

PATENT NEWSLETTER

SECOND MEDICAL USE CLAIMS AND DOSAGE REGIMES

The European Patent Convention (EPC) excludes methods of treatment by surgery or therapy and diagnostic methods from patent protection. The EPC considers these methods as not being susceptible to industrial application (a key requirement for patentability). The reasoning behind this exclusion is that medical decisions or actions which are specific to the professional activity of the physician should not be restricted by patent rights.

Over the years ample case law has established that this exclusion requires a very narrow interpretation. For example, methods are allowable if they do not comprise a single therapeutic step to be practiced on the living human or animal body. Also, methods which are practiced on the living human or animal body but which are not therapeutic (e.g. cosmetic) are, under specific circumstances, not excluded by the EPC provision.

Most importantly, it was established that the exclusion of methods of treatment should not apply to products such as compounds. The Enlarged Board of Appeal decided in the case G 5/83 that an applicant could obtain purpose limited product protection for a known compound or composition if this compound or composition was not previously used in medicine (first medical use). In this case the available protection extends to the "compound as a medicament" or "compound for use in medicine". Second (or further) medical use protection is available for a compound or composition which has already been used in therapy but for a different indication.



The second medical use claim format has been the subject of numerous decisions of the Technical Boards of Appeal. Some of the questions which have been decided were, for example, whether the mode of administration alone could convey novelty to an otherwise known medical use of a compound (yes, it could); whether the mechanism of action alone could convey novelty to an otherwise known medical use of a compound (no); or whether the mechanism of action leading to the identification of a novel patient subgroup could convey novelty (yes).

Recently, there has been a great interest in the area of dosage regimes protected by medical use claims. Dosage regimes are generally schedules covering the frequency of administration and/or dosage of a compound or composition to an individual patient (for example, compound X for treatment of disease Y, whereby compound X is administered every morning for a 10 day period).

The allowability of these claims has been subject to considerable debate at the EPO. The main consideration is whether the determination of the best individual treatment schedule, in particular the prescribing of drug dosage regimes used for administering a medicament to achieve the desired result of the treatment in an individual patient, is within the freedom and expertise of the

medical practitioner. In this case, a specific dosage regime would be

considered a medical decision which is specific to the professional activity of the physician and should therefore not be restricted by patent rights. Previous case law contains several decisions which considered dosage regimes as not allowable, but in recent years the boards allowed a number of cases wherein the novelty of the claimed use was found only in the dosage regime. Some of these cases are summarised below.

In T1020/03 the patent related to the use of insulin-like growth factor-I in the preparation of a medicament for administering to a mammal in a specific discontinuous administration pattern. The board decided that

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EDITORIAL

Welcome to the August edition of our Patent Newsletter. In this edition we have articles ranging from medical use claims to an update of software patentability cases in the UK. These articles represent merely examples from the wide areas of technology covered by the patent groups in D Young & Co.

In the last edition of the Patent Newsletter, in June, we featured our chemistry and biotechnology group. In this edition we have included a removable reference guide introducing our electrical and mechanical engineering group. Our trade mark group regularly produces a separate Trade Mark Newsletter. If you do not already receive the patent or trade mark newsletters, and would like to do so, please email rjd@dyoung.co.uk.

We hope that you will find the articles in this edition of interest.

second medical use claims where the only novelty can be found in the dose to be used or application did not contravene the provisions of the EPC.

In T0230/01 the patent in suit related to the treatment of an allergic reaction. The board found the use of an active agent for treating allergic rhinitis allowable where the only novel feature in the claimed invention was the low dose of the active agent.

The conflicting view within the EPO regarding the patentability of dosage regimes will be clarified in the near future. The case G2/08, based on T1319/04, is currently pending before the Enlarged Board of Appeal. In this case, the first instance referred 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) EPC 2000?

The outcome of this referral will most certainly affect the evaluation of inventions and the drafting of claims protecting valuable medical know-how.

Interestingly, the UK Court of Appeal has decided in a recent case (*Actavis v Merck* [2008] EWCA Civ 444; Court of Appeal) that a second medical use claim was allowable where the only novel feature was the dosage regime, thus overturning the High Court's prior decision to revoke the patent for lack of novelty. This decision also diverged from an earlier decision (*Bristol Myers Squibb Co v Baker Norton Pharmaceuticals Inc* (2001)), which stated that a novel non-obvious dosage regime specified in a second medical use claim could not make it novel and such a claim was for a method of treatment (and therefore not allowable).

