknowledged in the case law (such as e.g. a new mode of administration or a different patient group), which answered the second question of the referral.

#### ***Swiss claims no longer allowed in the future***

The Swiss claim formulation, which referred to the use of a compound for the manufacture of a medicament for the treatment of a certain disease was a praetorian approach provided under the G 5/83 to allow further medical indication patents for substances for which a first medical use was already known. Such claims were not literally allowed under the then Article 54(5) EPC1973, which related only to the first medical indication of a known substance. In the view of the EBA, as the EPC2000 now expressly provides for compound protection for second and further medical indications under Article 54(5), there is no longer any need to use the Swiss claim formulation, nor is there any legal basis for the continuing use of that claim construction. Hence, the EBA ruled that the Swiss claim formulation is to be abolished, without retroactive effect, and such abolition will take effect for future applications three months after the publication of the G 2/08 decision in the Official Journal (which has hitherto not taken place)

## **5. Questions to the ECJ regarding embryonic stem cells: The Brüstle case**

The Enlarged Board of Appeal has ruled in its decision G 2/06 of 25 November 2008 that inventions pertaining to human embryonic stem cells (hESC), wherein for obtaining the stem cells the human embryo is destroyed, are not patentable as they are contrary to ordre public and morality under Rule 28(c) EPC2000: "Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: [...] (c) uses of human embryos for industrial or commercial purposes."

In a recent German case, the so-called Brüstle case (BGH Xa ZR 58/07, "Neurale Vorläuferzellen/Brüstle", decision of the German Federal Court de dato 17 December 2009), the German Federal Court (Bundesgerichtshof, hereinafter BGH) has also decided to refer a number of questions to the European Court of Justice (ECJ) pertaining to the issue of hESC and the use of human embryos. More in particular the referral pertains to Article 6(2)(c) of the biotech directive (Directive 98/44/EC), according to which "on the basis of paragraph 1, the following, in particular, shall be considered unpatentable: [...] (c) uses of human embryos for industrial or commercial purposes", which is the originator provision of Rule 28(c) EPC2000.

The invention in that case pertained to neural precursor cells. Claim 1 of German patent DE 197 56 864 reads in translation:

"Purified precursor cells with neural or glial properties, isolated from embryonic stem cells, containing no more than about 15% primitive embryonic and non-neural cells, obtainable by the following steps:

- a) cultivating embryonic stem cells into embryoid bodies,
  - b) cultivating the embryoid bodies into neural precursor cells,
  - c) proliferation of the neural precursor cells in a growth-factor containing serum-free medium,
  - d) proliferation of the neural precursor cells of step c) in another growth-factor containing serum-free medium and isolating the purified precursor cells and
  - e) proliferation of the neural precursor cells of step d) in another growth-factor containing serum-free medium and isolating the purified precursor cells with neural or glial properties,
- or
- a') cultivating of embryonic stem cells into embryoid bodies,
  - b') cultivating the embryoid bodies into neural precursor cells,
  - c') proliferating the neural precursor cells in a growth-factor containing serum-free medium,
  - d') proliferation of the neural precursor cells of step c') in another growth-factor containing serum-free medium into neural spheres with neural and glial differentiation potential and isolating the neural spheres and
  - e') proliferation of the neural spheres of step d') in another growth-factor containing serum-free until generation of a monolayer of glial precursor cells and isolation of the purified precursor cells with glial properties,

In the view of the BGH, a preferred embodiment of the invention would use human embryonic stem cells, and would thus be excluded from patentability to the extent that the use of human embryonic stem cells or for that matter the use of human embryos to derive these human embryonic stem cells from, would be excluded from patentability.

The BGH considered that Article 6(2)(c) of the biotech directive (Directive 98/44/EC) was far from clear, as it does not define what a human embryo is (see question 1) and it is not clear from the text of the provision what is meant by "for industrial or commercial purposes" (see questions 2). In a last issue, the German Federal Court brings up an issue which has in fact already been addressed by the EBA in the G 2/06 case, but for which the German Federal Court nevertheless has decided to ask a preliminary question to the ECJ. It concerns the question whether a use of human embryos within the scope of Article 6(2)(c) of the biotech directive is established only in the circumstance that the use of the human embryo is also part of the technical teaching of the invention. Claim 1 of the Brüstle patent does not claim the use of a human embryo in order to obtain the claimed precursor cells. However, the claimed invention can only be put into effect by producing precursor cells, which requires the use of embryonic stem cells, which in turn requires the use of a human embryo. This issue had been dealt with by the EBA in the G 2/06 case, however in a manner that has seemingly also puzzled the BGH (see question 3).

