Intellectual Property Office

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

May 2013

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Introduction

1 These Guidelines set out the practice within the Intellectual Property 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 2007. 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 Office practice, as set out in the Manual of Patent Practice (MoPP) and in decisions taken in Office hearings, has not been changed without good reason.

2 The Patents Act 2004, which received royal assent on 22 July 2004, amended the Patents Act 1977 in respect of medical inventions, to implement the European Patent Convention as revised in 2000 (EPC 2000). The Convention (and therefore the medical provisions of the Patents Act 2004) took effect on 13 December 2007. The Patents Act 2004 introduced a new Section 4A to the 1977 Act which states in Section 4A(1) 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. This replaces the former Section 4(2), and thereby removes the "legal fiction" that such methods lack industrial application – they are regarded as unpatentable in their own right.

3 In addition, Section 4A states that patents may be granted for a known substance or composition for use in medicine (Section 4A(3)), or for a specific medical use (Section 4A(4)). These provisions therefore explicitly allow patent protection for the first medical use of a known substance or composition (as previously, under the former Section 2(6)) and a second or further medical use. Prior to 13 December 2007, inventions relating to second medical uses could only be protected using the "Swiss-type" claim form of "the use of substance X for the manufacture of a medicament to treat disease Y". Section 4A(4) allows a simpler and more direct second medical use claim, of the form "substance X for use in the treatment of disease Y". Following the issue of our Practice Notice on second medical use claims on 26 May 2010, inventions relating to second medical uses may only be protected this way; the Office will no longer accept "Swiss-type" claims (see paragraphs 92-100)

4 It is very important to note that the changes introduced by the Patents Act 2004 have **not** lead to any substantive change in what is and is not patentable in this field. Previous case law under the repealed Section 4(2) (or the equivalent Article 54(2) of the EPC) relating to the exclusions of methods of treatment by surgery or therapy, or methods of diagnosis practised on the human or animal body, continues to govern our practice under Section 4A(1). Similarly, case law relating to first medical use under the repealed Section 2(6) (or the equivalent Article 54(5) of the EPC) governs our practice under Section 4A(3). Moreover, the body of case law relating to Swiss-type second medical use claims remains relevant to our practice in relation to the new form of second medical use claim under Section 4A(4). Throughout these Guidelines, reference is made to decisions under the law as it stood before 13 December 2007; all of these decisions are considered to be directly relevant to the law under the amended Patents Act.

5 **Any comments or questions arising from these Guidelines should be addressed to Richard Sewards, Room 2.Y52, Intellectual Property Office, Concept House, Cardiff Road, Newport, South Wales, NP10 8QQ (Telephone: 01633 813536)**.

Basic Principles

6 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. The invention must not fall wholly within the excluded categories defined in Section 1(2), and its commercial exploitation must not be contrary to public policy or morality.

7 In addition, patenting in the medical field is constrained by the exclusion from patentability of methods of treatment of the human or animal body by therapy or surgery, or methods of diagnosis performed on the human or animal body, under Section 4A(1) of the Patents Act 1977 (as amended), which states that such methods are not patentable. This exclusion applies only to methods of treatment and diagnosis and not to the materials used in such methods, as explicitly stated in Section 4A(2).

8 In addition, the definition of novelty for substances or compositions used in methods of treatment is addressed by Sections 4A(3) and (4). Section 4A(3) states that a substance or composition which is itself already known is regarded as novel "for use in" any method of treatment or diagnosis prohibited by Section 4A(1), provided that the substance or composition has not been known to be used in any such method before ("first medical use"). Section 4A(4) states that a substance or composition for use in a **specific** treatment, provided that the substance or composition has not been known for that specific use before ("second medical use").

9 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 substances or compositions.

"[The exclusion] has the limited purpose of ensuring that the actual use, by practitioners, of methods of medical treatment when treating patients should not be the subject of restraint or restriction by patent monopolies. The difficulty is to decide whether the restraint concerns a method of treatment as opposed to that which is available for treatment."

Bristol-Myers Squibb v Baker Norton Pharmaceuticals [2001] RPC 1 (Court of Appeal)

10 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 Intellectual Property Office set out the practice of the UK Intellectual Property Office in these areas. Our practice in relation to chemical inventions, including those relating to pharmaceuticals, is set out in the Examination Guidelines for Patent Applications relating to Chemical Inventions in the Intellectual Property Office

Methods Of Treatment Or Diagnosis

11 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 4A(1) of the Patents Act 1977 (as amended):

"A patent shall not be granted for the invention of—
(a) a method of treatment of the human or animal body by surgery or therapy, or
(b) a method of diagnosis practised on the human or animal body."

Section 4A(1) of the Patents Act 1977 (as amended by the Patents Act 2004)

12 Section 4A(1) replaced the previous Section 4(2), now repealed, which stated that such methods "shall not be taken to be capable of industrial application". Similarly, the equivalent Article 53(c) of the EPC 2000 replaced the repealed Article 52(4), which also related to industrial application. It had been clearly stated that the purpose of Section 4(2) (and Article 52(4)) was 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

13 The exclusion of medical methods on grounds of lack of industrial applicability under Section 4(2) was therefore a "legal fiction" designed to achieve a public policy objective, as medical and veterinary activities are clearly industries. Section 4A(1) removes this legal fiction and simply states that these methods cannot be patented.

14 Section 4A(1) does not prevent the patenting of materials or compositions used in such methods, as explicitly stated in Section 4A(2):

Subsection (1) above does not apply to an invention consisting of a substance or composition for use in any such method.

