Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Patent Office

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THE PATENT OFFICE
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Section 2(6) ................................................................. Paragraphs 71-73
First medical use - forms of claim ................................. Paragraphs 74-75
Searching and assessing novelty and inventive step of
first medical use claims ................................................. Paragraphs 76-82
Plurality ........................................................................ Paragraph 83
Applications with both first medical use and
non-medical claims ........................................................ Paragraph 84
Combined therapies ....................................................... Paragraph 85
First medical use and apparatus ................................... Paragraph 86
Support for first medical use claims ............................. Paragraphs 87-89
SECOND MEDICAL USE
“Swiss-type” claims ....................................................... Paragraph 90
Second medical use - forms of claim ........................... Paragraphs 91-92
Second medical use and Section 4(2) ............................ Paragraphs 93-97
Determining novelty and inventiveness of second
medical use claims ......................................................... Paragraphs 98-102
Second medical use claims - the new use
i) Treatment of a new disease or condition ............... Paragraph 103
ii) New method, time, frequency or dosage of
administration ............................................................... Paragraphs 104-109
iii) New patient group .................................................. Paragraphs 110-112
iv) New mechanism or technical effect ...................... Paragraphs 113-116
v) New advantage to known use .............................. Paragraph 117
vi) Definition of the new medical use ..................... Paragraph 118
vii) Use in association with another agent .......... Paragraph 119
Second medical use claims - the substance or
composition
i) Assessing novelty and inventive step .................... Paragraphs 120-121
ii) Assessing support when the substance is
defined by chemical structure or class ............... Paragraphs 122-123
iii) Searching and examining claims when the
substance is defined by functional activity ......... Paragraphs 124-125
Plurality ........................................................................ Paragraph 126
Second medical use and apparatus ............................... Paragraph 127
Support for the medical use in Swiss-type claims ...... Paragraphs 128-131
CLAIMS TO PHARMACEUTICAL COMPOSITIONS
Compositions adapted to a particular use .................. Paragraphs 132-134
Clarity of composition claims ...................................... Paragraph 135
Compositions with a new non-medical purpose or
property ........................................................................ Paragraph 136
Claims to unit dosage forms ........................................ Paragraphs 137-139
Combined preparations and packs of medicaments.. Paragraphs 140-145
ANNEX A - INDEX OF COURT CASES AND UK PATENT OFFICE DECISIONS
ANNEX B - INDEX OF EUROPEAN PATENT OFFICE DECISIONS
INTRODUCTION

1. These Guidelines set out the practice within the UK Patent Office as it relates to patent applications for medical inventions. The relevant legislation is the Patents Act 1977, as amended by subsequent legislation, and the Patents Rules 1995, as amended. The interpretation of this legislation has been informed by case law in the UK courts. It has also reflected the fact that judicial notice must be taken of international conventions (such as the European Patent Convention) and of decisions and opinions made under these conventions by the appropriate bodies. Accordingly, decisions taken by the UK courts relating to the 1977 Patents Act are binding on our practice, whilst EPO Board of Appeal decisions are strongly persuasive. UK court decisions under previous legislation may also be persuasive, depending on the extent to which that aspect of patent law had been changed by the 1977 Act. Existing UK Patent Office practice, as set out in the Manual of Patent Practice and in decisions taken in UK Patent Office hearings, has not been changed without good reason.

2. The Patents Act 2004, which received royal assent on 22 July 2004, will amend the Patents Act 1977 in respect of medical inventions, to implement the European Patent Convention as revised in 2000. However, the provisions relating to medical inventions will not come into force until the Convention does. The timing is dependent on ratification or accession of the Convention in other EPC contracting states. We currently understand that the European Patent Convention may come into force in 2007. These Guidelines are therefore based on the Patents Act 1977 as currently amended, and do not take account of the amendments to the 1977 Act that will be introduced by the new Act.

3. More specifically, the Patents Act 2004 will introduce a new Section 4A to the 1977 Act which states that the invention of a method of treatment of the human or animal body by surgery or therapy, or a method of diagnosis practised on the human or animal body, is not patentable. In addition, the new Section 4A states that patents may be granted for a known substance or composition for use in medicine, or for a specific medical use. These changes will therefore allow a simpler and clearer form of second medical use claim, of the form “Substance X for use in the treatment of disease Y”, rather than “The use of X for the manufacture of a medicament to treat Y”. They will also remove the “legal fiction” that methods of treatment by therapy or surgery, or methods of diagnosis performed on the body lack industrial application - they will instead simply be considered unpatentable. However, it should be noted that these amendments are not expected to lead to any change in what is and is not patentable in this field.

4. Any comments or questions arising from these Guidelines should be addressed to Richard Sewards, Room 2.Y52, The Patent Office, Concept House, Cardiff Road, Newport, South Wales, NP10 8QQ (Telephone: 01633 813536).
5. Patent applications in the medical field must meet the same requirements as applications in all other fields of technology; that is, they must be new, inventive and capable of industrial application, and the claims must clearly define the scope of the invention and be supported by the description.

6. However, patenting in this field is constrained by the exclusion from patentability of methods of treatment of the human or animal body by therapy or surgery, or diagnosis performed on the human or animal body, under Section 4(2) of the Patents Act 1977, which states that such methods are to be considered incapable of industrial application. This exclusion applies only to methods of treatment and not to the materials used in such treatments, as explicitly stated in Section 4(3).

7. In addition, the definition of novelty for substances or compositions used in methods of treatment is addressed by Section 2(6), which states that a substance or composition which is itself already known is regarded as novel “for use in” a method of treatment prohibited by Section 4(2), provided that the substance or composition has not been known to be used in any such method before (“first medical use”). Furthermore, following the decision of the EPO Enlarged Board of Appeal in G 05/83, claims for the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application (“second medical use”) are allowable.

8. Much of the case law relating to patenting in the medical field has focussed on boundaries between, on the one hand, the exclusion of methods of treatment from patents, and on the other hand the patentability of the materials used in such treatments, and in particular the first or subsequent medical uses of compounds or compositions.

9. There are an increasing number of patent applications in the medical field which relate to the use of biotechnological inventions for medical purposes, for example through gene therapy. Any such applications will also need to meet the requirements of Schedule A2 to the Act. The Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the UK Patent Office set out the practice of the UK Patent Office in these areas.

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1 G 05/83 Eisai/Second medical use OJEPO 1985, 64
METHODS OF TREATMENT OR DIAGNOSIS

10. Methods of treatment by therapy or surgery or methods of diagnosis performed directly on the human or animal body are unpatentable, as set out in Section 4(2) of the Patents Act 1977:

“An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application”

Section 4(2) of the Patents Act 1977

11. The purpose of Section 4(2) (and the equivalent Article 52(4) of the EPC) is to prevent medical or veterinary practitioners being restrained or hampered in their practice by patent legislation.

“The intention of article 52(4) EPC...is only to free from restraint non-commercial and non-industrial medical and veterinary activities.”

G 05/83 EISAI/Second medical use OJEPO 1985, 64

12. Section 4(2) does not prevent the patenting of materials or compositions used in such treatments, as stated in Section 4(3):

“Subsection (2) above shall not prevent a product consisting of a substance or composition being treated as capable of industrial application merely because it is invented for use in any such treatments”

Section 4(3) of the Patents Act 1977

13. The methods defined in Section 4(2) are considered incapable of industrial application regardless of their actual commercial or industrial application. For example, the veterinary treatment of stock animals on a farm is clearly a matter of commercial interest, and the definition of industrial application in Section 4(1) specifically includes inventions which can be made or used in agriculture. However Section 4(1) begins with the words “Subject to sub-section (2) below”, and it is therefore clear that Section 4(2) must be met before the definition of industrial application in Section 4(1) can be applied. This has been confirmed in the UK courts\(^2\) and the EPO\(^3\).

\(^2\) Unilever (Davis’s) Application [1983] RPC 21

\(^3\) T 116/85 WELLCOME/Pigs I OJEPO 1989, 13
14. Not all methods of treatments of the human or animal body are excluded; only those that fall within the scope of the terms “therapy” and “surgery”. In addition, claims to methods of diagnosis are only objectionable if they are performed directly on the human or animal body. This is discussed in more detail in the subsequent sections.

**THERAPY**

**Definition of “therapy”**

15. The definition of therapy used by both the UK courts and the EPO includes both treatments to cure or prevent disease, and so methods of, for example, vaccination of healthy individuals are considered to be methods of treatment by therapy and thus unpatentable. In *Unilever (Davis’s) Application* it was stated that therapy should be construed as the medical treatment of disease, including preventative treatment as well as curative treatment. Moreover, therapy encompasses methods of alleviating symptoms as well as curative treatments for a disease. In deciding whether a treatment can be considered to be “therapy”, the broad definition applied by the EPO in *T 24/91* and *T 58/87* should be used.

“any treatment which is designed to cure, alleviate, remove or lessen the symptoms of, or prevent or reduce the possibility of contracting any disorder or malfunction of the animal body”

*T 24/91 THOMPSON/Cornea OJEPO 1995, 512*

16. Veterinary treatment of a diseased or injured animal is regarded as therapy and it was pointed out in *Unilever (Davis’s) Application* (at pages 229-230) that therapy cannot have a different meaning for humans and animals.

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4 *T 19/86 DUPHAR/Pigs II OJEPO 1989, 24*
5 *T 81/84 RORER/Dysmenorrhoea OJEPO 1988, 202*
6 *Schultz’s Application BL O/174/86*
7 *T 24/91 THOMPSON/Cornea OJEPO 1995, 512*
8 *T 58/87 SALMINEN/Pigs III [1989] EPOR 125*
Therapeutic methods: form of claims

17. The following formats of claim are all considered to define methods of treatment by therapy, and are thus unpatentable under Section 4(2):

i) The treatment of (medical condition Y) with (substance X).

ii) The use of (substance X) to treat (medical condition Y).

iii) (Substance X) when used to treat (medical condition Y).

iv) The use of (substance X) as a pharmaceutical.

In G 05/83, the Enlarged Board of Appeal of the EPO decided that claims to “the use of X to treat Y” were indistinguishable from claims to “the treatment of Y with X”, and this was upheld by the Patents Court in John Wyeth’s and Schering’s Applications. These cases established that “Swiss-type” second medical use claims of the format “the use of X in manufacture of a medicament to treat Y” were acceptable (see below, paragraphs 90-131). However, where such claims also relate to mode of administration, dosage or frequency of dosage they may be rejected if they are in fact a disguised claim to a new method of treatment drafted in the Swiss format (Bristol-Myers Squibb v Baker Norton Pharmaceuticals) - see paragraphs 104-109 below.

18. Claims to the use of a substance “as a pharmaceutical” (claim (iv) above) are interpreted as a method claim to the use of the substance in therapeutic treatment, rather than simply a claim to its use in a pharmaceutical formulation. This is in accordance with the general rules for construction of claims in this format, as described in the Manual of Patent Practice at paragraph 2.16. Where appropriate, amendment to acceptable first or second medical use claims should be sought for claims of this type. The use of a substance as an adjuvant or immunostimulant may be acceptable if restricted to non-therapeutic uses, as adjuvants are often used to produce antibodies in animals for experimental use, as well as in therapy.

Guidelines for determining whether a method is “treatment by therapy”

19. It is useful to consider whether the method would normally be carried out by a medical professional such as a doctor or vet. Section 4(2) is intended to prevent medical or veterinary practitioners being restrained or hampered in exercising their professional skills by patent rights, and so a claimed method which does not impact on a practitioner’s medical discretion is likely to fall outside the scope of Section 4(2). A method in which a laser was used to modify a synthetic lenticule implanted on the cornea, on the other hand, was

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9 John Wyeth’s and Schering’s Applications [1985] RPC 545
10 Bristol-Myers Squibb v Baker Norton Pharmaceuticals [2001] RPC 1
11 T 245/87 SIEMENS/Flow measurement OJEPO 1989, 171
12 T 426/89 SIEMENS/Pacemaker OJEPO 1992, 199
considered to be unpatentable, in part because it would be performed by or under the supervision of a medical practitioner due to the health risks concerned\(^7\).

\[\text{“The intention underlying [Article 52(4)] is to ensure that nobody who wants to use the methods specified in this Article as part of the medical treatment of humans or animals should be prevented from this by patents. Such medical treatments need not necessarily be carried out by physicians...However, where, in view of the health risks connected with such a treatment, a claimed method of treatment has to be performed by a physician or under his supervision, it will normally fall within the exclusion...”}\]

T 24/91 THOMPSON/Cornea OJEPO 1995, 512

20. However, this consideration is not decisive, and the purpose and inevitable effect of the invention are more important. If a method has no therapeutic purpose or effect (for example in methods for collecting bodily fluids for analysis etc), then the fact that it may be carried out by a doctor does not render it unpatentable\(^{13,14}\). Conversely, methods for treating diseases in farm animals are excluded under Section 4(2), even if the method may routinely be carried out by the farmer rather than the vet.

\[\text{“...if a claimed method requires the treatment of an animal body by therapy, it is a method which falls within the prohibition on patentability set out in Article 52(4) EPC. It is not possible as a matter of law to draw a distinction between such a method as carried out by a farmer and the same method as carried out by a veterinarian, and to say that the method when carried out by a farmer is an industrial activity and therefore patentable... and when carried out by a veterinarian is a therapeutic treatment not patentable under Article 52(4).”}\]

T 116/85 WELLCOME/Pigs I OJEPO 1989, 13

21. Although both prevention and cure of diseases are considered to be therapeutic, there must be a direct link between the treatment and the condition to be treated or prevented. Methods of hygiene are not considered therapeutic even though they may result in a reduced incidence of infection. In Commonwealth Scientific & Industrial Research Organization’s Application\(^{15}\), the Hearing Officer held that a method for the destruction of wool follicles in the skin of a wool-bearing animal was not directly linked to a disease state to be cured or prevented, even though it could have the indirect effect of reducing parasite infestation.