The questions read:

"1. What is meant by the term 'human embryos' in Article 6(2)(c) of Directive 98/44/EC?

- (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:
  - 1. unfertilised human ova into which a cell nucleus from a mature human cell has been transplanted;
  - 2. 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?"

It goes without saying that this is an important referral, and that the outcome of the answers given to the questions might create a legal conundrum in case the ECJ would give an interpretation to Article 6(2)(c) of the Biotech directive which would be in conflict with the decision of the EBA in the G 2/06 case.

## 6. Eli Lilly v Human Genome Sciences: UK Court of Appeal v EPO on Article 57 EPC

In the field of biotechnology, the industrial application requirement under Article 57 EPC, very much like the requirement of sufficient disclosure under Article 83 EPC, remains a requirement bedevilled with lack of legal certainty. In the Eli Lilly versus Human Genome Sciences (HGS) case, the UK Court of Appeal (decision de dato February 9, 2010) came to the conclusion that on a proper interpretation of the statute, the invention in issue lacked industrial application, while for the same patent, the EPO Technical Board of Appeal had held earlier that the requirement of industrial application was fulfilled (T 0018/09).

The case is basically about the patentability or otherwise of a protein called by HGS Neutrokine- $\alpha$ , antibodies to it and the polynucleotide sequence encoding for it. The relevant part of claim 1 of European patent 0 939 804 reads:

- "1. A nucleic acid molecule comprising a polynucleotide sequence encoding a Neutrokine- $\alpha$  polypeptide wherein said polynucleotide sequence is selected from the group consisting of:*
- (a) a polynucleotide sequence encoding the full length Neutrokine- $\alpha$  polypeptide having the amino sequence of residues 1 to 285 of SEQ ID NO:2;*
  - (b) a polynucleotide sequence encoding the extracellular domain of the Neutrokine- $\alpha$  polypeptide having the amino acid sequence of residues 73 to 285 of SEQ ID NO:2;*
  - (c) [...]*
  - (d) [...]*
  - (e) [...]*
  - (f) [...]"*

The patentee also identified in the patent description a great number of potential applications of the protein.

At issue was predominantly the requirement of industrial application. Art. 57 of the EPC provides that "[a]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture." Jacob LJ in the UK case also considered Article 5 of the biotech directive (Directive 98/44/EC) to be crucial to the case, which 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."

### **The UK decision**

The UK Court considered paragraph 3 of Article 5 biotech directive to be crucial in this regard. Jacob LJ held in that respect that “the upshot, stated broadly, is that you can patent an isolated gene sequence but only if you disclose the industrial application of the protein for which it encodes. However clever and inventive you may have been in discovering a gene sequence, you cannot have a patent for it or for the protein for which it encodes if you do not disclose how it can be used.” Jacob LJ agreed with the ruling of Justice Kitchin in the first instance case where it was held that “the industrial application of a gene must be disclosed in the application. If it encodes a protein then the protein or its function must be specified”, subject to the rider that what matters is a sufficient specification of the function of the protein. Just describing the existence of a protein and its structure is not enough. Nor is it enough to describe the function at a high level of generality – e.g. that the compound must have a significant function biologically and so it (or its antibodies) may be usable to treat some sort of disease. You have to say what it is for with more particularity. What amounts to a sufficient specification of function will depend on the facts of the case and involves a question of degree.

Further underpinning his interpretation of the industrial application requirement, Jacob LJ held that “if you allow patenting of chemicals whose use you do not really know you will subvert the patent system and be likely to stultify research by others rather than encourage it. A merely “vague and speculative indication of possible objectives” is not enough. In his view, “the present case indeed provides an example of the danger of what can happen if patenting too far upstream is allowed. [...] If the patent were valid, the valuable research and development work done by Lilly into a field apparently not researched (and certainly not taken through to clinical trial) by HGS would potentially be rendered futile. The patent system would not be working as it should. It would be operating to prevent research, not to encourage it.” Jacob LJ further emphasizes the importance of the term “make at least plausible”, which in his view means more than a speculation, even if the speculation could be true. The word is not being used in the sense of “not incredible” but in the sense of having significant degree of likelihood to be true.