Section 4A(2) of the Patents Act 1977 (as amended by the Patents Act 2004)

This replaced the repealed Section 4(3), which stated that substances and compositions for use in medical and veterinary methods are capable of industrial application.

15 Not all methods of treatments of the human or animal body are excluded; only those that fall within the scope of the terms "therapy" or "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"

16 The definition of therapy used by both the UK courts[1] and the EPO[2] 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*[1] 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

1 Unilever (Davis's) Application [1983] RPC 21
2 T 19/86 DUPHAR/Pigs II OJEPO 1989, 24

symptoms as well as curative treatments for a disease[3] [4]. In deciding whether a treatment can be considered to be "therapy", the broad definition applied by the EPO in T 24/91[5] and T 58/87[6] 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

17 Veterinary treatment of a diseased or injured animal is regarded as therapy and it was pointed out in Unilever (Davis's) Application[1] (at pages 229-230) that therapy cannot have a different meaning for humans and animals. Similarly, the EPO Board of Appeal in T 116/85[7] held that therapeutic methods practised on farm animals are not patentable, and this applies regardless of who performs the method.

Therapeutic methods: form of claims

18 The following formats of claim are all considered to define methods of treatment by therapy, and are thus unpatentable under Section 4A(1):

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[8], 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*[9]. 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. However, since the implementation of the medical provisions of the Patents Act 2004, second medical use inventions can be protected by claims of the form "substance X for use in the treatment of disease Y", and following the decision of the EPO Enlarged Board of Appeal in G 02/08[10] and the release of our Practice Notice on 26 May 2010, "Swiss-type" claims are no longer allowable (see below, paragraphs 92-100).

19 A claim to the use of a substance "as a pharmaceutical" (claim (iv) above) is 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 MoPP 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.

3 T 81/84 RORER/Dysmenorrhoea OJEPO 1988, 202
4 Schultz's Application BL O/174/86
5 T 24/91 THOMPSON/Cornea OJEPO 1995, 512
6 T 58/87 SALMINEN/Pigs III [1989] EPOR 125
7 T 116/85 WELLCOME/Pigs I OJEPO 1989, 13
8 G 05/83 EISAI/Second medical use OJEPO 1985, 64
9 John Wyeth's and Schering's Applications [1985] RPC 545
10 G 02/08 ABBOTT RESPIRATORY/Dosage regime OJEPO 2010, 456

Guidelines for determining whether a method is "treatment by therapy"

20 It is useful to consider whether the method would normally be carried out by a medical professional such as a doctor or vet. Section 4A(1) 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 4A(1)[11] [12]. This principle was also applied (in relation to both therapy and surgery) in *Virulite's Application*[13], where the Hearing Officer held that the fundamental test for inventions in this field is whether the patent, if granted, would interfere with the work of a medical or veterinary practitioner in their treatment of patients. A method in which a laser was used to modify a synthetic lenticule implanted on the cornea, on the other hand, was 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[5].

"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

21 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[14] [15]. Conversely, methods for treating diseases in farm animals are excluded, even if the method may routinely be carried out by the farmer rather than the vet.

"...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

22 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*[16], 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.

11 T 245/87 SIEMENS/Flow measurement OJEPO 1989, 171
12 T 426/89 SIEMENS/Pacemaker OJEPO 1992, 199
13 Virulite's Application BL O/058/10
14 T 329/94 BAXTER/Blood extraction method OJEPO 1998, 241
15 T 1165/97 ULTRAFEM/Feminine hygiene device [2002] EPOR 384
16 Commonwealth Scientific & Industrial Research Organization's Application BL O/248/04

Claims to both therapeutic and non-therapeutic methods

23 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 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.

24 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.

25 The EPO Enlarged Board of Appeal in G 01/03[17] considered whether, and under what circumstances, an "undisclosed disclaimer" – that is, one where neither the disclaimer nor the subject matter excluded by it – may be allowable. The Enlarged Board held that an undisclosed disclaimer to exclude unpatentable subject material, including methods of treatment by therapy or surgery, or methods of diagnosis practised on the human or animal body, is in principle allowable and does not necessarily constitute added matter. This principle was applied in the specific medical context by the Enlarged Board in G 01/07[18] and subsequent decisions[19] [20]. The Enlarged Board's later decision in G 02/10[21] confirmed that the subject matter remaining in the claim after the introduction of the disclaimer must be disclosed in the application as filed, whether or not the disclaimer itself is disclosed in the application. This is in accordance with UK Office practice, which is explained in more detail in MoPP 14.126-14.127. Therefore if claims are limited, either by disclaimer or otherwise, to patentable methods, there must be support in the description for a non-therapeutic method – if there is not, then the amended claim will constitute added matter, as well as being objectionable through lack of support. In *ICI (Richardson's) Application*[22] 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. The words "cosmetic" or "non-therapeutic" in a claim to a method of treatment are generally acceptable as sufficient limitation[23]; the use of the phrase "preimplanted", to disclaim a surgical method step in an otherwise patentable method, is also allowable[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. Any disclaimer needs to exclude therapeutic methods and leave the scope of the remaining monopoly clear. A disclaimer which merely uses the words of the Act is considered to leave the scope of the monopoly unclear[22].

26 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 unpatentable, 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.