**Claims to both therapeutic and non-therapeutic methods**

22. There are many instances where claims may potentially include within their scope both patentable and non-patentable methods. For example, a claim to “A method for inhibiting the coagulation of blood by contacting the blood with a carrier containing

\(^{13}\) T 329/94 BAXTER/Blood extraction method OJEPO 1998, 241
\(^{14}\) T 1165/97 ULTRAFEM/Feminine hygiene device [2002] EPOR 384
\(^{15}\) Commonwealth Scientific & Industrial Research Organization’s Application BL O/248/04
compounds X and Y" could include a method of treating the blood in a patient as part of a therapeutic method (not patentable), and also a method of treating stored blood in a bottle (patentable). In cases where it is unambiguously clear from the specification that the claims relate only to patentable methods, then no amendment is required.

23. If it is apparent from the specification that the claims could cover non-patentable embodiments of the method then amendment is required to clearly limit the claim to methods which are patentable, and if necessary to amend the description to clarify that therapeutic methods do not form part of the invention.

24. The EPO Enlarged Board of Appeal confirmed in G 01/03\(^{16}\) that disclaimers to exclude unpantentable methods of treatment by therapy or surgery, or methods of diagnosis practised on the human or animal body, are in principle allowable and do not constitute added matter. This is in accordance with UK Office practice. However, if claims are limited, either by disclaimer or otherwise, to patentable methods, then there must be support in the description for a non-therapeutic method. This was not held to be the case in ICI (Richardson's) Application\(^{17}\), where a claim was made to a method of producing an anti-oestrogenic effect in a human, but excluding any method of treatment by therapy. It was considered that the specification did not describe any application of the method other than in the treatment of breast cancer or infertility, and so the claim was rejected. Any disclaimer needs to exclude therapeutic methods and leave the scope of the remaining monopoly clear. The word “cosmetic" in a claim to a method of treatment is generally acceptable as a sufficient limitation\(^{18}\). Of course, if a claim is amended to “cosmetic methods", there must be disclosure of such methods in the application as filed. If there is not, then the amended claim will constitute added matter, as well as being objectionable through lack of support. A disclaimer which merely uses the words of Section 4(2) is considered to leave the scope of the monopoly unclear\(^{17}\).

25. Moreover, it must be possible to distinguish the therapeutic and non-therapeutic effects of a claimed method. If the non-therapeutic effect is inseparable from the therapeutic effect, or if it is merely a secondary consequence of the therapy, then the invention is unpantentable, regardless of the wording used. For example, it has been held in both the UK courts and the EPO that it is not possible to claim a cosmetic method for the removal of plaque from teeth, as such a method will inevitably have therapeutic benefits in preventing tooth decay and gum disease.

\(^{16}\) G 01/03 PPG/Disclaimer OJEPO 2004, 413
\(^{17}\) ICI (Richardson's) Application [1981] FSR 609
\(^{18}\) T 36/83 ROUSSEL-UCLAF/Thenoyl peroxide OJEPO 1986, 295
26. On the other hand, if the effects are separable, then the existence of a possible therapeutic use should not prevent a cosmetic or other non-therapeutic method from being patentable. For example, a treatment may be therapeutic or cosmetic depending on the subject being treated. This distinction was accepted in the case of an appetite suppressant\(^{19}\) and an antibacterial skin treatment\(^{18}\). A similar distinction between therapeutic and non-therapeutic uses of the same method was made in T 584/88\(^{20}\), wherein a treatment of snoring was regarded as either therapeutic in cases where the snoring was harmful to health, or non-therapeutic if the snoring was merely troublesome. In this case it was accepted that it was difficult to draw a precise boundary between harmful or merely troublesome snoring, but this did not prevent a method claim from being accepted for the latter (and a second medical use claim for the former).

27. The way these general principles have been applied by the courts and the EPO Boards of Appeal to specific, contentious areas is discussed below.

**Therapeutic and non-therapeutic methods: specific examples**

**i) Cosmetic treatments**

28. Purely cosmetic treatments of the skin and hair are patentable. These may include cosmetic methods of strengthening hair and nails (following Joos v. Commissioner of Patents\(^{21}\)), and cosmetic methods to prevent hair loss\(^{22}\). Methods of protecting the skin by simply blocking UV radiation are not considered to be therapy, but where a method includes physiological effects then it is considered to be therapeutic (T 1077/93\(^{23}\)). In this case the Technical Board decided that the cosmetic and therapeutic aspects of the claimed method of protecting skin were “inevitably linked, such that each one necessarily develops together with the other and such that it is impossible to separate them”. The argument that the treatment was effectively directed towards natural ageing of the skin, and was therefore not therapeutic, was rejected on the grounds that “a natural process of cell degeneration loses its physiological normality when it develops in an abnormal manner, and in particular faster than its normal process”. A similar view was taken by the Board of Appeal in T 67/02\(^{24}\), wherein a “non-

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19 T 144/83 DU PONT/Appetite suppressant OJ EPO 1986, 30
20 T 584/88 REICHART/Anti-snoring means [1989] EPOR 449
22 T 453/95 REDKEN (Unpublished)
23 T 1077/93 L’OREAL/Protection against UV [1997] EPOR 546
24 T 67/02 BEIERSDORF (Unpublished)
“therapeutic” method of prevention of skin ageing was held (on the facts of the case) to be inseparable from therapeutic effects acting on the skin. In the same case however, the use of the same agent to protect the lips (eg. from sunburn) was held to be a purely cosmetic application with no therapeutic benefit. The use of a composition for the local treatment of comedones (blackheads) was regarded as a cosmetic method of non-medical body hygiene, although when applied for the treatment of acne this would be regarded as therapeutic\textsuperscript{18}.

\textbf{ii) Removal of parasites}

29. Methods of treating or preventing infestation of internal parasites are regarded as therapy; the argument that the host animal is unaffected and that it is only the parasites that are being killed and that therefore this is not therapy of the animal body, has been rejected\textsuperscript{25}. Treatment of parasites residing on the skin of a human or animal is considered to be therapy (T 116/85\textsuperscript{3}). The Board of Appeal in this decision explicitly rejected the view that a treatment of an ectoparasite infection was therapeutic in the case of “permanent” ectoparasites residing in the skin, and not in the case of “temporary” ectoparasites residing on the skin. Treatment of, for example, head lice, is therefore considered therapeutic, despite the decision made under the 1949 Act in \textit{Stafford-Millers Application}\textsuperscript{26}.

30. However, the procedure must be \textbf{directly} related to the treatment or prevention of parasite infestation to be excluded. A procedure to remove hairs from the skin of an animal, which had the indirect effect of reducing the incidence of blowfly strike, was held to be non-therapeutic\textsuperscript{15}.

\textbf{iii) Oral care}

31. Methods for the removal of dental plaque, or preventing the formation of plaque are considered to be therapeutic and thus unpatentable. All such methods have the effect of treating or preventing dental caries, and have been refused on these grounds under the 1949 Act\textsuperscript{27, 28} and under Section 4(2) of the current Act\textsuperscript{29}. In EPO decision T 290/86\textsuperscript{30} it was found that the inherent therapeutic effect of removing plaque could not be separated from the purely cosmetic effect of improved appearance of the teeth, and so restriction of such a claim to a cosmetic method is not possible.

\textbf{iv) Pain, fatigue and addiction}

32. The relief of pain is considered to be therapeutic, even where the pain has no pathological cause:

\textsuperscript{25} \textit{Ciba-Geigy’s Application} BL O/35/85
\textsuperscript{26} \textit{Stafford-Miller’s Application} [1984] FSR 258
\textsuperscript{27} \textit{Oral Health Products (Halsteads) Application} [1977] RPC 612
\textsuperscript{28} \textit{Lee Pharmaceuticals’ Applications} [1975] RPC 51
\textsuperscript{29} \textit{ICI Ltd’s Application} BL O/73/82
\textsuperscript{30} T 290/86 ICI/Cleaning plaque OJEPO 1992, 414
33. However, in T 469/94 \(^{31}\) it was held that a method of reducing the perception of fatigue (for example, following exercise) was not comparable with the relief of pain, discomfort or incapacity, and could be considered to be non-therapeutic when carried out on healthy individuals, although there were clearly therapeutic uses of the treatment as well.

34. Methods of treatment of addiction or withdrawal symptoms, including methods to help stop smoking, are considered to be therapeutic.

\textit{v) Obesity and weight reduction}

35. Methods of weight reduction for purely cosmetic reasons, including the suppression of appetite, are patentable. In T 144/83 \(^{19}\) a claim to a “method of improving the bodily appearance of a non-opiate-addicted mammal” was considered to have industrial application insofar as it related to cosmetic weight loss only. It was recognised that the method could also be used for therapeutic effects such as the treatment of obesity. Claims to such methods therefore need to clearly relate to cosmetic weight loss only.

\textit{vi) Contraception, abortion and fertility treatment}

36. Claims to methods of abortion, termination of pregnancy or induction of labour are considered to be unpatentable treatments, as they will always be carried out under medical supervision (see \textit{UpJohn (Kirton’s) Application}\(^{32}\) - 1949 Act). This applies regardless of the reasons for performing these methods.

37. Methods of contraception are not considered to be therapeutic, and may be patented (following the decision under the 1949 Act in \textit{Schering’s Application}\(^{33}\)). Pregnancy is not an illness or disorder, and so its prevention is not regarded as therapy. This has been confirmed in decisions of the EPO Boards of Appeal\(^{34, 35}\). However, contraceptive methods are excluded under Section 4(2) if they contain a therapeutic element\(^{34}\). Methods of contraception are not considered to lack industrial application merely because they are for “private and personal use”. The private use of such a method would not constitute an infringement of a patent according to Section 60(5) of the Patents Act 1977, and so a patent to such a method is allowable (notwithstanding the EPO decision in T 74/93\(^{35}\)).

38. Methods of treatment of infertility, including methods utilising \textit{in vitro} fertilisation, are considered to be therapeutic. Moreover, the implantation of an \textit{in vitro} fertilised embryo

\begin{quote}
\textit{“Irrespective of the origin of pain, discomfort or incapacity, its relief, by the administration of an appropriate agent, is to be construed as ‘therapy’...”}
\end{quote}

T 81/84 RORER/Dysmenorrhoea OJEPO 1988, 202
would, in most cases at least, be considered to be a surgical process and thus not patentable. In addition, the implantation of a human embryo would constitute a "commercial or industrial use" of such an embryo, and so would be unpatentable under Schedule A2 of the Patents Act.

vii) Methods utilising implanted devices

39. If a claimed method has a therapeutic purpose or effect then it is unpatentable under Section 4(2) even if the direct effect of the method is targeted on a non-living object such as an implant. A method of operating a pacemaker in which its output to the heart was adjusted was rejected as being a method of treatment by therapy in T 82/93\textsuperscript{36}. The applicant's argument that this was a "technical operation performed on a technical object" was considered to be irrelevant. On the other hand, a method of controlling the input energy to a pacemaker, which had the effect of minimising the energy requirements of the device but did not affect the output to the heart was accepted\textsuperscript{37}. Similarly, a method for measuring the flow of a drug from an implant, which did not actually control the flow, was held to be non-therapeutic\textsuperscript{11}.

viii) Treatments performed outside the body

40. A therapeutic treatment of the human or animal body is unpatentable under Section 4(2) even if the actual treatment takes place outside the body, as in an extracorporeal blood dialysis or filtration method (Calmic Engineering's Application\textsuperscript{38} (1949 Act) and Schultz's Application\textsuperscript{6}). In the latter case it, was observed that the words "practised on the human or animal body" relate only to methods of diagnosis, and not methods of treatment by therapy or surgery. However, methods of treating blood removed from the body are only regarded as therapeutic where the blood is returned to the same body. Treatment of blood for storage in a blood bank is not regarded as therapeutic treatment.

ix) Treatment of stock animals

41. The treatment of stock animals in order to improve their meat or other products, eg. milk yields, or to improve their growth by administration of substances or compositions in their food is not regarded as therapy, even if the substances concerned may have therapeutic benefits. However, where an increase in meat yield or other industrial benefit is merely an inevitable consequence of improved health through therapeutic treatment, then such a method is unpatentable. Claims have been rejected for this reason to methods involving general immunostimulation\textsuperscript{39} or through a specific effect on a pathogen\textsuperscript{40}.

42. On the other hand, a claim to the non-therapeutic use of antibiotics may be acceptable if the effect on meat or milk production is not a mere consequence of improved health. The test used in T 774/89\textsuperscript{41} was that a non-therapeutic method would be expected to show an improvement on the normal condition of the subject, rather then merely restoring an animal

\textsuperscript{36} T 82/93 TELELECTRONICS/Cardiac pacing OJ EPO 1996, 274
\textsuperscript{37} T 789/96 ELA MEDICAL/Therapeutic method OJEPO 2002, 364
\textsuperscript{38} Calmic Engineering's Application [1973] RPC 684
\textsuperscript{39} T 780/89 BAYER/Immunostimulant OJEPO 1994,797
\textsuperscript{40} T 438/91 MEIJI/Feeds [1999] EPOR 333
\textsuperscript{41} T 774/89 BAYER (Unpublished)
to a normal, healthy condition. In such cases, the non-therapeutic effects must be distinguishable from the therapeutic benefit, and any therapeutic methods must be specifically disclaimed (see paragraphs 22-26 above).

**SURGERY**

**Definition of “surgery”**

43. Surgery is defined as the treatment of the body by operation or manipulation. It is not limited to cutting the body but includes manipulation such as the setting of broken bones or relocating dislocated joints (sometimes called “closed surgery”), and also dental surgery. Furthermore, in *Occidental Petroleum’s Application*[^42], it was observed that a method of implanting an embryo could still be viewed as surgery even if the method did not require incision. The EPO Technical Board of Appeal in T 182/90[^43] stated that the definition of surgery includes “endoscopy, puncture, injection, excision and catheterisation”. However, simple injection methods, either for taking blood samples or introducing compositions would not be regarded as a method of surgery, as they involve relatively low levels of technical expertise. However, this would not be the case for any such method which required more specialist medical skills, such as lumbar punctures to deliver epidural injections.

44. The definition of surgery used in applying Section 4(2) relates to the nature of the treatment, and not its purpose. The exclusion of methods of surgery is not limited to therapeutic surgery; methods of surgery for cosmetic purposes, or other non-therapeutic purposes such as sterilisation, are not patentable.

> "...surgery can be curative of the disease or diseased conditions, or prophylactic, that is, preventative of diseased conditions, as for example, where an appendix or tonsils may be removed before any diseased condition starts up, and surgery may even be cosmetic without being curative or preventative. So that the subsection it seems to me is saying that any method of surgical treatment, whether it is curative, prophylactic or cosmetic, is not patentable."