The Enlarged Board of Appeal decision in respect of G02/08 is expected within the next 12 months and it will be reported in a future edition of this newsletter.

COMPUTER TECHNOLOGY CASES CONTINUE IN THE UK



In theory, the treatment in the UK of computer-implemented inventions was resolved by the Court of Appeal judgement in *Macrossan/Aerotel* in 2006. However, since this decision the number of court cases in this difficult area has increased rather

than decreased, and there continues to be considerable uncertainty and debate.

As reported in the June 2008 edition of this Newsletter, in one of these cases (*Symbian*) the High Court overturned a statutory subject matter rejection from the UKIPO. The UKIPO took rather unfavourably to this outcome, and the case has now gone up to the Court of Appeal, with a hearing in July and a decision expected later in the year (we will report on this in a future edition of this Newsletter).

Another case where a rejection from the UKIPO went up

INTERLOCUTORY REVISION AT THE EPO

The European Patent Office (EPO) offers an appeal procedure whereby any party adversely affected by a final decision made by an EPO department may seek to have the decision reversed. A number of Boards of Appeal exist to handle appeals.

However, for appeals from Examining Division decisions refusing applications, there is a preliminary procedure known as interlocutory revision which can resolve appeals. A new appeal is reviewed by the original Examining Division within three months of receipt. If the Division finds that the appeal overcomes the grounds on which the application was refused, the Division should reverse its decision in an interlocutory revision. Typically, overcoming the grounds for refusal produces a patentable application and the Examining Division will then process the application to grant. This is normally beneficial for the patent applicant, since the patent can be granted much more quickly than following a decision of the Board of Appeal. Should the appeal fail to satisfy the Examining Division however, the

original refusal stands and the case is passed to the Board of Appeal. The procedure is similar to the pre-appeal brief request for review available at the United States Patent & Trademark Office.

There is a further, less welcome, possibility, however. Imagine a case in which the appeal overcomes the original grounds for refusal, but introduces other problems which make the application unpatentable in the eyes of the Examining Division. For example, an application refused for lack of inventive step may be amended so as to be found inventive, but by introduction of a feature which is deemed to add subject matter. An application refused for lack of clarity may be amended to be clear, but the clarified claims may then lack inventive step.

In such circumstances, the Examining Division should perform interlocutory revision to reverse its original decision, because that has been overcome, but cannot pass the case to the Board of Appeal. Continued prosecution of the application then stays with the Examining Division.

Given that the Division has now found other reasons to deem the application unpatentable, the likely result will be another refusal of the application. This second refusal can be appealed, but the money spent on the original appeal has essentially been wasted.



to the High Court on appeal was *Autonomy*. The application covered a method of looking for content related to a window that is active on a computer, and then displaying an icon representing a link to the content within the window. The UKIPO rejected the claims as a program for a computer and as a presentation of information (both excluded subject matter under UK and European law).

A further case arising from a rejection by the UKIPO was *IGT*. The invention in this application controlled access to a casino account using a card issued by some third party, based on un-decrypted data from such a card (since the raw data stream would almost certainly be unique). The UKIPO rejected the case as a method of doing business. This rejection was overturned by the High Court, which did, however, identify some clarity issues with the claim (so the case was therefore sent back to the UKIPO for further review).

The majority of UK cases relating to computer-implemented inventions are ex parte appeals from a rejection by the UKIPO, but the courts have also had to consider some inter parties cases. Two such cases this year have been of particular interest to practitioners.

The *RIM v Visto* case (RIM being the makers of the well-known Blackberry device) dealt with many issues, including added matter, obviousness, insufficiency and inventive step. The judge held the patent invalid, firstly on obviousness, and secondly because the contribution lies solely in excluded matter. The Visto patent was granted by the EPO and is also undergoing opposition before the EPO. The EPO did not raise any objections concerning excluded matter, nor has this been a feature so far of the opposition. Accordingly the decision in *RIM v Visto* highlights the ongoing uncertainty in the approach of the UK courts with

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It is therefore recommended that anyone considering appealing a decision of the Examining Division gives careful thought to the desired result. If it is clear that the refusal can be overcome in a way that is useful to the applicant and likely to be acceptable to the Examining Division, filing an appeal based on a suitably amended application should hopefully produce a granted patent via the interlocutory revision procedure. In contrast, if the views of the Examining Division to date seem unreasonable it may be better to try to ensure that the application is placed with the Board of Appeal in the hope of an alternative opinion.