17 G 01/03 PPG/Disclaimer OJEPO 2004, 413
18 G 01/07 MEDI-PHYSICS/Treatment by surgery OJEPO 2011, 134
19 T 385/09 LELY ENTERPRISES
20 T 266/07 WISCONSIN ALUMNI RESEARCH FOUNDATION
21 G 02/10 SCRIPPS/Disclaimer OJEPO 2012, 376
22 ICI (Richardson's) Application [1981] FSR 609
23 T 36/83 ROUSSEL-UCLAF/Thenoyl peroxide OJEPO 1986, 295

"...the claimed use of a lanthanum-containing composition for cleaning plaque and/or stains from human teeth...will always inevitably have a therapeutic effect (at least in the prophylactic sense) as well as a cosmetic effect. Thus the invention as here claimed is not directed solely to a cosmetic effect, but is also necessarily defining 'a treatment of the human body by therapy' as well"

T 290/86 ICI/*Cleaning plaque* OJEPO 1992, 414

27 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[24] and an antibacterial skin treatment[23]. A similar distinction between therapeutic and non-therapeutic uses of the same method was made in T 584/88[25], 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).

28 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

29 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*[26]), and cosmetic methods to prevent hair loss[27]. In *Virulite's Application*[13] the Hearing Officer observed that the removal of wrinkles caused by ageing had no conceivable therapeutic benefit, and so a cosmetic method claim for removing wrinkles by phototherapy was allowed. Methods of protecting the skin by simply blocking UV radiation are not considered to be therapy, but where a method includes physiological protective effects against UV-associated damage then it is considered to be therapeutic (T 1077/93[28]). 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[29], wherein a "non-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[23].

24 T 144/83 DU PONT/Appetite suppressant OJEPO 1986, 30
25 T 584/88 REICHART/Anti-snoring means [1989] EPOR 449
26 Joos v. Commissioner of Patents [1973] RPC 59
27 T 453/95 REDKEN
28 T 1077/93 L'OREAL /Protection against UV [1997] EPOR 546
29 T 67/02 BEIERSDORF

ii) Removal of parasites

30 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[30]. Treatment of parasites residing on the skin of a human or animal is considered to be therapy (T 116/85[7]). 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 *Stafford-Miller's Application*[31].

31 However, the procedure must be **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[16].

iii) Oral care

32 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[32] [33] and under the previous Section 4(2) of the 1977 Act[34]. In EPO decision T 290/86[35] 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.

iv) Pain, fatigue and addiction

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

"Irrespective of the origin of pain, discomfort or incapacity, its relief, by the administration of an appropriate agent, is to be construed as 'therapy'..."

T 81/84 RORER/*Dysmenorrhoea* OJEPO 1988, 202

34 However, in T 385/09[19] the Board of Appeal rejected the argument that any alleviation of discomfort is by definition therapeutic – in this case a claim to a non-therapeutic method of cooling farm animals (for example, to encourage them to enter a milking stall) was allowed. In addition, in T 469/94[36] 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.

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

30 Ciba-Geigy's Application BL O/35/85
31 Stafford-Miller's Application [1984] FSR 258
32 Oral Health Products (Halstead's) Application [1977] RPC 612
33 Lee Pharmaceuticals' Applications [1975] RPC 51
34 ICI Ltd's Application BL O/73/82
35 T 290/86 ICI/Cleaning plaque OJEPO 1992, 414
36 T 469/94 MIT

v) Obesity, weight reduction and fitness

36 Methods of weight reduction for purely cosmetic reasons, including the suppression of appetite, are patentable. In T 144/83[24] a claim to a "method of improving the bodily appearance of a non-opiate-addicted mammal" was considered allowed 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. Similarly, a method for "enhancing skeletal muscle performance of normal healthy subjects" was considered to be non-therapeutic by virtue of its limitation to healthy subjects[37].

vi) Contraception, abortion and fertility treatment

37 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 *UpJohn (Kirton's) Application*[38] - 1949 Act). This applies regardless of the reasons for performing these methods.

38 Methods of contraception are not considered to be therapeutic, and may be patented (following the decision under the 1949 Act in *Schering's Application*[39]). 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[40] [41]. However, contraceptive methods are excluded under Section 4A(1) if they contain a therapeutic element[40]. 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[41]).

39 Methods of treatment of infertility, including methods utilising *in vitro* fertilisation, are considered to be therapeutic. Moreover, the implantation of an *in vitro* fertilised embryo 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

40 If a claimed method has a therapeutic purpose or effect then it is unpatentable under Section 4A(1) 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[42]. 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[43]. 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[11].

37 T 1230/05 BIOENERGY
38 UpJohn (Kirton's) Application [1976] RPC 324
39 Schering's Application [1971] RPC 337
40 T 820/92 GENERAL HOSPITAL/Contraceptive method OJEPO 1995, 113
41 T 74/93 BRITISH TECHNOLOGY/Contraceptive method OJEPO 1995, 712
42 T 82/93 TELECTRONICS/Cardiac pacing OJEPO 1996, 274
43 T 789/96 ELA MEDICAL/Therapeutic method OJEPO 2002, 364

viii) Treatments performed outside the body

41 A therapeutic treatment of the human or animal body is unpatentable under Section 4A(1) even if the actual treatment takes place outside the body, as in an extracorporeal blood dialysis or filtration method (*Calmic Engineering's Application*[44] (1949 Act) and *Schultz's Application*[4]). 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

42 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[45] or through a specific effect on a pathogen[46].

43 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[47] was that a non-therapeutic method would be expected to show an improvement on the normal condition of the subject, rather than merely restoring an animal 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 23-27 above).

Surgery

44 Decisions of the UK courts, Intellectual Property Office Hearing Officers and EPO Boards of Appeal concerning the interpretation of the term "methods of surgery" in section 4A(1) of the Act and Article 53(c) have considered the nature of the procedure in question, its purpose, and by whom the method is carried out.

Methods of surgery: the nature of the procedure

45 The dictionary (OED) definition of surgery is the treatment of the body by incision or manipulation. It is therefore 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*[48], it was observed that a method of implanting an embryo could still be viewed as surgery even if the method did not require incision. Similarly, a method comprising the insertion of devices into the respiratory cavities of the body (without incision) was also considered to be surgical by the EPO[49].