*Unilever (Davis’s) Application* [1983] RPC 219 (NB remarks on surgery were *obiter*)

45. The EPO Board of Appeal in T 35/99[^44] held that excluded surgical methods embraced any physical interventions on the body in which maintaining the life and health of the subject was of paramount importance. This is distinguished from those interventions which result in the death of the subject (eg. slaughter of farm animals or sacrifice of laboratory animals, which are not excluded[^43].)

[^42]: *Occidental Petroleum’s Application* BL O/35/84
[^43]: T 182/90 SEE-SHELF/Blood flow OJEPO 1994, 641
[^44]: T 35/99 GEORGETOWN UNIVERSITY/Pericardial access OJEPO 2000, 447
46. This remains the practice of the UK Patent Office with respect to cosmetic surgery, notwithstanding the recent decision by the Technical Board of Appeal in T 383/03. In this case it was decided that the only surgical methods which are excluded from patentability are those potentially suitable for “maintaining and restoring the health, the physical integrity, and the physical well-being of a human being or animal, and to prevent diseases.” A method of hair removal by optical radiation was held to be surgical in character, but nonetheless patentable as its purpose was purely cosmetic. However, in view of the opinion of the judge in Unilever (Davis’s Application), claims to methods of surgery should be refused regardless of their purpose. The type of procedure at issue in T 383/03 (a method of hair removal by treatment of the skin and hair follicles with optical radiation) would not generally be considered to be surgical in nature under UK Patent Office practice - indeed, it is very similar to the claimed method in Commonwealth Scientific & Industrial Research Organization's Application, which was accepted as non-surgical by the Hearing Officer. It should also be noted that the Technical Board of Appeal considered that procedures such as breast augmentation and nose reshaping are still unpatentable, as they could be used to restore the “physical integrity” of a patient, for example following cancer or trauma.

Guidelines for determining whether a method is “treatment by surgery”

47. In general, any operation on the body which requires the skill or knowledge of a surgeon or other medical practitioner is regarded as being surgery, whether or not it is therapeutic. A method of embryo implantation which required the intervention of a surgeon or veterinary surgeon was held to be a surgical method, regardless of its purpose (Occidental Petroleum’s Application). In this case, it was stated that “if a method requires a surgeon for its execution then it must be surgery.” However, in Allen’s Application (which related to a method of inserting implanted markers into the body for NMR or CT scans) it was held that this did not mean that a method which did not necessarily require a surgeon could not be considered to be surgery. A physical intervention which required the medical skills of, for example, a nurse, could still be regarded as surgery. Similarly, methods of dental surgery require specialist dental skills and so are not patentable. If a method does not require medical skills or knowledge, on the other hand, (such as, for example, a method for cosmetic ear-piercing, or a method of tattooing the body) then it would not be excluded as a method of surgery.
48. Similarly, the setting of bones is carried out by doctors and is considered to be surgical in nature, while making and applying a plaster cast is normally carried out by a technician and so would not be regarded as surgery. A method of making a plaster cast would also not be treated as therapeutic, as the therapy resides in holding the bone in position while it heals and this occurs after the method of making the cast is complete. Methods of making artificial limbs or taking measurements or making casts are therefore not regarded as surgery or therapy.

**Use of parts of bodies in surgery**

49. Section 4(1) indicates that if an invention can be made or used in any kind of industry it shall be taken to be capable of industrial application. Parts of bodies, either of animals or humans, in themselves cannot be regarded as being made in any kind of industry. Moreover, since methods of surgery are stated not to be capable of industrial application in Section 4(2), when parts of bodies are to be used as prostheses in surgery they cannot be regarded as being used in any form of industry. Thus parts of bodies intended to be used as prostheses in surgery are not per se capable of industrial application and are not patentable. In most cases this is academic as such a claim in respect of human body parts would also lack novelty.

50. However pieces of animal body such as bone which have been subjected to technical processing (beyond normal surgical procedures) such as machining, demineralisation or tanning could be regarded as capable of industrial application since the prosthesis thus formed can be regarded as having been made in a kind of industry.

51. In the case of an organ derived from a genetically-modified animal (for example, to improve immunological compatibility with humans), the animal is the product of a technical process, and so an organ derived from it may also be considered to be the result of technical process, and thus industrially applicable. However, in this case, it would only be novel if the organ was inherently different from one taken from a wild-type animal (for example, by carrying a transgene conferring a desired trait) - it cannot derive novelty solely from its method of production, following the decision of the House of Lords in *Kirin Amgen v Hoechst Marion Roussel*[^47]. In any such cases care will need to be taken to ensure that the claims do not conflict with Schedule A2 of the Act (see the Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the UK Patent Office).

52. The obtaining of a part from a dead human body is not regarded as surgery, but any claim to such a method would need to be considered on a case-by-case basis as to whether the commercial exploitation of such a method would be contrary to public policy or morality (Section 1(3)).

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**DIAGNOSIS**

[^47]: *Kirin Amgen v Hoechst Marion Roussel* [2005] RPC 8
Definition of diagnosis

53. Diagnosis is the determination of the nature of a medical condition, usually by investigating its history, aetiology and symptoms and by applying tests. Diagnosis in itself is an intellectual exercise which is not patentable in view of Section 1(2)(c). Section 4(2) however relates to methods of diagnosis practised on the human or animal body. Diagnosis includes a negative finding that a particular condition can be ruled out, as well as a positive identification of a disease. However, determination of the general physical state of an individual (for example, for a fitness test) is not considered to be diagnostic if it is not intended to identify or uncover a pathology.

The meaning of “methods of diagnosis”

54. Typically, the process of diagnosis involves a number of steps leading towards identification of a condition. The EPO Enlarged Board of Appeal in G 01/04 characterised these steps as including the examination and collection of data, comparison of the data with normal values, recording any deviation, and finally attributing the deviation to a particular clinical picture. If a claimed method includes all these steps, and thereby makes it possible to decide on a particular course of treatment, it clearly constitutes a method of diagnosis.

55. Alternatively, claims may be directed towards methods which are of value in diagnosis, but which do not in isolation enable a full diagnosis to be made. Examples include methods of internal imaging or methods of taking samples for subsequent in vitro analysis. Where a claimed method does not encompass all the steps necessary to enable a diagnosis to be made, then it is not considered to be a “method of diagnosis” and is not excluded from patentability under Section 4(2). In G 01/04 the EPO Enlarged Board of Appeal decided that the term “method of diagnosis” in Article 52(4) (equivalent to Section 4(2)) should be interpreted narrowly. Only a method comprising all the steps necessary to identify a pathological condition falls within this definition.

“The method steps to be carried out prior to making a diagnosis as an intellectual exercise... are related to examination, data gathering and comparison.... If only one of the preceding steps which are constitutive for making such a diagnosis is lacking, there is no diagnostic method, but at best a method of data acquisition or data processing that can be used in a diagnostic method...”

G 01/04 Diagnostic methods (Unpublished)
56. This represents a significant change of practice from that described in the previous edition of these Guidelines. The UK Patent Office and the EPO had adopted a broader definition of a method of diagnosis, based on the decision of the EPO Technical Board of Appeal in T 964/99\(^50\). In this case it was held that all methods practised on the human or animal body which related to diagnosis or which were of value for the purposes of diagnosis were excluded. Thus, a method of taking a sample from the body for the purpose of medical examination was held to be an unpatentable method of diagnosis. The Enlarged Board in G 01/04\(^50\) overturned this interpretation, and instead endorsed the narrow definition used in the earlier decision T 385/86\(^51\), relating to a method of determining temperature and pH by magnetic resonance imaging. A method of taking a sample, or determining internal temperature or pH, does not in itself identify a condition, and so it is no longer considered to be a method of diagnosis. (This is also consistent with the earlier UK Office practice prior to T 964/99, which followed T 385/86 and the decision under the 1949 Act in *Bio-Digital Sciences’ Application*\(^52\)).

57. A method performed on the body which does not enable a disease to be identified, but which may be of value in diagnosis is therefore not excluded under Section 4(2). A method practised on the body (see paragraphs 58-60 below) which does include all the steps leading to a diagnosis should be objected to under Section 4(2). However, care should be taken to ensure that the claim does not simply omit the final step of identifying the disorder (or another necessary step), if it is apparent from the description that the method does in fact necessarily enable a specific diagnosis to be made. Section 14(5)(a) requires that the claims adequately define the matter for which the applicant seeks protection. If an essential step of the method is omitted (including the final, deductive step) then the claim does not adequately define the invention\(^49\). However, this does not mean that the claim must explicitly refer to every detail of the process. In particular, a claim to a diagnostic method performed *in vitro* on a sample taken from the body does not need to explicitly include the step of obtaining the sample (unless the invention actually lies in the method of obtaining the sample from the body).

**The meaning of “practised on the body”**

58. Section 4(2) states that a method of diagnosis practised on the human or animal body is not capable of industrial application. *In vitro* diagnostic tests, performed on blood or other samples removed from the body, are therefore patentable. Furthermore, to be excluded from patentability, diagnostic methods must be carried out on the living human or animal body. A method carried out on a dead body, for example to determine the cause of death, would not be objectionable.

59. Moreover, diagnostic methods may encompass both *in vivo* and *in vitro* steps. If the claimed method includes new and inventive technical steps performed *in vitro* then the method as a whole is not considered to be practised on the body. Examples of such steps might include analysis of a sample using a microarray, or new and inventive technical steps performed *in vitro* on a sample taken from the body.

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\(^{50}\) T 964/99 CYGNUS/Diagnostic device OJEPO 2002, 4

\(^{51}\) T 385/86 BRUKER/Non-invasive measurement OJEPO 1988, 308

\(^{52}\) *Bio-Digital Sciences’ Application* [1973] RPC 668
methods of data gathering, comparison or analysis performed by a device away from the body. The Enlarged Board in G 01/04\textsuperscript{49} considered whether all, or just one of the steps leading to a diagnosis had to be performed on the body for a method to be excluded. It was concluded that a method is only excluded if all of the technical steps in a method are practised on the human or animal body. The final deductive step of determining the condition is a purely intellectual exercise carried out by the doctor or vet. It is not necessary for the patient to be present for this step, but as it is not a technical step this is irrelevant for deciding whether a method is practised on the body. Similarly, a comparison of data with standard values which are common general knowledge in the art is also not a technical feature.

“if... some or all of the method steps of a technical nature... are carried out by a device without implying any interaction with the human or animal body, for instance by using a specific software program, these steps may not be considered to satisfy the criterion "practised on the human or animal body", because their performance does not necessitate the presence of the latter. By the same token, this criterion is neither complied with in respect of method steps carried out in vitro in a laboratory."

G 01/04 Diagnostic methods (Unpublished)

60. To decide whether a particular step in a method is “practised on the human or animal body”, the key test is whether the step requires the presence of the patient to perform it. It is irrelevant whether the procedure is invasive, or capable of causing harm to the patient\textsuperscript{49}.

Who performs the method?

61. The question of whether a claimed method is excluded under Section 4(2) depends on whether it falls within the definition of a “method of diagnosis” (paragraphs 54-57), and whether it is “practised on the human or animal body” (paragraphs 58-60). It is not dependent on who carries out the method, or whether a physician needs to be present.

“whether or not a method is a diagnostic method within the meaning of Article 52(4) EPC should neither depend on the participation of a medical or veterinary practitioner, by being present or by bearing the responsibility, nor on the fact that all method steps can also, or only, be practised by medicinal or non-medicinal support staff, the patient himself or herself or an automated system."

G 01/04 Diagnostic methods (Unpublished)

At most, if a doctor is required to be present for a given step then this would appear to imply that the step is performed on the body. However, the decision of the Enlarged Board in G 01/04\textsuperscript{49} makes it clear that this is not a decisive factor in determining whether a method is excluded or not. This contrasts with the decision of the Technical Board in T 655/92\textsuperscript{53}, where a method of NMR imaging included a step of injecting contrast agents into the body.

\textsuperscript{53} T 655/92 NYCOMED/Contrast agent for imaging OJEPO 1998, 17
These agents carried the risk of side effects, including potentially fatal anaphylactic shock, and so the method required the involvement of medical as well as technical staff. It was therefore held that this was a diagnostic method falling within the scope of the exclusion. In view of the clear direction given by the Enlarged Board in G 01/04, this reasoning is no longer relevant.

Diagnostic methods and Section 1(2)

62. Diagnostic methods typically include steps of data analysis and interpretation. This may include steps which fall into the excluded categories defined in Section 1(2); in particular mathematical methods (Section 1(2)(a)), or methods of performing a mental act or computer programs (Section 1(2)(c)). In such cases, the approach set out in *CFPH's Application*[^54] should be followed to determine patentability. This requires the following steps to be taken:

- a) To identify what is the advance in the art that is said to be new and not obvious (and susceptible of industrial application); and

- b) To determine whether it is both new and not obvious (and susceptible of industrial application) under the description of an "invention" in the sense of Article 52(2) of the European Patent Convention - which section 1(2) Patents Act reflects.

This approach to assessing patentability under Section 1(2) should be taken regardless of whether the original diagnostic method is carried out *in vitro* or *in vivo*.

In vivo testing of drugs etc.

63. *In vivo* methods of testing pharmacological efficacy or toxicity of drugs, or experimental methods of investigating diseases in animals are not considered to be methods of diagnosis as defined in Section 4(2). However, if the method would cause suffering to the animal and the application does not disclose any potential medical use or medical research benefit, then objection may be made that the method is incapable of industrial application, and moreover that the commercial exploitation of such a method would be contrary to public policy or morality (Section 1(3)).