Continuing on the issue of plausibility, Jacob LJ formulated the crucial question to be whether it is “enough to make the invention “susceptible of industrial application” to tell the skilled reader that Neutrokine- $\alpha$  is “structurally similar to TNF and related cytokines and is believed to have similar biological effects and activities”? That depends on what was known about the biological effects and activities of the known members of the superfamily. Each of the postulated uses of Neutrokine- $\alpha$  or its antagonists was possible in the sense that one could not rule that out as a matter of science based on what was known about other superfamily members. So in one sense each was “plausible”, even though all of them collectively were not and indeed some contradicted others so both could not be true. But that is miles away from being able to say that any particular use was plausible in the sense of being taken, by the reader, to be reasonably so. In reality one was faced with a research program to see which, if any, of the possible uses of the Neutrokine- $\alpha$  or its antagonists was real.”

Regarding the issue of post-published evidence, Jacob LJ held that he cannot see how a reference to post-published evidence could include post-published evidence establishing for the first time or adding to what the potential industrial application of the patented subject-matter may be. It is surely axiomatic that whatever the standard for susceptibility to industrial application may be, the information about it must be in the patent (supplemented if necessary by the common general knowledge of the time). Otherwise you could satisfy the Art 57 requirement by just identifying a compound in the patent and finding a use for it later. That would contravene, for example, Art. 5(3) of the biotech directive. You cannot have a patent for an invention when only years later you or someone else finds out what it is for.



### **The decision of the EPO in T 0018/09**

The TBA came in its decision pertaining to the same patent to exactly the opposite conclusion, and held that the patent was industrially applicable. The TBA started its analysis of the patent under Article 57 EPC by stating that "on the basis of its structural properties, Neutrokin- $\alpha$  has been correctly identified in the patent-in-suit as a new member of the TNF ligand superfamily. No reasons have been put forward to dispute this conclusion. A large body of post-published evidence on file supports this finding. The question arises under Article 57 EPC whether this in itself suffices to suggest a practical way to exploit the claimed invention which is centred on Neutrokin- $\alpha$ , thereby providing an "immediate concrete benefit" (cf. T 898/05)."

In the view of the Board, "in many cases the allocation of a newly found protein to a known protein family with known activities suffices to assign a specific function to the protein because normally the members of the family share a specific function. This may be a well-characterized and perfectly understood function which provides in a straightforward manner enough support for industrial applicability. In such cases, the "immediate concrete benefit" is manifest. In other cases, where the members of a protein family have different, pleiotropic effects which may even be opposite and neither completely characterized nor understood, no effect can be assigned to a new member without relying on some experimental data. Between these two extreme situations, a variety of other situations may arise for which a detailed examination of all the facts may be required. Indeed, this is the case for the TNF ligand superfamily."

Further arguing in favour of industrial applicability, the Board held that "as known in the art and acknowledged in the patent-in-suit, all members of the TNF ligand superfamily are known to participate in the regulation of (immune) cell proliferation, activation, and differentiation, and are involved in various medical conditions. They are pleiotropic cytokines which display a wide range of activities and have distinctive, but also overlapping biological functions. As acknowledged in the art, a feature common to all members (without exception) of the TNF ligand superfamily is the expression on activated T-cells and the ability to co-stimulate T-cell proliferation "(l)ike other members of TNF family, Neutrokin- $\alpha$  exhibits activity on leukocytes including for example monocytes, lymphocytes and neutrophils. For this reason Neutrokin- $\alpha$  is active in directing the proliferation, differentiation and migration of these cell types". This broad statement, far from contradicting the ability of Neutrokin- $\alpha$  to co-stimulate T-cell proliferation, actually supports it. In the light of the common general knowledge of the TNF ligand superfamily and its properties, no serious doubts can be cast on this explicit additional information. Nor can this information be taken as a mere theoretical or purely hypothetical assumption. First of all, it is plausible and, secondly, there is ample post-published evidence on file confirming both the presence of Neutrokin- $\alpha$  on activated T-cells and its ability to co-stimulate T-cell proliferation."

It was argued by the respondent that, in view of the numerous contradictory statements and of the broad range of conditions and diseases referred to in the patent-in-suit, the skilled person would have disregarded such information as constituting only hypothetical assumptions, or speculations with no actual significant relevance. Filing patents with such long lists of conditions and activities and subsequently relying on the few which have been confirmed or demonstrated is what the respondent criticised as a "boiler-plate" and "cherry-picking" practice. The Board did not agree with this view.

According to the Board, "in the present case, the description of the patent delivers sufficient technical information, namely the effect of Neutrokin- $\alpha$  on T-cells and the tissue distribution of Neutrokin- $\alpha$  mRNA, to satisfy the requirement of disclosing the nature and purpose of the invention and how it can be used in industrial practice."