44 Calmic Engineering's Application [1973] RPC 684
45 T 780/89 BAYER/Immunostimulant OJEPO 1994,797
46 T 438/91 MEIJI/Feeds [1999] EPOR 333
47 T 774/89 BAYER
48 Occidental Petroleum's Application BL O/35/84
49 T 05/04 CAMTECH

46 In T 35/99[50] a very broad interpretation of the term "methods of surgery" was put forward, which included any physical interventions on the body in which maintaining the life and health of the subject was of paramount importance. This was distinguished from those interventions which result in the death of the subject (e.g. slaughter of farm animals or sacrifice of laboratory animals), which are not excluded. This followed the Technical Board of Appeal decision in T 182/90[51], which stated that the definition of surgery includes (amongst other things) "endoscopy, puncture, injection, excision and catheterisation". However, the Enlarged Board of Appeal in G 01/07[18] held that such a broad interpretation of "method of surgery" was unjustifiable, given the advances in medical techniques. Although the Enlarged Board did not provide an authoritative definition of the term "methods of surgery", it did state that a method should be excluded if it constitutes a non-insignificant physical intervention, which entails a substantial health risk even when carried out by a medical professional, and subsequent Technical Board of Appeal decisions have followed this approach. Therefore, in deciding whether a claimed method is objectionable under s.4A(1) on the grounds that it is a method of surgery, examiners should be satisfied that the method is invasive, requires professional skill and carried a potential risk. For example, 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. On the other hand, a method which requires more specialist medical skills, such as a lumbar puncture to deliver epidural injections, is unlikely to be patentable. In deciding whether a claimed method of introducing an agent (such as a pharmaceutical or contrast agent) is surgical in nature, it is the risk of the invasive procedure, and not the risk of any side effects of the agent, that should be considered[18].

47 Methods which define the implanting or insertion of devices by surgical means are clearly unpatentable – as in the cases considered in *Allen's Application*[52] and T 05/04[49]. The same applies for methods which control a surgical device, for example a surgical robot, in a manner which impacts on the body. However, methods of attaching exoprostheses to the skin using an adhesive were found to be patentable in T 635/08[53]. Claims to methods involving the internal operation of implanted devices, or the interaction between the implanted device and an external user or system, are not objectionable if they do not relate to the implantation of the device, and do not impact on the body. The fact that the device needs to have been implanted by surgical means prior to performing the claimed method does not render the claim unpatentable[54] [55]. Nevertheless, the claims must adequately define the invention, and so if a surgical step is an essential feature of the invention (rather than being simply a necessary prerequisite) then disclaiming or omitting the surgical step may lead to an objection under s.14(5)[18]. Further, in G 01/07[18] it was held that a method (such as an imaging method) which is useful for or during surgery, or which allows a surgeon to make a real-time decision during a surgical intervention, is not a method of surgery as such.

50 T 35/99 GEORGETOWN UNIVERSITY/Pericardial access OJEPO 2000, 447
51 T 182/90 SEE-SHELL/Blood flow OJEPO 1994, 641
52 Allen's Application BL O/59/92
53 T 635/08 DOW CORNING FRANCE
54 T 09/04 KONONKLIJKE PHILIPS ELECTRONICS
55 T 1102/02 MAQUET CRITICAL CARE

Methods of surgery: purpose

48 The definition of surgery used in applying Section 4A(1) 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*)

49 This remains the practice of the Intellectual Property Office with respect to cosmetic surgery, and is also in line with EPO practice following the Enlarged Board's decision in G 01/07[18]:

"Hence, the Enlarged Board concludes that the meaning of the term "treatment by surgery" is not to be interpreted as being confined to surgical methods pursuing a therapeutic purpose."

G 01/07 MEDI-PHYSICS/*Treatment by surgery* OJEPO 2011, 134

This overturned previous EPO practice as established in the decision by the Technical Board of Appeal in T 383/03[56], where 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." In this case, a method of hair removal by optical radiation was held to be surgical in character, but nonetheless patentable as its purpose was purely cosmetic. This type of procedure would not in any case be considered to be surgical in nature under UK Office practice. (Indeed, it is very similar to the procedure in *Commonwealth Scientific & Industrial Research Organization's Application*[16], in which method claims were granted, although the question of whether this was a surgical method was not considered at the hearing).

56 T 383/03 GENERAL HOSPITAL/Hair removal method OJEPO 2005, 159

Methods of surgery: who carries out the method?

50 The Enlarged Board in G 01/07[18] stated that whether a method is excluded or not as a "method of surgery" cannot depend on who carries it out, not least because of the changing medical roles in healthcare systems. Nevertheless, the Board did consider that the exclusion is intended to cover methods which require professional medical skills, and so the level of medical skill needed to perform a method can be a useful guide in determining whether a method is excluded or not. 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*[48]). 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*[52] (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. In T 663/02[57] it was held that tasks which are likely to be delegated or are carried out on such a routine basis as to be thought commonplace, with a low health risk, may be patentable. This case also reinforced the notion that consideration of the surgical aspect is separate from any possible therapeutic effects of what, exactly, is introduced.

51 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.

Diagnosis

Definition of diagnosis

52 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 4A(1) 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[58]. 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"

53 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[59] characterised these steps as being;

(1) the examination and collection of data;

(2) comparison of the data with normal values;

57 T 663/02 PRINCE
58 T 807/98 ST JUDE
59 G 01/04 Diagnostic methods OJEPO 2006, 334

(3) recording any deviation from the norm; and finally

(4) 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. (In practice, if the method includes the first measurement step, and the final deductive step, then the intermediate steps may be implied.)