MULTI-STEP METHODS INVOLVING A SURGICAL, THERAPEUTIC OR DIAGNOSTIC STEP

64. Where a claimed method involves a number of steps, one or more of which is surgical, therapeutic or diagnostic in nature, then the nature of the invention as a whole, and in

[^54]: *CFPH's Application* [2006] RPC 5
particular its inventive contribution, should be considered. The invention is taken to be that
specified in the claims, as interpreted by the description (Section 125). Section 4(2) states
that an invention of a method of treatment of the human or animal body by surgery or therapy
or of diagnosis performed on the human or animal body is not patentable. If the invention,
taken as a whole, clearly defines such a method then it is not patentable. For example, a
claim to a method of manufacturing a pharmaceutical, and then using it to treat a disease,
defines a method of therapy, as defined in paragraphs 15-16, even if the new and inventive
feature of the claim is the manufacturing method. Such a claim would not be patentable. On
the other hand, a method of producing a transgenic animal could involve a number of steps,
including a surgical method of embryo transplantation. This could not be described as being
a method of surgery. Such a claim does not prevent a vet from carrying out embryo
transplantation - infringement will not occur unless all the steps in producing a transgenic
animal are carried out. However, care should be taken to determine the substance of the
claims rather than their form, by considering where the new and inventive feature lies.
Simply adding on known or obvious features to an unpatentable method would not make the
claim patentable. In *Occidental Petroleum’s Application*, amendment of a claim to a
surgical embryo transplantation method to a claim to a “method of enhancing the production
of thoroughbred mammalian animal stock” did not save the application from refusal under
Section 4(2). The invention was held to be to a method of surgery, and thus unpatentable.

65. In contrast, the EPO has taken the view that any multi-step method which involves a
surgical or therapeutic step is excluded from patentability under Article 52(4) although
this principle is not applied to diagnostic steps, following the decision in G 01/04.
However, to exclude claims that do not (taken as a whole) define a surgical or therapeutic
method would appear to go beyond the meaning of the Patents Act, and so this principle has
not been followed.

66. In the case of multi-step methods involving an *in vivo* diagnostic step, it should also
be noted that the claim is only excluded if all the new and inventive technical steps are
practised on the body, as described in detail in paragraphs 58-60.

APPARATUS FOR SURGERY, THERAPY OR DIAGNOSIS

67. Claims to medical apparatus are allowable in the same way as claims to non-medical
apparatus. However, the exclusion of methods of surgery, therapy or diagnosis performed on
the human body means that claims to such apparatus “when used” in such a method are not
patentable. In other words, while a surgical instrument is patentable, it cannot derive novelty
from the way it is intended to be used in a surgical method. Similarly, a claim to a
pacemaker, which was characterised in part by its method of use, was rejected in T 82/93.

68. Moreover, it is not possible to claim the first or second medical use of apparatus.
Section 2(6) is restricted to substances and compositions, and cannot be used to protect
apparatus (*National Research & Development Corporation’s Application*), and similarly it

55 *Visx v Nidek* [1998] FSR 405
56 *National Research & Development Corporation’s Application* BL O/117/85
has been held in this decision and by EPO Boards of Appeal that second medical use claims
are not allowable with respect to apparatus. The rationale for this distinction given in T
227/91 was that compositions are expended in use, and so any new use is correlated with an
expansion in the manufacture of the composition for this purpose. This does not apply to
surgical apparatus, where there is the possibility of repeated and different uses of the same
item.

69. An implanted piece of apparatus, or assembly of items, which can only be constructed
inside the body in a process involving a surgical step is not patentable, as such a claim is
effectively a claim to a method of surgery even if it is framed as a product claim.

[quote]
...no European patent can be granted with claims directed to a new and even possibly
inventive way of using devices, in particular endoprostheses, involving a treatment by
surgery. This is equally true in the case of product claims defined by a construction which is
only arrived at in the human or animal body following a surgical method step.
[quote]

T 775/97 EXPANDABLE GRAFTS/Surgical device [2002] EPOR 24

70. While the use of a device in surgery, therapy or diagnosis performed on the human
body is unpatentable, the existence of functional features (for example, defining a prosthesis
in relation to the human anatomy) in a product claim does not in itself transform the claim
into a method claim. However, such a claim may be open to objection on clarity grounds,
as being defined by its desired result.

**FIRST MEDICAL USE**

**Section 2(6)**

71. In order to alleviate the effects of the Section 4(2) prohibition on the claiming of
methods of medical treatment, the 1977 Act includes Section 2(6), which states that:

[quote]
In the case of an invention consisting of a substance or composition for use in a method of
treatment of the human or animal body by surgery or therapy or of diagnosis practised on the
human or animal body, the fact that the substance or composition forms part of the state of
the art shall not prevent the invention from being taken to be new if the use of the substance
or composition in any such method does not form part of the state of the art.
[quote]

Section 2(6) of the Patents Act 1977

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57 T 775/97 EXPANDABLE GRAFTS/Surgical device [2002] EPOR 24
58 T 227/91 CODMAN/Second surgical use OJIEPO 1994, 491
59 T 712/93 JOINT MEDICAL PRODUCTS (Unpublished)
72. Under this section, and the equivalent Article 54(5) of the EPC, a substance or composition which is itself already known is regarded as novel “for use in” a method of treatment prohibited by Section 4(2) provided that the substance or composition has not been known to be used in any such method before. This provides an exception to the general rule of anticipation that once a substance or composition is known for whatever purpose then it cannot be patented again for another purpose, because it is old.

73. Section 2(6) protects the first medical use only. Even if the claim defines a substance “for use in” the treatment of a specific disease, the claim will not be novel if that substance has been used in the treatment of any other disease previously, although this will change when the relevant provisions of the Patents Act 2004 come into force, to implement the European Patent Convention as revised in 2000. A claim to a substance “for use in” the treatment of a specified disease will then be treated as a second medical use claim, and will only be anticipated by the specified medical use - see paragraphs 2-3. First medical use claims are normally used in cases where the substance is known. However, first (and second) medical use claims are acceptable for new compounds, for example, as a fall-back in the event of a prior disclosure of the compound coming to light after grant.

First medical use - forms of claim

74. Suitable forms of claim which have been allowed for the first medical use of a known compound are:

   i) (Substance X) for use in the treatment of (medical condition Y).

   ii) (Substance X) for use as a (Y-treating agent).

   iii) As a (Y treating agent), the (substance X).

   iv) (Substance X) for use in therapy (or for use as a medicament).

75. The broad form of first medical use claim (iv) was considered by the EPO Board of Appeal in T 128/82. It was decided that claims which did not state the specific therapeutic purpose were allowable if the substance in question had not been used in therapy, even if the specification only disclosed a single therapeutic use. It was argued that, as the inventor of a new chemical compound is granted absolute protection for all uses of the compound, an inventor who for the first time makes a known compound available for therapy should be able to gain protection over the whole field of therapy.

60 Sopharma’s Application [1983] RPC 195
61 T 09/81 ASTA/Cytostatic combination OJEPO 1983, 372
62 T 128/82 HOFFMAN-LA ROCHE/Pyrrolidine-derivatives OJEPO 1984, 164
Searching and assessing novelty and inventive step of first medical use claims

76. All claims to the first medical use of a compound are treated identically when assessing novelty. Any prior use of the compound in question in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body will anticipate the claim. This is true regardless of whether the claim is in the form “X for use in the treatment of Y”, or the more general form “X for use in therapy”, although as discussed above (see paragraph 73) this will change when the relevant provisions of the Patents Act 2004 come into force, to implement the European Patent Convention as revised in 2000.

77. However, these forms of claim have a different scope, and this does make a difference when assessing inventiveness - this was discussed by the Board of Appeal in T 128/8262. To illustrate thus, consider a hypothetical example in which Substance X is a known compound which has not previously been used in therapy but is very similar to a known therapeutic agent for heart disease. A claim to “Substance X for use in therapy” might not be considered inventive. On the other hand, a claim to “Substance X for use in treating cancer” would be more likely to be considered inventive. If, however, Substance X had been used in the prior art for treating heart disease, then both forms of claim would be anticipated, and a second medical use claim (for example, for use against cancer) would be the only acceptable form of claim. Consequently, when searching a “for use” type of main claim which concerns a specific type of therapy any prior medical use may be cited for lack of novelty, with the explanation that the claimed invention is not the first medical use as required under section 2(6). The search should nevertheless be focussed on the use specified in the claim, as amendment of the claim to the second medical use format is likely if any prior medical use is found.

78. In general, to provide evidence of prior use of a substance or composition in therapy, actual disclosure of therapeutic use must be found. A research paper which discloses experiments which show an activity which would make the substance or composition suitable for use in therapy, or discloses in vitro testing for such a use, does not constitute prior use. Such disclosures of experiments and tests might of course be used as a basis for an obviousness objection under Section 3.

79. Moreover, if the experimental evidence provided in the application in support of the claimed medical use relates to experiments carried out in vitro or in animal models, and the same evidence is provided in the prior art, then the inventiveness objection carries particular weight. In such a case the claimed use is either obvious from the disclosure of the prior art, or speculative and unsupported by the experiments provided. (First medical use claims must be supported by evidence of the likely effectiveness of the claimed treatment, as discussed below in paragraphs 87-89). It cannot be credibly argued that experimental data provides support for a claimed medical use, but the same data does not render it obvious.

80. A general statement of the medical use of a large class of chemical substances does not necessarily anticipate a first medical use claim to a specific compound falling within the class63. A document (typically a patent document) which states that the substance is used in

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63 T 07/86 DRACO/Xanthines OJEPO 1988, 381
therapy without describing actual clinical data may be cited for novelty. It would then be open to the applicant to challenge whether such a statement constitutes an enabling disclosure.

81. The wording of the Section does not require the substance or composition to display any activity in therapy; it is enough that it is for use in therapy. Thus if a known substance is used as a carrier material for a therapeutic substance in a particular treatment, it could be protected by a first medical use claim if the substance had not previously been used in surgery, therapy and diagnosis. Conversely a claim to a known substance for use in a particular method of therapy could not be sustained if the substance had previously been used as a carrier material in a therapeutic method, even if its use as an active agent was new.

82. A substance or composition known to have use in, say, therapy cannot be patented for use in surgery or diagnosis under Section 2(6)). Similarly, a substance or composition known to be used in surgery, therapy or diagnosis of a human cannot be protected by this Section for use in treating an animal, and vice versa.

Plurality

83. Only the first medical use of a known substance or composition may be protected by Section 2(6) against a charge of lack of novelty, but a number of distinct surgical, therapeutic or diagnostic uses may be independently claimed in the one application without objection to plurality of invention.

Applications with both first medical use and non-medical claims

84. It is a general principle that a substance or composition cannot be protected by Section 2(6) unless the method for which it is to be used is prohibited by Section 4(2) (cf Articles 54(5) and 52(4) of the EPC). The two Sections run hand-in-hand, and if the substance or composition is known in itself (but is not known for use in surgery, therapy or diagnosis) and the method falls foul of Section 4(2), then a claim to the substance or composition for use in the method is protected by Section 2(6) against lack of novelty. The meanings to be given to “surgery”, “therapy” and “diagnosis” in Section 2(6), are therefore the same meanings as used for Section 4(2). Since non-surgical cosmetic methods of treatment of the human body are not considered to be therapeutic, a substance or composition for use in a cosmetic method cannot be protected by Section 2(6). However, an application may include both claims to the first medical use of a compound for therapeutic purposes, and claims to cosmetic methods using the compound (as in T 36/8318). Moreover, known compositions or substances cannot derive novelty under Section 2(6) in a claim worded as a first medical use claim where there is no disclosure of actual prophylactic or therapeutic effect achieved beyond, for example, the maintenance of a healthy diet64.

Combined therapies

64 T 135/98 NORSK HYDRO [2004] EPOR 14
85. A first medical use claim to the use of two different agents (both of which are known in the prior art for therapeutic use separately) for simultaneous, separate or sequential use in a particular therapy is considered novel, if there has been no disclosure of the use of the two agents together in therapy. However, it should be noted that the inventiveness of claims of this type needs to be scrutinised carefully, to determine whether the claim represents a mere collocation of known elements - see paragraphs 140-142 below.

"The Board also takes the view that combined products intended under Article 54(5) EPC for therapeutic, surgical or diagnostic methods also include compositions in which the components are presented side by side and can therefore be applied simultaneously, separately or at intervals to one and the same human or animal body."

T 09/81 ASTA/Cytostatic combination OJEPO 1983, 372

First medical use and apparatus

86. Section 2(6) is restricted to substances and compositions; apparatus cannot be so protected 56.

Support for first medical use claims

87. A claim to the first medical use of a known substance or composition should be supported by evidence of its likely efficacy in therapy, surgery or diagnosis. In the absence of any such evidence, the claim is merely speculative. This is a new requirement for first medical use claims, which follows from the logic of the decision by the Patents Court in Prendergast’s Applications 65. This case (and earlier related hearings) concerned support for second medical use claims. It was held that, as the claims are distinguished from the prior art by their use, this use must be supported by evidence. The Hearing Officer in F. Hoffmann - La Roche’s Application 66 applied the same reasoning to claims in the first medical use format - the essential feature of such claims is the intended use and so there must be support for it. The form of evidence is not critical; the application may provide in vivo or in vitro data, and in silico modelling data may be sufficient if it is considered to provide a credible basis for support. In F. Hoffmann - La Roche’s Application, the evidence was in the form of sequence homology with related genes and proteins; on the facts of the case it was held that this provided credible support for a medical use for a nucleic acid, but not for the protein coded by it.

88. The evidence in support of the medical use must be provided in the application as filed, and cannot be overcome by later-filed results. A warning, in the form of an examination opinion, should therefore be provided at the search stage if the main claims relate to first (or second) medical use, and no data is provided.

89. Where the substance or composition is known, and the invention as defined by the

65 Prendergast’s Applications [2000] RPC 446
66 F. Hoffmann - La Roche’s Application BL O/192/04
main claim or claims relates to the medical use, a support objection under Section 14(5)(c) should always be made if there is no evidence provided. If on the other hand the first medical use claim is included as a subsidiary claim to a per se claim to the substance or composition, then - as a general rule - if the substance or composition claim is new, inventive and supported by the description, further consideration of support for the medical use claim(s) is not necessary as a matter of practicality. Of course attention should be paid to any claims which were filed later than the application to check that they are supported by the description (see paragraph 18.43 of the Manual of Patent Practice).

SECOND MEDICAL USE

“Swiss-type” claims

90. While Section 2(6) only gives protection for the first medical use of a known substance or composition, the further or second medical use of a substance or composition can be protected by a claim to the use of the substance for the manufacture of a medicament for a specified medical use. If the use of the compound for the specified medical purpose is new, then such a claim is considered to be novel even if the same substance had previously been used in medicine for a different purpose before. This type of claim is known as a “Swiss-type” claim, as they were first allowed by the Swiss Patent Office. The protection of second medical use by “Swiss-type” claims was allowed by the Enlarged Board of Appeal in G 05/83¹, and this was followed by the Patents Court in John Wyeth’s and Schering’s Applications ⁹.