To achieve this and to avoid an unwanted interlocutory revision the appeal should not overcome the original grounds for refusal while simultaneously bringing up potential new grounds. For example, an appeal can be filed with a main request based on the application exactly as refused, without amendment (amendments can be submitted as auxiliary requests). This will be unlikely to satisfy the Examining Division, who will send the case to the Board of Appeal.

It should be borne in mind, however, that although the first instance (e.g. the Examining Division) should review the grounds of appeal to determine whether an interlocutory revision is appropriate, practice suggests that in many cases the appeal will simply be referred to the Board of Appeal irrespective of its merits.

respect to the EPO, despite a commonality of law.

The *Aerotel v Wavecrest* case is related to the invention considered by the Court of Appeal in *Macrossan/Aerotel* (as mentioned above). Whereas the Court of Appeal had regarded the *Aerotel* invention as statutory subject matter, the invention was now held to be excluded subject matter (in part because the patent was found to make only a small contribution to the state of the art).

The decisions in *RIM v Visto* and *Aerotel v Wavecrest* appear to have swung the pendulum slightly away from patenting computer-implemented inventions in the UK, although the *Symbian* case may swing the pendulum back again shortly.

D Young & Co's electronics and mechanical engineering group boasts Chartered and European patent attorneys with a diverse range of technical and legal experience. With 16 qualified Patent Attorneys, the group is headed up by the following partners: Nigel Robinson, Ian Harris, James Turner, David Horner, Miles Haines, Jonathan DeVile, Simon Davies, David Meldrum and Julia Mills.

Clients of the group are located worldwide and include academic institutions, research institutes, start-up companies, SMEs and blue-chip organisations.

The patent attorneys in the electronics and mechanical engineering group provide a depth of experience across a very diverse range of technical subject matter, including:

- Aeronautical technology
- Analog and digital electronics
- Audio and visual electronics
- Automotive technology
- Battery and fuel cell technology
- Bioinformatics
- Business method technology
- Computer entertainment engineering
- Computer hardware, software and devices
- Control engineering
- Display technology
- Electrical engineering and power systems
- Eco-systems
- Geophysics
- Heating technology
- Hydraulics
- Information technology
- Manufacturing systems and technology
- Marine technology
- Materials science
- Medical systems and devices
- Mobile radio communications
- Motors and magnetic systems
- Nanotechnology
- Oil/gas processing and exploration
- Optics, optical systems and devices
- Radiation technology
- Robotics
- Scientific instrumentation
- Semiconductors
- Signal and image processing
- Software engineering
- Telecommunications and network systems
- Television systems

Members of the group are active in lecturing on IP issues both in the UK and overseas; have published papers on technical and IP matters in international journals and sit on UK and international IP committees.

Please visit our website for more information about D Young & Co Patent services: www.dyoung.com/expertise/patents.htm and see overleaf for electronics and mechanical engineering group attorney contact details.

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RESTORING A LAPSED PATENT IN THE UK

Missing a renewal fee payment can render years of hard-fought prosecution worthless. Section 28 of the UK Patents Act provides the patent proprietor with the possibility of reinstating a patent which has lapsed by failure to pay a renewal fee on time.

In the past, restoring a lapsed patent required that the patentee demonstrated 'reasonable care' to see that any renewal fee was paid within the prescribed time limit. The test which evolved was one in which this 'reasonable care' required a robust system for making timely renewal fee payments and for many proprietors clearly demonstrating this 'care' was a challenge.

However, under the existing Rules the test is less severe and now requires that the proprietor demonstrates that the failure to pay the necessary fee was 'unintentional'. Consequently, submitting a successful application for Restoration under the



Act requires that suitable evidence is gathered which clearly demonstrates that the Proprietor always intended for the prescribed fee to be paid on time, but that for whatever reason payment was not, or perhaps could not, be made.

It would therefore seem that the failure of an annuity service, or party making a payment on behalf of the patent proprietor and under specific instruction to do so, might well fall within the requirements of this test. This is of course provided that the proprietor's 'intention' can be evidenced to the satisfaction of the UKIPO.

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