54 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 4A(1). In G 01/04[59] the EPO Enlarged Board of Appeal decided that the term "method of diagnosis" should be interpreted narrowly. Only a method which comprises all of the 4 steps listed above, and therefore allows the identification of 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* OJEPO 2006, 334

55 This decision led to a significant change in practice in this Office and the EPO. We 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[60]. In that 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[59] overturned this interpretation, and instead endorsed the narrow definition used in the earlier decision T 385/86[61], 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*[62]).

56 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 4A(1). For example, a method of imaging using CT scanning[54], a method of measuring blood glucose[63] and a method of assessing tissue viability by measuring total haemoglobin, oxygen saturation and hydration[64] were all considered to provide only intermediate results which did not enable a diagnosis to be made.

57 A method practised on the body (see paragraphs 59-63 below) which includes all of the steps leading to a diagnosis should be objected to under Section 4A(1). This is usually clear-cut if the claim relates to the identification of a specific condition. In addition, it may be apparent from the description that a claimed method does in fact result in a diagnosis, even if the words of the claim do not specify a specific disease. In T 125/02[65], the measurement of nitrogen monoxide levels in exhaled air was used to identify "impaired respiratory function". The description indicated that the method allowed a particular course of treatment to be selected, and so the claimed method was considered to encompass all the steps leading to a diagnosis.

60 T 964/99 CYGNUS/Diagnostic device OJEPO 2002, 4
61 T 385/86 BRUKER/Non-invasive measurement OJEPO 1988, 308
62 Bio-Digital Sciences' Application [1973] RPC 668
63 T 330/03 ABBOTT LABORATORIES
64 T 41/04 NATIONAL RESEARCH COUNCIL OF CANADA
65 T 125/02 AEROCRINE

58 It should be noted that 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 may not adequately define the invention[59]. 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"

59 Section 4A(1) states that methods of diagnosis practised on the human or animal body cannot be patented. *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.

60 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. The Enlarged Board in G 01/04[59] 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.

"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* OJEPO 2006, 334

61 In practice, the key question is whether the examination and collection of data is practised on the body. As discussed above, a method is only considered to be a "method of diagnosis" if it has all the steps (1) to (4) listed in paragraph 53 leading to a diagnosis – ie examination and collection of data, comparison of the data with normal values, recording any deviation, and attributing the deviation to a particular clinical picture. If the method includes all these steps, and the examination stage – step (1) – is practised on the body, then objection should be made under Section 4A(1).

62 Formally, the practice set out in G 01/04[59] is that for each of these 4 steps, there are two questions. Firstly, is this a technical step? For each **technical** step, the 2nd question is to ask whether the step is practised on the body. The method is not patentable if all the technical steps are practised on the body, but is patentable if any of these 4 steps are technical in nature but are carried out away from the body. In practice, the first step of examination and collection of data is the only one that may be "practised on the body", and is (in most cases at least) the only "technical" step. The final deductive step of determining the condition is a purely intellectual exercise carried out by the doctor or vet, and so is not considered to be a technical step. In most cases, the comparison of data with standard values and recording of any deviation (steps 2 and 3) are also not technical features, and so are irrelevant for deciding whether the claim is objectionable. Moreover, in T 1197/02[66] it was held that any additional or preparatory steps (other than these 4) are irrelevant – the claim may still be objectionable even if these additional steps are both technical and *in vitro*.

66 T 1197/02 AUSTRALIAN NATIONAL UNIVERSITY

63 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[59]. For example, in T 125/02[65], the first step was the measurement of the nitrogen monoxide content during exhalation. As this step required the presence of the patient, it was considered to be a technical step practised on the human body. The other steps of the method - comparison with standard values, finding of a deviation, and attribution of the deviation to a clinical picture – were all held to be non-technical in nature, and so the claim in question was considered to be an unpatentable method of diagnosis.

Who performs the method?

64 The question of whether a claimed method is excluded under Section 4A(1) depends on whether it falls within the definition of a "method of diagnosis" (paragraphs 53-58), and whether it is "practised on the human or animal body" (paragraphs 59-63). 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* OJEPO 2006, 334

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[59] 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[67], where a method of NMR imaging included a step of injecting contrast agents into the body. 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)

65 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 four-step approach set out by the Court of Appeal in *Aerotel/Macrossan*[68] should be followed to determine patentability;

(1) properly construe the claim;

(2) identify the actual contribution;

(3) ask whether it falls solely within the excluded subject matter; and

(4) check whether the actual or alleged contribution is actually technical in nature.

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*.

67 T 655/92 NYCOMED/Contrast agent for imaging OJEPO 1998, 17
68 Aerotel Ltd v Telco Holdings; Macrossan's Application [2007] RPC 7

In vivo testing of drugs etc.

66 *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 4A(1). 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

67 Section 4A(1) states that a patent shall not be granted for an invention of a method of treatment of the human or animal body by surgery or therapy or a method of diagnosis performed on the human or animal. Unlike section 1(2) of the Act, there is no proviso in s.4A(1) that methods are only excluded "to the extent that a patent or application for a patent relates to that thing as such". The EPO Enlarged Board of Appeal on G 01/07[18], confirming a body of earlier EPO case law (e.g. T 820/92[40] and T 35/99[50]), held that any multi-step method which includes a step comprising a method of surgery or therapy step is excluded from patentability. The claimed method in question in G 01/07 encompassed the step of injecting contrast media into the heart and as such was considered to fall within the exclusion, although it was also held that the claim could be saved by disclaiming the surgical step using the phrase 'pre-implanted' or similar. A similar conclusion was reached in T 266/07[20].