“...it is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case where the process of manufacture as such does not differ from known processes using the same active ingredient.”

G 05/83 EISAI/Second medical use OJEPO 1985, 64

Second medical use - forms of claim

91. The following forms of second medical use claim have been accepted as allowable.⁹

i) “The use of (substance X) in the manufacture of a medicament for the therapeutic and/or prophylactic treatment of (medical condition Y).” This is the usual form of Swiss-type claim.

ii) “The use of (substance X) in the preparation of (an anti-Y agent) in ready-to-use drug form for treating or preventing (medical condition Y).” The expression “in ready-to-use drug form” was intended to mean “as presented for sale”, ie packaged, as explained in the Hearing Officer’s decisions in John Wyeth’s Application, cited in
iii) “The use of (substance X) in the manufacture of (an anti-Y agent) in a package together with instructions for its use in the treatment of (medical condition Y)”.

In addition, the following types of claim are not acceptable second medical use claims:

i) Substance X for use in the treatment of medical condition Y. *This is a claim to the first medical use of substance X, as discussed above (see paragraph 74)*

ii) “the use of substance X in the treatment of disease Y”. *This is an unpatentable method of treatment claim.*

iii) "Commercial package containing as an active pharmaceutical agent compound X together with instructions ... for treating condition Y". *If the pharmaceutical use of X is already known, the claim is only distinguished from the prior art by the content of the instructions, and this represents a mere presentation of information and thus not a patentable invention under Section 1(2)(d).*

iv) “A process for the manufacture of a medicament for use in the treatment of medical condition Y, characterised by the use of substance X.”

The interpretation of claims (i) to (iii) given above was set out by the Patents Court in *John Wyeth’s and Schering’s Applications:* and remains current practice. Claim (iv) is worded as a method claim, but it does not define any of the steps of the method. This form of claim is therefore objectionable under Section 14(5)(a), as it does not adequately define the invention (although claims of this type have been accepted by the EPO67). Although claim (i) is currently considered to be a first medical use claim, it should be noted that this will change when the relevant provisions of the Patents Act 2004 come into force, to implement the European Patent Convention as revised in 2000. This form of claim will then be treated as a second medical use claim, and will only be anticipated by the specified medical use - see paragraphs 2-3.

**Second medical use and Section 4(2)**

93. Swiss-type claims to substances or compositions can only derive novelty from their intended use if the use is in a medical method excluded under Section 4(2)

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"It is to be clearly understood that the application of this special approach to the derivation of novelty can only be applied to claims to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC."

67 T 958/94l Thérapeutiques substitutives/Anti-tumoral agent OJEPO 1997, 241
94. This means that Swiss-type claims are not allowable for the new use of a known substance in, for example, non-surgical cosmetic or hygiene methods. However, an application may include both claims to the second medical use of a compound for therapeutic purposes, and claims to cosmetic or other patentable methods using the compound, providing the therapeutic and non-therapeutic methods are distinguishable (as in T 584/88, relating to therapeutic and non-therapeutic treatments for snoring).

95. Although the Enlarged Board of Appeal refers only to “therapeutic” methods in its decision in G 05/83, Swiss-type claims may be used to protect the use of a known substance or composition in any method falling within the exclusion of Section 4(2). For example, in T 655/92, a Swiss-type claim was allowed for the use of a compound, previously used for therapeutic treatment, as a reagent in a diagnostic method performed directly on the human body.

96. Swiss-type claims are acceptable whether or not the substance is known or has been used in therapy previously. There is no requirement for evidence concerning prior medical use to be included in the specification.

97. If an application includes unpatentable method of treatment claims, such as “The use of X to treat Y”, amendment of these claims to convert them into Swiss-type claims does not constitute added matter.

**Determining novelty and inventiveness of second medical use claims**

98. In general, to show prior use of the agent in the specified therapeutic application, actual disclosure of the specified therapeutic use must be found. As in the case of first medical use (see paragraph 78), a research paper that merely discloses experiments which show an activity suggesting the specified use, or disclosing in vitro testing for such a use, would not anticipate a Swiss-type claim for the specified medical use. However, experimental data showing that an animal with the condition in question was successfully treated with the specified agent would constitute anticipation. This is a slightly different approach to that taken by the EPO, as it was stated in T 241/95 that “a pharmacological effect or any other effect such as a behavioural effect observed either in vitro or in animal models is accepted as sufficient evidence of a therapeutic application if for the skilled person this observed effect directly and unambiguously reflects such a therapeutic application”. Nonetheless, any document which “directly and unambiguously reflects such a therapeutic application" would be a very strong inventiveness citation.

99. Moreover, if the experimental evidence provided in the application in support of the specified use relates to experiments carried out in vitro or in animal models, and the same

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68 T 143/94 MAI/Trigonelline OJEPO 1996, 430
69 T 241/95 ELI LILLY/Serotonin receptor OJEPO 2001, 103
evidence is provided in the prior art, then the inventiveness objection carries particular weight. In such a case the claimed use is either obvious from the disclosure of the prior art, or speculative and unsupported by the experiments provided. (Second medical use claims must be supported by evidence of the likely effectiveness of the claimed treatment, as discussed below in paragraphs 128 - 131). It cannot be credibly argued that experimental data provides support for a claimed use, but the same data does not render it obvious. The EPO Board of Appeal in T 1031/00\(^{70}\) took this a step further and rejected a claimed second medical use on grounds of novelty, where the experimental data provided in the application was considered to be the same as that in a published research paper. The rationale for this was that there was no new technical feature provided in the application - the only new feature was the assertion of a therapeutic use. Our view is that a document that does not actually disclose a therapeutic use cannot be cited for novelty, but if the application makes no technical advance over the prior art a second medical use claim will not be patentable even if a novelty objection cannot be made. It will fall on grounds of either inventiveness or support.

100. A document which states that the substance is used to treat the particular disease without describing actual clinical data may be cited for novelty - such statements are common in patent documents. It would then be open to the applicant to challenge whether such a statement constitutes an enabling disclosure. It should be noted that the disclosure that an agent is being evaluated in clinical trials for a condition (in particular early stage trials to determine toxicity) does not necessarily constitute evidence of therapeutic use\(^{71}\), although clearly such a disclosure would be likely to be a very strong inventiveness citation at least.

101. If the compound in question has been used in the treatment of the specified disease, then this will anticipate the claim even if the treatment was not effective for all patients, or only minimally effective. The Court of Appeal in *Bristol-Myers Squibb v Baker Norton Pharmaceuticals*\(^{10}\) held that the words "for treating disease X" should be construed as "suitable for trying to treat disease X", since the skilled person would realise that drugs which are suitable for treatment will not always have a 100% success rate. However, drugs which are perceived as being suitable for treatment, but actually have no effect, do not fall within the scope of the claim. The efficacy of the treatment is not relevant, but it must be more than a mere placebo effect\(^{72}\). A second medical use claim is anticipated by the prior use of the compound to treat the disease in question, even if the only previous use was in association with another compound\(^{72}\).

102. Where there is no prior disclosure of the use of the agent to treat the specified condition, then the claim in question is clearly novel. If the agent has been used to treat a related condition, then the inventiveness of the claim may be called into question. This will obviously have to be dealt with on a case-by-case basis, but some guidance may be derived from the decision of the EPO Board of Appeal in T 913/94\(^{73}\). The first question to be asked is whether the diseases have a common origin, causative factors or mechanism. If this is the case, then this does not automatically mean that the claim lacks inventiveness. However, if

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\(^{70}\) T 1031/00 SEPRACOR (Unpublished)

\(^{71}\) T 158/96 PFIZER/Sertraline [1999] EPOR 285

\(^{72}\) Pfizer’s Patent [2001] FSR 16

\(^{73}\) T 913/94 EISAI/Medicament for gastritis [2001] EPOR 362
the symptoms of the disease already treated in the prior art are shared with, and are more serious than, the claimed condition, then this strongly suggests that the agent will be effective in the latter case as well.

**Second medical use claims - the new use**

**i) Treatment of a new disease or condition**

103. The decisions of the EPO Enlarged Board of Appeal in G 05/83 \(^1\) and the Patents Court in *John Wyeth's and Schering's Applications* \(^9\) established that the use of a substance for a “new and inventive therapeutic application” can be protected by a Swiss-type claim. Typically, Swiss-type claims are used to protect the use of a substance or composition in the treatment of a specified disease, where it had previously been used for the treatment of a different disease. Providing the use of the substance in the treatment of the specified disease is not known, such claims are considered to be novel.

**ii) New method, time, frequency or dosage of administration**

104. “Swiss-type” claims which attempt to distinguish the new use from the prior art by the way in which the medicament is used are not acceptable, as they effectively define a new method of treatment. Such claims are therefore excluded from patentability under Section 4(2) of the Act. A claim which defines the use in terms of the mode of administration, or the quantity, frequency or timing of dosage is therefore considered to be an attempt to monopolise a new method of treatment, disguised by drafting it in the Swiss format. This follows from the decision of the Court of Appeal in the *Taxol* case (*Bristol-Myers Squibb v Baker Norton Pharmaceuticals* \(^10\)).

105. The claim in question in this case had the wording:

> “Use of taxol and sufficient medications to prevent severe anaphylactic reactions, for manufacturing a medicamentation for simultaneous, separate, or sequential application for the administration of from 135 mg/m\(^2\) up to 175 mg/m\(^2\) taxol over a period of about 3 hours or less as a means for treating cancer and simultaneously reducing neutropenia.”

The Court of Appeal held that this claim defined an improvement in the method of administering an existing treatment; it did not define a new and inventive therapeutic purpose (*Taxol*\(^{\text{RTM}}\) was known to treat cancer). In particular, it was noted that all the claimed steps were in fact directed at actions taken by the doctor, tailored to the individual patient, rather than being directed at the manufacturer.

> “The claim is an unsuccessful attempt to monopolise a new method of treatment by drafting it along the lines of a Swiss-type claim. When analysed it is directed step-by-step to the treatment. The premedication is chosen by the doctor, and administered prior to the taxol according to the directions of the doctor. The amount of taxol is selected by the doctor as is the time of administration. The actual medicament that is said to be suitable for treatment is produced in the patient under supervision of the medical team. It is not part of a manufacture.”

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106. Therefore, if the “new medical use” in a claim relates to the manner in which the doctor performs the treatment then an objection should be made under Section 4(2) that the claim defines a method of treatment. For example, a claim which includes a dosage specific to the weight or size of the patient (as in the Taxol\textsuperscript{10} case) is not allowable. Any claim in which the “medicament” is only synthesised inside the patient’s body also defines a method of treatment. This is consistent with the EPO Board of Appeal’s decision in T 56/97\textsuperscript{74}, where a Swiss-type claim was made to the use of a thiazide diuretic for the manufacture of a composition, comprising an amount of thiazide diuretic “with the range of 7-25% by weight of the predetermined diuretic effective dose”. The Board noted that the pre-determination of the “diuretic-effective dose”, and the determination of the dosage for achieving the desired result, required the exercise by the medical practitioner of his professional skill, and thus the claim was no more than an attempt to protect a method of treatment by framing it in the Swiss format.

107. Moreover, the Court of Appeal in Taxol\textsuperscript{10} concluded that the second medical use must be aimed at a different end-result from the prior art, rather than merely a different method of obtaining the end-result.

"The novelty cannot lie in the method of use, but in the new therapeutic purpose for which the substance is based."

Buxton LJ, *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [2001] RPC 1

While this is compatible with Swiss-type claims to treat a different disease, it is not compatible with claims which are distinguished from the prior art by the mode of administration or the amount, timing or frequency of dosage. This conclusion was supported by the Patent’s Court in *Merck’s Patents [Alendronate]*\textsuperscript{75} (upheld by the Court of Appeal\textsuperscript{76}). In this case, a Swiss-type claim based on a new dosage regime (a single weekly administration of 70 mg of alendronate as opposed to daily administration of 10mg) was refused under Section 4(2).

108. Although this decision rules out second medical use claims based purely on new dosage forms, it should be noted that Swiss-type claims are allowable for the further medical use of a known substance or composition. Exceptionally, a change in dosage form may result in a significant change in the composition (for example, in terms of the concentration of the active ingredient with respect to the other ingredients). In such a case it would need to be established that the new composition has a clear functional or therapeutic significance. Moreover, if the new composition could easily be delivered by the doctor manipulating the dose of the prior art composition (for example, by diluting the formulation or doubling-up the number of tablets), then such a claim would impact on the doctor’s professional skill and so
would constitute an unpatentable method of treatment claim\(^75\). In *Advance Biofactures of Curacao’s Application*\(^77\), the Hearing Officer considered whether an injectable medicament comprising a specified concentration and amount of collagenase constituted a different “composition” from the prior art treatment of the same condition, which used a smaller amount of collagenase in a more dilute formulation, or whether this was merely an attempt to monopolise a new method of treatment. On the facts of the case, it was held that the more concentrated form amounted to more than a mere dosage regime. The reasons for this were firstly, that the concentration was substantially more concentrated than the prior art, and it was impossible in practice to deliver the required dose with the prior art concentration (unlike the situation in *Merck’s Patents [Alendronate]*\(^75\)). Moreover, the person skilled in the art would have considered this higher concentration to have unacceptable side effects, and the concentrated composition was successful in treating a group of patients who did not benefit from treatment with the prior art compositions. However, it was emphasised that this did not mean that specifying a different concentration of a particular ingredient necessarily constituted a new composition.

109. The EPO has generally taken a more liberal view of what constitutes a “new therapeutic use”. Claims have been accepted in which the prescription regime of the treatment was specified\(^78\) and where the distinguishing feature was mode of administration\(^79\). Indeed, in the recent decision T 1020/03\(^80\) it was held that the new therapeutic use may relate to any new and inventive use falling within Section 4(2) – the claim in question was distinguished by the precise dosage regime. However, in view of the binding decision of the Court of Appeal in the *Taxol*\(^10\) case, such claims cannot be accepted in a UK patent application.