As regards the effect on T-cells, the respondent argued that, in view of the technical difficulties involved in measuring the co-stimulation of T-cells by Neutrokin- $\alpha$  and in the absence of any detailed experimental information on the activities of Neutrokin- $\alpha$  listed in the patent-in-suit, the skilled person would not have been able to reproduce them without the undue burden of undertaking a research programme. Moreover, in its view, no industrial application can be directly derived from a mere co-stimulation of T-cells.

The Board did not accept this line of argument: “Firstly, in the light of the great number of documents concerned with known members of the TNF ligand superfamily which - as explicitly acknowledged in the patent-in-suit - disclose standard assays for measuring their activities and effects on (immune) cells, no particular effort would be required to verify the co-stimulation of T-cells by Neutrokin- $\alpha$ . Even though a few contradictory results are reported in post-published documents on file, there is also a convincing body of post-published evidence showing that, using standard assays, Neutrokin- $\alpha$  activity is indeed present on T-cells, in particular on mature T-cells at all stages of differentiation.

Secondly, the reference in the patent-in-suit to the presence of Neutrokin- $\alpha$  activity in lymphocytes would inevitably prompt the skilled person to look for that activity in all types of lymphocytes, not only in T-lymphocytes but also in B-lymphocytes. There is post-published evidence on file showing that Neutrokin- $\alpha$  activity in B-lymphocytes could be easily measured with standard assays.”

In the Board's judgment, the tissue distribution of Neutrokin- $\alpha$  mRNA disclosed in the patent-in-suit, in particular the expression of Neutrokin- $\alpha$  mRNA in B-cell and T-cell lymphomas, provides in itself in the context of the disclosure a valid basis for an industrial application. The presence of Neutrokin- $\alpha$  in these lymphomas, which is also confirmed by post-published evidence on file, may be used to develop appropriate means and methods for their diagnosis and treatment based on the disclosure of the patent-in-suit.

The Board then also concluded that there was no reason to assume that the patent lacked industrial applicability.

#### **Comment**

Whether the two decisions effectively apply a different concept of industrial applicability is difficult to say. Jacob LJ looked for the differing conclusion in the manner how evidence is evaluated under the English legal system, which he deemed, without using these very words, to be superior to the way how such is done under the EPO system.

Important to note, however, is that the UK court has placed considerable emphasis on the relevance of Article 5(3) of the biotech directive, which is also implemented in Rule 29(3) EPC2000. In the view of Jacob LJ, you can patent an isolated gene sequence but only if you disclose the industrial application of the protein for which it encodes. However clever and inventive you may have been in discovering a gene sequence, you cannot have a patent for it or for the protein for which it encodes if you do not disclose how it can be used. The industrial application of a gene must be disclosed in the application. If it encodes a protein then the protein or its function must be specified, subject to the rider that what matters is a sufficient specification of the function of the protein. The TBA has not addressed this concept in its decision.

In another respect, there seems to be an effective divergence between the approach followed by the UK court and the EPO regarding the industrial application requirement. Where the EPO readily accepted post-published evidence, Jacob LJ openly doubted the allowability of this post-published evidence when he held that he cannot see how a reference to post-published evidence could include post-published evidence establishing for the first time or adding to what the potential industrial application of the patented subject-matter may be.

It is obviously to be deplored that after disclosed divergence in the application of the requirement of inventive step, there is now added a divergence in Europe on the issue of industrial application, a requirement which was traditionally not very problematic in the past, but the importance of which has increased with the advent of biotechnology. European harmonisation is again one step further away.



## 7.G 4/08: use of languages

The Enlarged Board of Appeal (EBA) has been very active, recently. Not only issued the Board three decisions within one week, i.e. G1/07, G2/08 and G4/08, but also shed the Board light on future problems, which are not an issue (yet).

G4/08 issued on February 16, 2010 addresses the language of the proceedings and whether it can change.

In the case at issue, an applicant filed an international patent application in French (PCT-application). This application was subsequently published in French (being one of the PCT-publication languages). The EPO was Designated Office and International Searching Authority under the PCT. At the entry of the Regional phase before the EPO, the applicant attached an English translation of the French PCT-application, and requested that the language of proceedings would henceforth be English. In the alternative, it was requested that all written communications including the decisions were issued in English. The department of first instance rejected the application, arguing that the language of the proceedings was French and could not be changed, based on Art. 14(3) EPC1973, specifying that the official language of the EPO in which the European patent application is filed or that of the translation, shall be used as the language of the proceedings in all proceedings before the EPO, and Art. 158 EPC1973, specifying that the publication under the PCT for which the EPO is a Designated Office shall take the place of the publication of a European patent application, provided the international application is published in an official language of the EPO (which was the case). In appeal the Legal Board recognized that different, ambiguous interpretations of Art. 158 EPC1973 were conceivable. However, the Legal Board also realized that all case law interpreted Art. 158 EPC1973 in a consistent manner. In order to ensure uniform application of law, the Legal Board referred this case to the EBA (cf. J 8/07).