68 In view of this settled view of the EPO Boards of Appeal, where a claimed method involves a number of steps, one or more of which constitutes a method of therapy or surgery (as defined above), then objection should be raised under s.4A(1). This represents a change in practice from that set out in previous editions of these Guidelines. This means that, for example, a claim to a method of manufacturing a pharmaceutical, and then using it to treat a disease, is objectionable as a method of treatment by therapy. In addition, a method of producing a transgenic animal which includes a surgical method of embryo transplantation is also objectionable under s.4A(1). This is consistent with Hearing Officer's decision in *Occidental Petroleum's Application*[48], where 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" (which still encompassed the surgical step) did not save the application from refusal. The invention was held to be to a method of surgery, and thus unpatentable.

69 The principle that one excluded step renders the whole claim unpatentable does not apply to methods of diagnosis practiced on the body, following the decision in G 01/04[59]. As discussed above (see paragraphs 53-63) the Enlarged Board in this decision held that diagnostic methods are inherently multi-step methods, and claims are only excluded if they include all the steps necessary for making a diagnosis, and all the new and inventive technical steps are practised on the body.

Apparatus for Surgery, Therapy or Diagnosis

70 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[69]. Similarly, a claim to a pacemaker, which was characterised in part by its method of use, was rejected in T 82/93[42].

69 Visx v Nidex [1998] FSR 405

71 Moreover, it is not possible to claim the first or second medical use of apparatus. Sections 4A(3) and 4A(4) are restricted to substances and compositions, and cannot be used to protect apparatus. This has been confirmed in respect of first medical use claims by the UK courts (*National Research & Development Corporation's Application*[70]), and similarly it has been held in this decision and by EPO Boards of Appeal that second medical use claims are not allowable with respect to apparatus[71] or prostheses[72] [73]. The rationale for this distinction given in T 227/91[71] 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.

72 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.

"...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."

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

73 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[74]. However, such a claim may be open to objection on clarity grounds, as being defined by its desired result.

First Medical Use

Section 4A(3)

74 In order to alleviate the effects of the Section 4A(1) prohibition on the claiming of methods of medical treatment, Section 4A(3) of the Patents Act 1977 (as amended by the Patents Act 2004) states that:

"In the case of an invention consisting of a substance or composition for use in any such method, 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."

Section 4A(3) of the Patents Act 1977

75 This replaced the similarly-worded Section 2(6) of the Patents Act 1977, which was repealed by the Patents Act 2004. The words "any such method" refers to any method rendered unpatentable by Section 4A(1); ie 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. Under this section, and the equivalent Article 54(4) of the EPC 2000, a substance or composition which is itself already known is regarded as novel "for use in" a method of treatment prohibited by Section 4A(1) 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.

70 National Research & Development Corporation's Application BL O/117/85
71 T 227/91 CODMAN/Second surgical use OJEPO 1994, 491
72 T 775/97 EXPANDABLE GRAFTS/Surgical device [2002] EPOR 24
73 T 213/07 TAYSIDE FLOW TECHNOLOGIES
74 T 712/93 JOINT MEDICAL PRODUCTS

76 Section 4A(3) protects the **first** medical use only. However, Section 4A(4) allows further, specific medical uses for a known substance or composition to be claimed, using the same basic format. This is discussed in more detail in the next section. 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[75].

77 The case law relating to first medical use under the repealed Section 2(6) (or the equivalent Article 54(5) of the EPC 1973) continues to govern our practice under Section 4A(3). The exception to this is the case law relating to the novelty of claims of the form "substance X, for use in treating disease Y", which is now governed by Section 4A(4) as discussed below.

First medical use - forms of claim

78 A claim to the first medical use of a known substance or composition may broadly claim any therapeutic use. Such claims may have the wording:

i) (Substance X) for use in therapy; or

ii) (Substance X) for use as a medicament.

Obviously no single drug is suitable for treating all diseases. Nonetheless, this broad form of first medical use claim is allowable for the first medical use of a substance or composition, providing there is support in the form of evidence for at least one medical use (see paragraphs 89-91). The question of the allowability of this broad form of medical use claim was considered by the EPO Board of Appeal in T 128/82[76]. 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.

79 In addition, the first (or subsequent) medical use of a known substance or composition may be protected by a specific medical use claim of the form:

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

Following the implementation of the EPC 2000 by the Patents Act 2004, claims of this form are treated as second medical use claims for the purpose of novelty, under Section 4A(4). In other words, they are only anticipated by the use of X for the specific purpose of treating disease Y. This represented a change in UK and European patent practice; formerly, a claim of this type was considered to be anticipated by **any** medical use of the substance or composition[9 77]. This type of claim is discussed in more detail in the next section. However, essentially the distinction between "first" and "second" medical use claims is artificial; both types of claim are considered to be limited in scope to the substance when prepared for the defined use (whether general or specific), and both types of claim are only anticipated by the use of the substance or composition for the purpose (whether general or specific) defined in the claim.

80 Claims of the form "the use of (substance X) in therapy" or "the use of (substance X) as a medicament" are **not** first medical use claims; these are unpatentable method of treatment claims, as discussed in paragraphs 18-19.

75 T 09/81 ASTA/Cytostatic combination OJEPO 1983, 372
76 T 128/82 HOFFMAN-LA ROCHE/Pyrrolidine-derivatives OJEPO 1984, 164
77 Sopharma's Application [1983] RPC 195

Searching and assessing novelty and inventive step of first medical use claims

81 A first medical use claim of the form "(substance X) for use in therapy" would be anticipated by any prior use of the substance in therapy. The search should nevertheless be focussed on the use(s) disclosed in the application, as amendment of the claim to the second medical use format is likely if any prior medical use is found.