### iii) New patient group

110. A Swiss type claim may, in very limited circumstances, rely for novelty and inventive step solely on the type of patient to be treated, despite the fact that the active agent and disease treated have already been associated in the prior art. This type of claim was first considered in T 19/86.\(^4\) It was held that the use of a known vaccine for preventing a known disease constituted a second medical use which could be protected by a Swiss-type claim when the type of animal treated (sero-positive pigs) was different from that previously treated in the art (sero-negative pigs). Similarly, in T 893/90\(^81\), the use of a composition to treat bleeding in non-haemophiliac humans was not anticipated by its use in treating bleeding in haemophiliac patients.

111. However, this must be considered in light of the decision in the *Taxol*\(^10\) case that the second medical use must relate to a different medical purpose, rather than merely a different method of use. In this case, Holman LJ had observed that the rationale for allowing “Swiss-type” claims was to give protection to inventions based on the discovery of “previously

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\(^{77}\) *Advance Biofactures of Curacao’s Application* BL O/303/04

\(^{78}\) T 570/92 BAYER (Unpublished)

\(^{79}\) T 51/93 SERONO (Unpublished)

\(^{80}\) T 1020/03 GENENTECH (Unpublished)

\(^{81}\) T 893/90 QUEEN’S UNIVERSITY KINGSTON (Unpublished)
unrecognised advantageous properties" in a chemical compound. Therefore a “Swiss-type" claim based on a new patient group can only be patentable if it is based on such "previously unrecognised advantageous properties" This is consistent with the decision of the Technical Board of Appeal in T 233/96\textsuperscript{82}, which set out a number of conditions for this type of second medical use claim. Firstly, the new patient group must be clearly distinct from the subjects treated in the prior art, and the two groups must not overlap. Secondly, the distinction must not be arbitrary, but must be based on a functional relationship between the physiological or pathological characteristics of the new group and the therapeutic effect. In other words, the discovery of a new advantageous property enables the treatment to be used for a different patient group, via a different physiological mechanism.

112. The claim should also clearly define the patient group in question. In this respect, the Office would take a more restrictive approach to that of the EPO Board of Appeal in T 836/01\textsuperscript{83}. In this case, the use of a medicament to directly restrict the growth of tumour cells was held to be novel over its previous use in immunotherapy for cancer, on the grounds that the new technical effect led to a different category of patients who would be suitable for treatment. While this may be the case, without defining the patient group it is difficult to see how the scope of the claim could be interpreted for infringement purposes.

\textit{iv) New mechanism or technical effect}

113. Swiss-type claims which relate to the same therapeutic use as the prior art, but claim a different technical effect or mechanism of action, should be rejected as lacking novelty; how a treatment works is irrelevant. An objection under Section 1(2)(a) that the claim defines a discovery may also be made.

114. This question was considered by the Patents Court in the \textit{Taxol} case \textit{(Bristol-Myers Squibb v Baker Norton Pharmaceuticals)\textsuperscript{84}). It was held that a new piece of information about how a treatment worked did not constitute an invention if it did not lead to a new use. This was upheld by the Court of Appeal\textsuperscript{10}. This contrasts with the decision in T 290/86\textsuperscript{30} that a second medical use claim can derive novelty from a new technical effect (in this case, strengthening of tooth enamel as opposed to removal plaque), even where the condition to be treated and the agent are the same. The Patent's Court in \textit{Taxol} considered the precedent of T 290/86 and specifically rejected this approach. Swiss-type claims based solely on a new technical effect when treating the same condition should not therefore be allowed.

115. In a later decision\textsuperscript{85} the EPO Technical Board of Appeal held that a new technical effect could only be considered to provide novelty to a claim if it resulted in a new use. If the substance has been used for the same purpose in the same way previously, then the claimed “technical effect" relates merely to an explanation of the mechanism behind the treatment.

\textsuperscript{82} T 233/96 MEDCO RESEARCH (Unpublished)
\textsuperscript{83} T 836/01 YEDA (Unpublished)
\textsuperscript{84} \textit{Bristol-Myers Squibb v Baker Norton Pharmaceuticals} [1999] RPC 253
\textsuperscript{85} T 254/93 ORTHO PHARMACEUTICAL/Prevention of skin atrophy OJEPO 1998, 285
116. This was reinforced by the EPO Board of Appeal in T 486/01, which held that the discovery of an additional mechanism of action of the protein IGF-1 in treating neurological diseases did not give rise to any new use over the prior art.

“For a medicinal application to be construed as a “further medical use”, this new technical effect would have to lead to a truly new therapeutic application, such as the healing of a different pathology or the treatment of the same disease with the same compound, however, when carried out on a new group of subjects distinguishable from the previously suggested subjects for such treatment…”

T 486/01 GENENTECH (Unpublished)

As discussed above (see paragraphs 110-112), if the new technical effect results in a different category of patients treated, then the patient group needs to be clearly defined in the claim, and must meet the requirements for claims of this type.

v) New advantage to known use

117. The discovery of an unexpected advantage in a known treatment does not constitute a new therapeutic use, although it may form the basis of such a use. In the Taxol case, the claim was based partly on the unexpected discovery that a shorter infusion time for a chemotherapeutic agent led to a lessening of the harmful reduction in white blood cells (neutropenia). However, the shorter infusion time had already been disclosed - this was merely an additional piece of information about a known treatment.

“...there is a big difference between new information that a prior proposal previously thought unworkable in fact works and new information to the effect that a prior proposal has an additional advantage.”

Jacob J, Bristol-Myers Squibb v Baker Norton Pharmaceuticals [1999] RPC 253

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"The Board considers that the mere explanation of an effect obtained when using a compound in a known composition...cannot confer novelty on a known process if the skilled person was already aware of the occurrence of the desired effect when applying the known process"

T 254/93 ORTHO PHARMACEUTICAL/Prevention of skin atrophy OJEPO 1998, 285
An improvement in an existing treatment is also not a new therapeutic application. The “hastened onset” of pain relief was not considered to be a new medical use when the substance in question was already known as an analgesic.

vi) Definition of the new medical use

118. Swiss-type claims can only be used to protect the use of a substance for a specified new and inventive therapeutic application. Claims to the further medical use of a known composition or substance must therefore specify the disease(s) to be treated. Claims in which the conditions are only specified in mechanistic terms should be objected to as being speculative and lacking clarity. The EPO Board of Appeal in T 241/95 rejected a Swiss-type claim for the use of a compound in the treatment of “a condition which can be improved or prevented by selective occupation of the 5-HT\textsubscript{iic} receptor”.

“...the “selective occupation” of a receptor, although being indisputably a pharmacological effect, cannot in itself be considered a therapeutic application. The discovery on which an invention is based, even if representing an important piece of scientific knowledge, still needs to find a practical application in the form of a defined, real treatment of any pathological condition in order to make a technical contribution to the art and be considered an invention eligible for patent protection.”

T 241/95 ELI LILLY/Serotonin receptor OJEPO 2001, 103

The Board of Appeal in T 241/95 did not entirely rule out claims in which the condition is defined in functional terms, if instructions (such as testable criteria) were provided to enable the skilled person to determine whether a disease fell within the scope of the claim. However, it should be carefully considered whether any such claim would put an undue burden of experimentation on third parties. A common mechanistic feature, if new and inventive, may nevertheless provide the common subject matter between Swiss-type claims for different diseases (see below, paragraph 126).

vii) Use in association with another agent

119. Swiss-type claims to the use of two or more agents together, for simultaneous or sequential administration, are allowable providing the combination has not previously been used for the specified purpose. The inventiveness of claims of this type needs to be scrutinised carefully, to determine whether the claim represents a mere collocation of known elements - see paragraphs 140 - 142 below. A claim to the use of an agent for the manufacture of a medicament to reduce the side effects, or enhance the effectiveness, of another agent in the treatment of a disease will only be considered novel if the two agents have not been used together before for the treatment of that disease. It is irrelevant whether

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87 T 315/98 STERLING/S(+)-ibuprofen [2000] EPO 401
the prior art discloses the specific effect of that the agent has - this is merely the discovery of an additional advantage to a known treatment\textsuperscript{85}. 

**Second medical use claims - the substance or composition**

**i) Assessing novelty and inventive step**

120. The scope of the substance defined in a second medical use claim was considered by the Court of Appeal in *American Home Products v Novartis*\textsuperscript{88}, concerning Swiss-type claims for the use of a known antibiotic (rapamycin) for inhibiting organ or tissue transplant rejection. The Court of Appeal held that the claim did not cover derivatives of rapamycin - thus finding the claim not infringed by the use of a rapamycin derivative as an immunosuppressant.

121. A prior art citation showing the use of a substance produced by a chemical reaction from the compound in question does not anticipate a Swiss-type claim (though it may be relevant for inventiveness). The Court of Appeal in *Monsanto v Merck*\textsuperscript{89} considered whether a claim to "the use of compound X in the manufacture of a medicament for the treatment of disease Y" encompassed the use of X as a chemical intermediate in the production of the active agent in the medicament. It was held that it was at least arguable that it could, although it did not come to a final conclusion on the matter. However, the Court of Appeal in *American Home Products v Novartis*\textsuperscript{88} (see above, paragraph 120) concluded that, had the claim in question been construed as covering derivatives (or presumably, worded as covering derivatives), the patent would have been insufficient because there was no disclosure in the description enabling the skilled person to decide which of the many possible derivatives would have worked. Although there was a strong possibility that some of the large number of derivatives would work in the same way as rapamycin itself, it was impossible to say which would so work, unless the skilled person undertook the "vast and correspondingly burdensome" research task necessary.

122. Swiss type claims are often worded to cover derivatives of a compound, or compounds **comprising** a particular structure, which by definition include derivatives. Claims of this type must be considered carefully to determine whether there is support for a claim extending beyond the exemplified embodiment(s), particularly where there is only one such embodiment. The Court of Appeal in *American Home Products v Novartis*\textsuperscript{88} (see above, paragraph 120) concluded that, had the claim in question been construed as covering derivatives (or presumably, worded as covering derivatives), the patent would have been insufficient because there was no disclosure in the description enabling the skilled person to decide which of the many possible derivatives would have worked. Although there was a strong possibility that some of the large number of derivatives would work in the same way as rapamycin itself, it was impossible to say which would so work, unless the skilled person undertook the "vast and correspondingly burdensome" research task necessary.

123. However, if the specification discloses a general principle capable of general application, a claim in correspondingly general terms may be acceptable. There is no need to

\textsuperscript{88} *American Home Products v Novartis* [2001] RPC 8
\textsuperscript{89} *Monsanto v Merck* [2000] RPC 77
show proof of its application in every individual possible instance which could fall within the scope of the claim. This principle is, of course, applicable to more than just Swiss-type claims, but is particularly important for such claims as they are defined by the purpose of the product.

“Thus if the patentee has hit upon a new product which has a beneficial effect but cannot demonstrate that there is a common principle by which that effect will be shared by other products in that class, he will be entitled to a patent for that product but not for the class, even though some may subsequently turn out to have the same beneficial effect... On the other hand, if he has disclosed a beneficial property which is common to the class, he will be entitled to a patent for all products of that class (assuming them to be new) even though he has not himself made more than one or two of them.”

Aldous LJ, American Home Products v Novartis [2001] RPC 8

### iii) Searching and examining claims when the substance is defined by functional activity

124. Claims are often made for the second medical use of a group of compounds defined functionally; for example, antagonists of a particular receptor. This type of claim was at issue in Pfizer’s Patent, which included claims to the second medical use of phosphodiesterase inhibitors. Such claims are not inherently objectionable, and in this case there was no suggestion that this form of claim was unduly broad and speculative. However, as with claims to classes of chemical compounds, the support for such claims must be considered. Clearly, the mere fact that a member of a functional class of compounds can be used to treat a disease does not mean that all such compounds will, particularly if there is no evidence that the treatment is related to that specific activity. It was established in Pfizer’s Patent that a claim to, for example, “the use of an inhibitor of A in the manufacture of a medicament for the treatment of disease X” is anticipated by any disclosure of the use in treating disease X of a compound which inhibits A, regardless of whether the treatment is explicitly stated as being caused by the inhibition of A.

125. Claims of this type give particular problems when searching. It is not feasible or economic for the examiner to identify all such agents and search should be directed to the specific examples of the agents given in the application since finding these would produce the most relevant citations. In addition, keywords based on the functional class defined in the claim should be searched. An appropriate comment should be added to the search letter to indicate the extent to which the invention has been searched. The search examiner may also contemplate citing any compounds known to treat the particular condition and challenge the applicant to prove that they do not fall within the defined category.

### Plurality

126. Where the substance is known to have a medical use, second medical use claims directed to a variety of different diseases may give rise to a plurality objection (unlike first medical use claims to different diseases). A plurality objection may be avoided if the
conditions are related (and unrelated to the known conditions), or if there is a common mechanism linking the treatments (see paragraph 118).

**Second medical use and apparatus**

127. Swiss-type claims, like first medical use claims under Section 2(6), can only be used in relation to substances or compositions. Claims to a new use of surgical apparatus framed in the Swiss format were disallowed by the EPO in T 775/97 and T 227/91, and by the Hearing Officer in National Research & Development Corporation’s Application. The EPO have allowed a claim to the use of a substance in the manufacture of a “device” for intrapulmonary administration. However, a claim of this form is not allowable for a UK patent, as the new use is distinguished from the prior art by the mode of administration of the compound, rather than its purpose, and this is not allowable following the decision in the Taxol case.

**Support for the medical use in Swiss-type claims**

128. Swiss-type claims to the further medical use of a substance or composition must be supported by evidence that it is (or at least is likely to be) effective for the specified use. The specification should therefore provide, in the description as filed, an indication that in vivo or in vitro tests have been conducted and that positive or encouraging results ensued (not necessarily quantified). Exceptionally, it may be possible for the application to rely on, for example, in silico modelling, or sequence homology, if this is considered to provide a credible level of support. Lack of any data, even rudimentary, in the description of an application which relates to a second medical use should be objected to under section 14(5)(c) as lacking support. The Hearing Officer rejected second medical use claims for this reason in Hoerrmann’s Application and McManus’s Application.

"...unless there is some indication in the description of applications of this type of tests, however rudimentary, demonstrating that the invention has been carried out in an effective manner then the application must fail for lack of support for the invention claimed."