The first question submitted was: "If an international patent application has been filed and published under the PCT in an official language of the EPO, can the applicant, on entry into the regional phase before the EPO [Euro-PCT], file a translation of the application into one of the other EPO official languages with the effect that the language of this translation must then be considered as language of the proceedings to be used in all proceedings before the EPO?". The EBA settled this issue not only under EPC1973, but also under EPC2000, which notably contains only cosmetic changes regarding the language provisions. Considering among others the importance of the subtleties of individual languages, the EBA crisply concluded that "Where an international application for patent has been filed and published under the PCT in a language of the EPO, it is not possible at the entry phase of European file a translation of the application in one of two other languages."

The EBA also affirmed that the EPO departments cannot use in its written proceedings regarding a European patent or Euro-PCT application one of the official EPO languages other than the one used under Art. 14(3) EPC. Although this may seem inconvenient for the end-user, it must be borne in mind that one of the criteria for dividing applications is based on the language skills of the examiner.

Hence, nothing changed really since the deletion in 1991 of then Rule 3 EPC1973, which allowed the change of language of proceedings. The EBA confirmed the consistent practice of the EPO. Any party can still use any official language, but for amendments of the application or patent which must be made in the language of the proceedings. Even more so, the EPO maintains its accommodating attitude in oral proceedings, in which it even makes provisions for translation into other official languages if necessary.



## 8. Important changes in the Rules of the EPC entering into force on April 1, 2010: Time limit of filing of Divisional applications

Last year, a whole series of changes to the European patent system have been approved by the Administrative Council of the EPO. These new rules came into force on April 1, 2010 and we take the opportunity to outline these changes again and to provide you with some background information and insights as to what these changes might mean for your daily practice.

The EPO has limited the possibilities of filing divisional applications, i.e. applications which are filed by the Applicant to claim typically subject matter which is disclosed but not claimed in the earlier-filed (parent) application. Despite being filed later, a divisional application retains the filing date of the parent application. Divisional applications filed as a response to a lack of unity objection are referred to as "mandatory divisionals" to differentiate over divisional applications which are filed at the initiative of the Applicant, also called "voluntary divisionals".

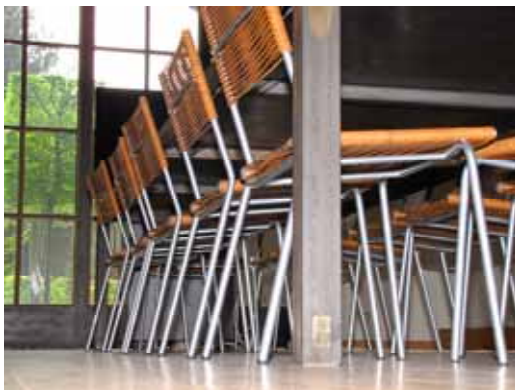
With the new rules, Applicants will no longer have the opportunity to randomly file divisional applications at any time during the pendency of a European application or any divisional application thereof, as has been the case in the past.

For the so called "voluntary divisional applications" (i.e. not due to a new lack of unity objection), the time limit for filing is set at "twenty-four months from the Examining Division's first communication in respect of the earliest application for which a communication has been issued". By referring to the "earliest" application, this paragraph implies that a first communication issued by the EPO Examining Division in respect of the parent application sets the clock for the filing of any future divisional applications (to be filed either from the parent application or from divisional applications).

In addition, "mandatory divisionals" will have to be filed within 24 months from the communication in which the relevant lack of unity objection is raised by the Examining Division for the first time. This implies that where a "new" objection of lack of unity is made (note that the definition of "new" is not exactly clear yet) it will remain possible to file a divisional application within two years of the issuance of the communication.

This limitation on the filing of divisionals applies to all divisional applications filed after April 1, 2010, including divisionals to be filed on currently pending applications. The EPO has however provided a transitional period for the filing of divisionals on all pending applications at least until October 1, 2010.

This major change requires a thorough review of the desirability of filing one or more divisional applications for all pending European applications and implies that from now on Applicants will need to make decisions on whether or not one or more divisionals are to be filed at an early stage of the prosecution of the parent application. Our firm assists anyone who has questions in this regard and aids in developing the optimal strategy.





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