82 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.

83 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 class[78]. A document (typically a patent document) which states that the substance is used in 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.

84 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.

Plurality

85 If a substance or composition has not previously been used in medicine, a number of general and/or specific 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

86 It is a general principle that a substance or composition cannot be protected by Section 4A(3) unless the method for which it is to be used is prohibited by Section 4A(1) (cf Articles 54(4) and 53(c) of the EPC 2000). 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 4A(1), then a claim to the substance or composition for use in the method is protected by Section 4A(3) against an objection of lack of novelty. The meanings to be given to "surgery", "therapy" and "diagnosis" in Section 4A(1) therefore apply equally to Section 4A(3). 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 4A(3). 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 36/83[23]). Moreover, known compositions or substances cannot derive novelty under Section 4A(3) 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 diet[79].

78 T 07/86 DRACO/Xanthines OJEPO 1988, 381
79 T 135/98 NORSK HYDRO [2004] EPOR 14

Combined therapies

87 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 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 176-179 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

88 Section 4A(3) is restricted to substances and compositions; apparatus cannot be so protected[70].

Support for first medical use claims

89 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 requirement for first medical use claims follows from the logic of the decision by the Patents Court in *Prendergast's Applications*[80]. This case (and earlier related hearings) concerned support for Swiss-type 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*[81] 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.

90 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, usually 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.

91 Where the substance or composition is known, and the invention as defined by the 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 MoPP 18.43).

80 Prendergast's Applications [2000] RPC 446

81 F. Hoffmann - La Roche's Application BL O/192/04

Second Medical Use

Section 4A(4)

92 Section 4A(3) of the Patents Act 1977 allows patent protection for the first medical use of a known substance or composition, in the same way as the now-repealed Section 2(6). Section 4A(4), on the other hand, allows for the protection of further, specific uses of a known substances or compositions ("second medical use"), and has no equivalent in the Patents Act prior to implementation of the EPC 2000.

"In the case of an invention consisting of a substance or composition for a specific use in any such method, 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 that specific use does not form part of the state of the art"

Section 4A(4) of the Patents Act 1977

93 The effect of this section (and the equivalent Article 54(5) of the EPC 2000) is that a claim to a known substance or composition for a **specific** medical use is considered to be novel if the substance or composition has not previously been used for that specific purpose, even if it has been used for other medical methods. This section for the first time introduces a statutory mechanism for the protection of inventions relating to second or further medical uses, and allows them to be defined using the same direct claim format as first medical use claims. However, it is important to note that **Section 4A(4) has not changed the boundaries of what is and is not patentable**, as for many years previously second medical use inventions were patentable through the "Swiss-type" claim format. A large body of case law in both the UK courts and the EPO has helped to define the scope, requirements and limits of Swiss-type second medical use claims. It was the express intention of the legislators, in drawing up both the EPC 2000 and the 2004 Act, that the new provisions were not intended to lead to any change in what is and is not patentable, and so the case law concerning Swiss-type claims is considered (with a very few exceptions which are highlighted below) to apply equally to the new form of second medical use claims.

Second medical use: claim format and "Swiss-type" claims

94 Before implementation of the EPC 2000, second or further medical uses of a known substance or composition could only 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 was new, then such a claim was 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 uses by Swiss-type claims was allowed by the Enlarged Board of Appeal in G 05/83[8], and this was followed by the Patents Court in *John Wyeth's and Schering's Applications*[9].

95 Since the implementation of the medical provisions of the EPC 2000 on 13 December 2007, applicants have been able to protect inventions relating to second medical uses through the simpler and more direct claim form "substance X for use in the treatment of disease Y". Initially, applicants were allowed to claim inventions relating to second medical uses using either the new second medical use claim format, the Swiss-type format, or both, pending guidance from the UK courts and/or the EPO Boards of Appeal. In 2010, the EPO Enlarged Board of Appeal issued its decision on G 02/08[10]: this addressed, amongst other questions concerning second medical use claims, whether there were any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) of the EPC 2000 (equivalent to sections 4A(1) and 4A(4)). The Enlarged Board considered that Swiss-type claims were accepted in G 05/83[8] as the only possible means of protecting inventions relating to second medical uses in order to fill a loophole in the provisions of the EPC 1973. Article 54(5) of the EPC 2000 and section 4A(4) of the Act fill this loophole by explicitly allowing claims to the further specific use of a known drug, and so the Board held that the reason for this judge-made or "praetorian" law no longer exists. It was therefore decided that Swiss-type claims for the second or further medical use of a

known substance or composition should no longer be allowed. However, the Board set out transitional provisions such that this only applies to new applications filed at the EPO more than 3 months after the publication of the decision in the Official Journal – the EPO therefore only reject Swiss-type claims in applications with an earliest priority date of 29 January 2011 or later.

96 Following this decision, the Office issued a Practice Notice on 26 May 2010, which sets out the Office practice on second medical use claims. In view of the desirability of maintaining conformity with EPO practice as established in Board of Appeal decisions in this field, the Office no longer allows claims in the Swiss format, and so any claims in this format must either be deleted or replaced by claims of the form "substance X for use in the treatment of disease Y". This applies to both new and pending applications, regardless of their filing or priority date. While it is recognised that this is inconsistent with the transitional provisions set out in G 02/08[10], there is no clear legal basis under UK patent law for treating new and pending applications differently following a change in the interpretation of the statutes.