Hoerrmann’s Application [1996] RPC 341

In Consultant Suppliers Application, it was emphasised that mere assertion that tests had been carried out was not sufficient. The decision of the Patents Court in Prendergast’s Applications confirmed that speculative Swiss type claims are not allowable. It was emphasised that full clinical trials on humans are not needed to satisfy the requirements of section 14(5)(c), but there must be some evidence.

90 T 138/95 GENENTECH (Unpublished)
91 Hoerrmann’s Application [1996] RPC 341
92 McManus’s Application [1994] FSR 558
93 Consultant Suppliers Application [1996] RPC 348
129. The evidence provided does not need to meet the standard required of, for example, a peer-reviewed journal\textsuperscript{77}. Nonetheless, there should be some evidence which supports the claimed use or uses, and objection should be made if the support is only available for some of the claimed diseases or substances\textsuperscript{15 66}.

130. The judge in Prendergast's Applications\textsuperscript{65} clearly stated that the specification must provide this support. This objection cannot therefore be overcome by subsequent filing of evidence which supports the claim - the evidence must be provided in the application as filed. This objection is therefore fatal if the application relates solely to a further medical use of a known substance or composition. A warning, in the form of an examination opinion, should therefore be provided at the search stage if the main claims relate to a second medical use, and no data is provided.

131. It is common for second medical use claims to be included as subsidiary claims to a main claim or claims relating to a new compound. In such cases, if the substance or composition claim is new, inventive and supported by the description, further consideration of support for the medical use claim(s) may not be necessary as a matter of practicality. Of course attention should be paid to any claims which were filed later than the application to check that they are supported by the description (see paragraph 18.43 of the Manual of Patent Practice).

\begin{quote}
"...where you have a claim for the use of a known active ingredient in the preparation of a medicament for the treatment of a particular condition, the specification must provide, by way of description, enough material to enable the relevantly skilled man to say this medicament does treat the condition alleged...pure assertion is insufficient."
\end{quote}

Prendergast's Applications [2000] RPC 446

132. The previous two sections have detailed the ways in which known substances can be protected for the first or subsequent medical uses, by the use of purpose-limited first or second medical use claims. In addition, known substances may be protected by \textit{per se} product claims to pharmaceutical compositions containing them, if the composition is in a form which is novel and inventive over any known products. In particular, a claim may be made to a medicament having a form of administration which is novel and distinct from the previous use, where this implies a difference in the chemical or physical composition. For example, an anti-eczema ointment containing X would be regarded as clearly distinct from a tablet containing X for controlling blood pressure. The ointment is new because X has never been formulated in this form before, and it would be inventive if the previous use of X would not suggest its use in topical form. A claim to a formulation "adapted for only topical, to the
exclusion of oral and injectable administration” was accepted by the EPO in T 289/84. In this case, the Board of Appeal held that there was a difference in meaning between a claim to composition adapted for topical use, as opposed to one suitable for such a use. Both eye drops and injectable formulations typically consist of sterile aqueous solutions, so either might be “suitable” for the other use. However, an eye-drop formulation was not “adapted” for use as an injectable solution or vice versa - injectable solutions had to both be sterile and pyrogen-free, whereas eye-drops do not need to be pyrogen-free but have a very narrow range of acceptable pH. However, a claim to a composition “adapted to” a specific use should be objected to on clarity grounds as being defined by its intended result, unless it would be clear to the person skilled in the art as to what is meant.

133. In two cases where the main claims related to a contraceptive composition comprising compounds that were already known as pharmaceuticals, the EPO Technical Board of Appeal, in decisions T 303/90 and T 401/90, was of the opinion that the words "contraceptive composition" was not sufficient to distinguish the claim from known pharmaceutical compositions. In these cases the claims were amended to “Swiss-type” claims, although this would not normally be appropriate for methods of contraception as they are not excluded under Section 4(2).

134. Claims to compositions with a novel physical characteristic, such as shaped forms or tablets with particular surface features, may be acceptable providing the feature relates to a genuine technical effect. For example, a claim to a tablet of a particular shape or structure would be acceptable if this resulted in a particularly favourable release profile for the active agent. However, if the new shape or form is merely presentational or conveys information (for example, by allowing blind patients to distinguish different types of pill), then it represents either an aesthetic creation or a mere presentation of information. As aesthetic creations and the presentation of information are not in themselves patentable, these features cannot impart novelty to the claim.

Clarity of composition claims

135. Composition claims of the form "a pharmaceutical composition containing compound X together with a diluent, excipient or carrier" are considered to be clear; X being a medically active compound which characterises the composition, and the diluent, excipient or carrier being any material suitable for the purpose and being selectable by knowledge of the art or by non-inventive experiment. There is no requirement for the diluent, excipient or carrier to be further characterised. However, a claim to the active ingredient “with an auxillary substance or substances”, was considered (in T 80/96) to be so broad as to be meaningless, and this could not distinguish the claim from the prior art. In addition, a claim to a solution of the compound, where the compound was known to be water soluble, could not make a claim novel. Terms such as “therapeutically effective amount” of an active ingredient are considered to be clear. However, the purity of a product cannot be defined merely by

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94 T 289/84 WELLCOME/3-Amino-pyrazoline derivatives [1987] EPOR 58
95 T 303/90 VICTORIA UNIVERSITY MANCHESTER (Unpublished)
96 T 401/90 VICTORIA UNIVERSITY MANCHESTER (Unpublished)
97 T 80/96 LONZA/L-Carnitine OJEPO 2000, 50
defining the substance “as a pharmaceutical product”\(^98\).

**Compositions with a new non-medical purpose or property**

136. Compositions which are allegedly distinguished from the same compositions in the prior art by the discovery of a new non-therapeutic property in one of the ingredients are not considered to be novel. Claims to the use of the agent in its non-therapeutic role are also not novel if the overall composition has previously been used in the same manner and the newly discovered property already put into effect, albeit unknowingly. Toothpastes with sodium bicarbonate as a cleaning/tingling agent are known, and so a claim to the use of sodium bicarbonate as a masking agent for bitter ingredients present in the known toothpaste formulations would not be novel. This follows the general principle of novelty in UK law that once a substance or composition is known for whatever purpose then it cannot be patented again for another purpose - first and second medical use claims are the only accepted exception to this rule. In this respect, the UK Patent Office has not followed the decision of the EPO Enlarged Board of Appeal in Decisions G 02/88\(^99\) and G 06/88\(^100\), where it was held that novelty could be derived from a new technical effect.

**Claims to unit dosage forms**

137. A unit dosage form consists of a tablet, suppository, ampoule or other device, containing a definite amount of a drug, the whole of which is intended to be administered as a single dose. It is thus distinguished from a supply of an indefinite amount of a medicament, eg a bottle of medicine, from which a dose has to be measured out.

138. It may be possible in cases where the required dosage for a new medical use is markedly different from that for the known use, to allow a claim to a unit dosage form containing the known active ingredient in such an amount that the unit dosage form is novel and not obvious to have been made up in that amount for the prior art use. Thus if the new medical use requires a dose of, for example, ten times (or one tenth) that for the prior art use, then a claim to a unit dosage form might be judged to be novel and inventive and allowable. In assessing the inventiveness of such claims it should be remembered that dosages required are usually related to body weight so that children’s doses are smaller than those for adults. It is also well known in medicine for patients to be asked to take more than one tablet at a time and it is known for half tablets to be taken.

139. Claims to unit dosage forms must clearly define a specific amount of medicament. A claim specifying an amount of medicament per unit body weight of patient is unclear in scope. Moreover there must be clear support in the description for a unit dosage form containing a specific amount of active ingredient. Claims derived from dosages of x mg/kg bodyweight by calculations using an average patients body weight have been rejected as lacking in support, as have claims derived from the amounts of active ingredient fed to

\(^{98}\) T 226/98 RICHTER GEDEON/Famotidine OJEPO 2002, 498

\(^{99}\) G 02/88 MOBIL/Friction reducing additive III OJEPO 1990, 93

\(^{100}\) G 06/88 BAYER/Second non-medical indication OJEPO 1990, 144
experimental animals.

Combined preparations and packs of medicaments

140. It is common in the pharmaceutical field for inventions to relate to the combine use of two or more known medicaments. Such claims may be in the form of per se composition claims or first or second medical use claims, and may also define a kit of parts for simultaneous or sequential administration. Following the practice established by the House of Lords in SABAF v MFI Furniture Centres[101] the first question that must be addressed is whether the claim in question relates to a single invention or plural inventions. If the two (or more) ingredients simply perform their usual function in the body, and there is no synergy between them, then the claim relates to two separate inventions, and there is no inventiveness in combining them.

141. Moreover, evidence for synergistic effects between the components must be provided in the specification[102]. Evidence of synergy provided after the filing date cannot be used to demonstrate inventiveness in this situation[103].

“If a synergistic effect is to be relied on, it must be possessed by everything covered by the claim, and it must be described in the specification. No effect is described in the present specification that is not the natural prediction from the properties of the two components of the combination.”

Glaxo Group's Patent [2005] RPC 43

142. Moreover, evidence of unexpected synergy between the two components does not render a combination inventive if the combination would in any case be obvious to the skilled person. In particular, if it is known to combine two categories of active agent (such as an analgesic and a decongestant), it is unlikely to be inventive to merely substitute a newer, more effective agent of one or other category in the combined preparation – the patents in question in both Glaxo Group's Patent[102] and Richardson-Vicks' Patent[103] were revoked on these grounds. If the synergy demonstrated by the new combination is no greater than the equivalent prior art combination, then it does not provide evidence of inventiveness[104].

143. In Richardson-Vicks' Patent[103] the argument was made that combined preparations faced particular difficulties in obtaining regulatory approval, and this would constitute a prejudice away from a new combination. This was rejected by the judge – any perceived regulatory difficulty is considered irrelevant for inventiveness.

144. Pack or "kit of parts" claims are sometimes used where the invention comprises the administration of two or more different drug compositions at particular time intervals, or merely simultaneously or sequentially. A claim of this form was considered by the EPO

101 SABAF v MFI Furniture Centres [2005] RPC 10
102 Glaxo Group's Patent [2005] RPC 43
103 Richardson-Vicks’ Patent [1995] RPC 568
104 T 492/99 NIPRO (Unpublished)
Board of Appeal in T 09/81. It was held in this case that the combination was novel and inventive, but needed to be "purpose limited" - ie in the first medical use format - to distinguish it from a medical kit, collection or package containing the two agents together for their known independent uses. This is in line with the practice of the UK Patent Office that such claims are allowable provided that the pack is stated to be for the method in which the invention really resides, and that the pack is novel and not obvious for any other application. In addition there must be clear support in the description for such a pack, and a claim for a kit or pack for carrying out a method must define all the essential elements for carrying out the method.

145. Claims to a pack or container containing a known substance with instructions for the new use should be rejected on the grounds that the only novel feature - the instructions - is merely a presentation of information and thus not a patentable invention under Section 1(2)(d) (Bayer's (Meyer's) Application105). However, the acceptance of "Swiss-type" second medical use claims has now made such claims redundant in the medical fields.

146. However, a new package may be new and inventive if there is some physical relationship between the new and inventive method and the package, which goes beyond merely presenting instructions for the new use. In Organon's Application106, a claim was allowed under the 1949 Act to a pack containing two types of known contraceptive pill arranged in the order in which they were to be taken, the arrangement being novel and not obvious from the art. This was despite the fact that packs containing contraceptive pills in a given order were known - the particular order defined in this case was not obvious as it was based on a new and inventive method of contraception.

105 Bayer’s (Meyer's) Application [1984] RPC 11
106 Organon’s Application [1970] RPC 235
### ANNEX A - INDEX OF COURT CASES AND UK PATENT OFFICE DECISIONS

<table>
<thead>
<tr>
<th>Case/Decision</th>
<th>Reference</th>
<th>Ref. No.</th>
<th>Paragraph in Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advance Biofactures of Curacao's Application</td>
<td>BL O/303/04</td>
<td>77</td>
<td>108, 129</td>
</tr>
<tr>
<td>Allen's Application</td>
<td>BL O/59/92</td>
<td>46</td>
<td>47</td>
</tr>
<tr>
<td>American Home Products v Novartis</td>
<td>[2001] RPC 8</td>
<td>88</td>
<td>120-123</td>
</tr>
<tr>
<td>Bayer's (Meyer's) Application</td>
<td>[1984] RPC 11</td>
<td>105</td>
<td>144</td>
</tr>
<tr>
<td>Bio-Digital Sciences' Application</td>
<td>[1973] RPC 668</td>
<td>52</td>
<td>56</td>
</tr>
<tr>
<td>Bristol-Myers Squibb v Baker Norton Pharmaceuticals</td>
<td>[2001] RPC 1</td>
<td>10</td>
<td>8, 17, 101, 104-107, 109, 111, 114, 117, 127</td>
</tr>
<tr>
<td>Bristol-Myers Squibb v Baker Norton Pharmaceuticals [Court of Appeal]</td>
<td>[1999] RPC 253</td>
<td>84</td>
<td>114, 117</td>
</tr>
<tr>
<td>Calmic Engineering's Application</td>
<td>[1973] RPC 684</td>
<td>38</td>
<td>40</td>
</tr>
<tr>
<td>CFPH's Application</td>
<td>[2006] RPC 5</td>
<td>54</td>
<td>62</td>
</tr>
<tr>
<td>Ciba-Geigy's Application</td>
<td>BL O/35/85</td>
<td>25</td>
<td>29</td>
</tr>
<tr>
<td>Commonwealth Scientific &amp; Industrial Research Organization's Application</td>
<td>BL O/248/04</td>
<td>15</td>
<td>30, 46, 94, 129</td>
</tr>
<tr>
<td>Consultant Suppliers Application</td>
<td>[1996] RPC 348</td>
<td>93</td>
<td>128</td>
</tr>
<tr>
<td>F. Hoffmann - La Roche's Application</td>
<td>BL O/192/04</td>
<td>66</td>
<td>87, 128, 129</td>
</tr>
<tr>
<td>Glaxo Group's Patent</td>
<td>[2005] RPC 43</td>
<td>102</td>
<td>141</td>
</tr>
<tr>
<td>Hoerrmann's Application</td>
<td>[1996] RPC 341</td>
<td>91</td>
<td>128</td>
</tr>
<tr>
<td>ICI Ltd's Application</td>
<td>BL O/73/82</td>
<td>29</td>
<td>31</td>
</tr>
<tr>
<td>ICI (Richardson's) Application</td>
<td>[1981] FSR 609</td>
<td>17</td>
<td>24</td>
</tr>
<tr>
<td>John Wyeth's and Schering's Applications</td>
<td>[1985] RPC 545</td>
<td>9</td>
<td>17, 73, 90-92, 103</td>
</tr>
<tr>
<td>Kirin Amgen v Hoechst Marion Roussel</td>
<td>[2005] RPC 8</td>
<td>47</td>
<td>51</td>
</tr>
<tr>
<td>Lee Pharmaceuticals' Applications</td>
<td>[1975] RPC 51</td>
<td>28</td>
<td>31</td>
</tr>
<tr>
<td>McManus's Application</td>
<td>[1994] FSR 558</td>
<td>92</td>
<td>128</td>
</tr>
<tr>
<td>Merck's Patents [Alendronate] [Court of Appeal]</td>
<td>[2004] FSR 330</td>
<td>76</td>
<td>107</td>
</tr>
<tr>
<td>Merck's Patents [Alendronate] [Patent's Court]</td>
<td>[2003] FSR 498</td>
<td>75</td>
<td>107, 108</td>
</tr>
<tr>
<td>Case/Decision</td>
<td>Reference</td>
<td>Ref. No.</td>
<td>Paragraph in Guidelines</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>------------------</td>
<td>----------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Monsanto v Merck</td>
<td>[2000] RPC 77</td>
<td>89</td>
<td>121</td>
</tr>
<tr>
<td>National Research &amp; Development Corporation’s Application</td>
<td>BL O/117/85</td>
<td>56</td>
<td>68, 86, 127</td>
</tr>
<tr>
<td>Occidental Petroleum’s Application</td>
<td>BL O/35/84</td>
<td>42</td>
<td>43, 47, 64</td>
</tr>
<tr>
<td>Oral Health Products (Halsteads) Application</td>
<td>[1977] RPC 612</td>
<td>27</td>
<td>31</td>
</tr>
<tr>
<td>Organon’s Application</td>
<td>[1970] RPC 235</td>
<td>106</td>
<td>145</td>
</tr>
<tr>
<td>Pfizer’s Patent</td>
<td>[2001] FSR 16</td>
<td>72</td>
<td>101, 124</td>
</tr>
<tr>
<td>Prendergast’s Applications</td>
<td>[2000] RPC 446</td>
<td>65</td>
<td>87, 128, 130</td>
</tr>
<tr>
<td>Richardson-Vicks’ Patent</td>
<td>[1995] RPC 568</td>
<td>103</td>
<td>141, 142</td>
</tr>
<tr>
<td>SABAF v MFI Furniture Centres</td>
<td>[2005] RPC 10</td>
<td>101</td>
<td>140</td>
</tr>
<tr>
<td>Schering’s Application</td>
<td>[1971] RPC 337</td>
<td>33</td>
<td>37</td>
</tr>
<tr>
<td>Schultz’s Application</td>
<td>BL O/174/86</td>
<td>6</td>
<td>15, 40</td>
</tr>
<tr>
<td>Sopharma’s Application</td>
<td>[1983] RPC 195</td>
<td>60</td>
<td>73</td>
</tr>
<tr>
<td>Stafford-Miller’s Application</td>
<td>[1984] FSR 258</td>
<td>26</td>
<td>29</td>
</tr>
<tr>
<td>Unilever (Davis’s) Application</td>
<td>[1983] RPC 21</td>
<td>2</td>
<td>13, 15, 16, 44, 46</td>
</tr>
<tr>
<td>UpJohn (Kirton’s) Application</td>
<td>[1976] RPC 324</td>
<td>32</td>
<td>36</td>
</tr>
</tbody>
</table>
## ANNEX B - INDEX OF EUROPEAN PATENT OFFICE DECISIONS

<table>
<thead>
<tr>
<th>Decision</th>
<th>Reference</th>
<th>Ref. No.</th>
<th>Paragraph in Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>G 05/83 EISAI/Second medical use</td>
<td>OJEPO 1985, 64</td>
<td>1</td>
<td>7, 11, 17, 90, 93, 95, 103</td>
</tr>
<tr>
<td>G 02/88 MOBIL/Friction reducing additive III</td>
<td>OJEPO 1990, 93</td>
<td>99</td>
<td>136</td>
</tr>
<tr>
<td>G 06/88 BAYER/Second non-medical indication</td>
<td>OJEPO 1990, 144</td>
<td>100</td>
<td>136</td>
</tr>
<tr>
<td>G 01/03 PPG/Disclaimer</td>
<td>OJEPO 2004, 413</td>
<td>16</td>
<td>24</td>
</tr>
<tr>
<td>G 01/04 Diagnostic methods</td>
<td>(Unpublished)</td>
<td>49</td>
<td>54-57, 59-61, 65</td>
</tr>
<tr>
<td>T 09/81 ASTA/Cytostatic combination</td>
<td>OJEPO 1983, 372</td>
<td>61</td>
<td>73, 85, 143</td>
</tr>
<tr>
<td>T 128/82 HOFFMAN-LA ROCHE/Pyrrolidine-derivatives</td>
<td>OJEPO 1984, 164</td>
<td>62</td>
<td>75, 77</td>
</tr>
<tr>
<td>T 36/83 ROUSSEL-UCLAF/Thenoyl peroxide</td>
<td>OJEPO 1986, 295</td>
<td>18</td>
<td>24, 26, 28, 84</td>
</tr>
<tr>
<td>T 144/83 DU PONT/Appetite suppressant</td>
<td>OJEPO 1986, 30</td>
<td>19</td>
<td>26, 35</td>
</tr>
<tr>
<td>T 81/84 RORER/Dysmenorrhoea</td>
<td>OJEPO 1988, 202</td>
<td>5</td>
<td>15, 32</td>
</tr>
<tr>
<td>T 289/84 WELLCOME/3-Amino-pyrazoline derivatives</td>
<td>[1987] EPOR 58</td>
<td>94</td>
<td>132</td>
</tr>
<tr>
<td>T 116/85 WELLCOME/Pigs I</td>
<td>OJEPO 1989, 13</td>
<td>3</td>
<td>13, 20, 29</td>
</tr>
<tr>
<td>T 07/86 DRACO/Xanthines</td>
<td>OJEPO 1988, 381</td>
<td>63</td>
<td>80</td>
</tr>
<tr>
<td>T 19/86 DUPHAR/Pigs II</td>
<td>OJEPO 1989, 24</td>
<td>4</td>
<td>15, 110</td>
</tr>
<tr>
<td>T 290/86 ICI/Cleaning plaque</td>
<td>OJEPO 1992, 414</td>
<td>30</td>
<td>25, 31, 114</td>
</tr>
<tr>
<td>T 385/86 BRUKER/Non-invasive measurement</td>
<td>OJEPO 1988, 308</td>
<td>51</td>
<td>56</td>
</tr>
<tr>
<td>T 58/87 SALMINEN/Pigs III</td>
<td>[1989] EPOR 125</td>
<td>8</td>
<td>15</td>
</tr>
<tr>
<td>T 245/87 SIEMENS/Flow measurement</td>
<td>OJEPO 1989, 171</td>
<td>11</td>
<td>19, 39</td>
</tr>
<tr>
<td>T 584/88 REICHART/Anti-snoring means</td>
<td>[1989] EPOR 449</td>
<td>20</td>
<td>26, 94</td>
</tr>
<tr>
<td>T 426/89 SIEMENS/Pacemaker</td>
<td>OJEPO 1992, 199</td>
<td>12</td>
<td>19</td>
</tr>
<tr>
<td>T 774/89 BAYER</td>
<td>(Unpublished)</td>
<td>41</td>
<td>42</td>
</tr>
<tr>
<td>T 780/89 BAYER/Immunostimulant</td>
<td>OJEPO 1994,797</td>
<td>39</td>
<td>41</td>
</tr>
<tr>
<td>T 182/90 SEE-SHELL/Blood flow</td>
<td>OJEPO 1994, 641</td>
<td>43</td>
<td>43, 45</td>
</tr>
<tr>
<td>T 303/90 VICTORIA UNIVERSITY MANCHESTER</td>
<td>(Unpublished)</td>
<td>95</td>
<td>133</td>
</tr>
<tr>
<td>T 401/90 VICTORIA UNIVERSITY MANCHESTER</td>
<td>(Unpublished)</td>
<td>96</td>
<td>133</td>
</tr>
<tr>
<td>T 893/90 QUEEN'S UNIVERSITY KINGSTON</td>
<td>(Unpublished)</td>
<td>81</td>
<td>110</td>
</tr>
<tr>
<td>T 24/91 THOMPSON/Cornea</td>
<td>OJEPO 1995, 512</td>
<td>7</td>
<td>15, 19</td>
</tr>
<tr>
<td>Decision</td>
<td>Reference</td>
<td>Ref. No.</td>
<td>Paragraph in Guidelines</td>
</tr>
<tr>
<td>----------</td>
<td>-----------</td>
<td>----------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>T 227/91 CODMAN/Second surgical use</td>
<td>OJEPO 1994, 491</td>
<td>58</td>
<td>68, 127</td>
</tr>
<tr>
<td>T 438/91 MEIJI/Feeds</td>
<td>[1999] EPOR 333</td>
<td>40</td>
<td>41</td>
</tr>
<tr>
<td>T 570/92 BAYER</td>
<td>(Unpublished)</td>
<td>78</td>
<td>109</td>
</tr>
<tr>
<td>T 655/92 NYCOMED/Contrast agent for imaging</td>
<td>OJEPO 1998, 17</td>
<td>53</td>
<td>53, 95</td>
</tr>
<tr>
<td>T 820/92 GENERAL HOSPITAL/Contraceptive method</td>
<td>OJEPO 1995, 113</td>
<td>34</td>
<td>37, 65</td>
</tr>
<tr>
<td>T 51/93 SERONO</td>
<td>(Unpublished)</td>
<td>79</td>
<td>109</td>
</tr>
<tr>
<td>T 74/93 BRITISH TECHNOLOGY/Contraceptive method</td>
<td>OJEPO 1995, 712</td>
<td>35</td>
<td>37</td>
</tr>
<tr>
<td>T 82/93 TELLECTRONICS/Cardiac pacing</td>
<td>OJEPO 1996, 274</td>
<td>36</td>
<td>39, 67</td>
</tr>
<tr>
<td>T 254/93 ORTHO PHARMACEUTICAL/Prevention of skin atrophy</td>
<td>OJEPO 1998, 285</td>
<td>85</td>
<td>115, 119</td>
</tr>
<tr>
<td>T 712/93 JOINT MEDICAL PRODUCTS</td>
<td>(Unpublished)</td>
<td>59</td>
<td>70</td>
</tr>
<tr>
<td>T 1077/93 L’OREAL/Protection against UV</td>
<td>[1997] EPOR 546</td>
<td>23</td>
<td>28</td>
</tr>
<tr>
<td>T 143/94 MAI/Trigonelline</td>
<td>OJEPO 1996, 430</td>
<td>68</td>
<td>96</td>
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<td>T 329/94 BAXTER/Blood extraction method</td>
<td>OJEPO 1998, 241</td>
<td>13</td>
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<td>T 469/94 MIT</td>
<td>(Unpublished)</td>
<td>31</td>
<td>33</td>
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<td>T 913/94 EISAI/Medicament for gastritis</td>
<td>[2001] EPOR 362</td>
<td>73</td>
<td>102</td>
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<td>T 958/94 THERAPEUTIQUES SUBSTITUTIVES/Anti-tumoral agent</td>
<td>OJEPO 1997, 241</td>
<td>67</td>
<td>92</td>
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<td>T 138/95 GENENTECH</td>
<td>(Unpublished)</td>
<td>90</td>
<td>127</td>
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<td>T 241/95 ELI LILLY/Serotonin receptor</td>
<td>OJEPO 2001, 103</td>
<td>69</td>
<td>98, 118</td>
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<tr>
<td>T 453/95 REDKEN</td>
<td>(Unpublished)</td>
<td>22</td>
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<td>T 80/96 LONZA/L-Carnitine</td>
<td>OJEPO 2000, 50</td>
<td>97</td>
<td>135</td>
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<td>T 158/96 PFIZER/Sertraline</td>
<td>[1999] EPOR 285</td>
<td>71</td>
<td>100</td>
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<td>T 233/96 MEDCO RESEARCH</td>
<td>(Unpublished)</td>
<td>82</td>
<td>111</td>
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<td>T 789/96 ELA MEDICAL/Therapeutic method</td>
<td>OJEPO 2002, 364</td>
<td>37</td>
<td>39</td>
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<td>T 56/97 TAKEDA</td>
<td>(Unpublished)</td>
<td>74</td>
<td>106</td>
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<td>T 775/97 EXPANDABLE GRAFTS/Surgical device</td>
<td>[2002] EPOR 24</td>
<td>57</td>
<td>68, 69, 127</td>
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<td>T 1165/97 ULTRAFEM/Feminine hygiene device</td>
<td>[2002] EPOR 384</td>
<td>14</td>
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<td>T 135/98 NORSK HYDRO</td>
<td>[2004] EPOR 14</td>
<td>64</td>
<td>84</td>
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<td>T 226/98 RICHTER GEDEON/Famotidine</td>
<td>OJEPO 2002, 498</td>
<td>98</td>
<td>135</td>
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<td>T 315/98 STERLING/S(+) ibuprofen</td>
<td>[2000] EPOR 401</td>
<td>87</td>
<td>117</td>
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<td>T 807/98 ST JUDE</td>
<td>(Unpublished)</td>
<td>48</td>
<td>53</td>
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<td>T 35/99 GEORGETOWN UNIVERSITY/Pericardial access</td>
<td>OJEPO 2000, 447</td>
<td>44</td>
<td>45, 65</td>
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<td>T 492/99 NIPRO</td>
<td>(Unpublished)</td>
<td>104</td>
<td>141</td>
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<td>T 964/99 CYGNUS/Diagnostic device</td>
<td>OJEPO 2002, 4</td>
<td>50</td>
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<td>T 1031/00 SEPRACOR</td>
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<td>24</td>
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<td>OJEPO 2005, 159</td>
<td>45</td>
<td>46</td>
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<td>T 1020/03 GENENTECH</td>
<td>(Unpublished)</td>
<td>80</td>
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