97 Examiners should therefore object to second medical use claims in the Swiss format on grounds of lack of clarity. Specifically, Swiss-type claims are considered to be unclear because, although they define a method of manufacturing a medicament, the invention does not in fact relate to the method of production but instead relates to the intended use of the medicament. As stated in G 02/08[10], there is no functional relationship between the feature conferring novelty (the intended use) and the claimed manufacturing process. As s.4A(4) now allows a simpler and clearer form of second medical use claim, there is no longer a reason to allow the more ambiguous Swiss form of claim.

98 It was clearly stated, in both the preparations for the EPC 2000, and the passage of the 2004 Act, that the new provisions were not intended to lead to any change in what is and is not patentable. Nevertheless, it is not clear whether the scope of the new form of second medical use claim is exactly the same as that of a corresponding Swiss claims; it was suggested in G 02/08[10] that the new form may be broader in scope. Regardless of the wording or scope of the claim, the technical disclosure (i.e., a new medical use for a substance or composition) is the same, and so where an application is filed with Swiss-type claims, replacement of these claims with the corresponding medical use claims in the new format does not constitute added matter.

99 The only form of second medical use claim that is now allowable is the following:

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

Under Section 4A(4) this claim is only anticipated by the prior use of substance X to treat disease Y. Prior to implementation of the EPC 2000, this form of claim was held (in *John Wyeth's and Schering's Applications*[9], and *Sopharma's Application*[77]) to be anticipated by any medical use of the substance in question.

100 The following types of claim are not acceptable second medical use claims:

ii) "The use of substance X in the manufacture of a medicament for the treatment of medical condition Y." This is the usual form of Swiss-type claim.

iii) "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 John Wyeth's and Schering's Applications*[9].

iv) "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."

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

All of claim forms (ii) to (iv) were considered to be allowable by the Patents Court in *John Wyeth's and Schering's Applications*[9], although claims (iii) and (iv) have rarely been used. Claims in any of these forms are objectionable on grounds of clarity as discussed above. The EPO Board of Appeal in T 958/94[82] considered that claim form (v) was an acceptable alternative to the Swiss form of claim. It is also now objectionable on grounds of clarity for the same reasons.

101 The following types of claim are also not acceptable as second medical use claims:

vi) "The use of substance X in the treatment of disease Y". *This is an unpatentable method of treatment claim.*

vii) "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).*

The interpretation of claims (vi) and (vii) given above was set out by the Patents Court in *John Wyeth's and Schering's Applications*[9] and remains current practice.

102 The examples above all relate to situations where the applicant wishes to protect the use of a known substance X to treat a specified disease Y. However, claims in the second medical use format may be used in a variety of more complex scenarios. These are discussed at greater length in the following sections of these Guidelines, but examples are provided below of the types of claim that may occur with a reference to the detailed discussion of such instances:

viii) "Substance X for use in a cosmetic method of treating the skin." *This is not a second medical use claim as the new use is not excluded under s.4A(1), and so will not be novel if substance X is known – see paragraphs 103-105.*

ix) "Substance X for use in the treatment of disease Y by administration of a dosage of 0.1-1mg." / "Substance X for use in the treatment of disease Y by intravenous administration." *The drug is used to treat the same disease as in the prior art, but using a new dosage regime or method of administration – see paragraphs 124-137.*

x) "Substance X for use in the treatment of disease Y in patients showing over-expression of receptor Q". *The drug has been used to treat the same disease as in the prior art, but the specific patient group is defined – see paragraphs 138-140.*

xi) "Substance X for use in the treatment of disease Y by inhibiting the activity of receptor Q". *The new use is defined, at least in part, by the mechanism of action by which the disease is treated – see paragraphs 141-146.*

xii) "Substance X for use in the treatment of disease Y with reduced immuno-suppression". *The new use is defined, at least in part, by an unexpected advantage such as greater efficacy or reduced side-effects – see paragraph 147.*

xiii) "Substance X for use in the treatment of diseases associated with over-expression of receptor Q." / "Substance X for use in inhibiting activity of receptor Q." *The disease to be treated, or the therapeutic use, is defined in mechanistic rather than clinical terms – see paragraphs 148-150.*

xiv) "Substance X for use in the treatment of disease Y by combined, sequential or separate administration with substance N." *The new use relates to the combined use of two or more agents – see paragraph 151.*

82 T 958/94 THERAPEUTIQUES SUBSTITUTIVES/Anti-tumoral agent OJEPO 1997, 241

xv) "Substance X for use in the extra-corporeal treatment of blood to treat disease Y." *The new use relates to a treatment performed on blood or tissue outside the body – see paragraphs 152-153.*

xvi) "An inhibitor of receptor Z, for use in the treatment of disease Y". *The active agent is defined in functional rather than chemical terms – see paragraphs 158-159.*

xvii) "A prosthetic device Z, for use the treatment of disease Y". *The "active agent" is a device or piece of apparatus – second medical use claims can only protect the new use of a substance or composition, and so this claim will not be novel if device Z is known – see paragraph 161.*

Second medical use and Section 4A(1)

103 Second medical use claims to substances or compositions can only derive novelty from their intended use if the use is in a medical method excluded under Section 4A(1).

"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."

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

104 This means that the second medical use claim format cannot be used to protect the new use of a known substance in, for example, non-surgical cosmetic or hygiene methods. A claim to "substance X for use in cosmetic method Y" is therefore not limited by its intended use, and will not be new if substance X is known. 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 supported and distinguishable (as in T 584/88[25], relating to therapeutic and non-therapeutic treatments for snoring).

105 Although the Enlarged Board of Appeal refers only to "therapeutic" methods in its decision in G 05/83[8], second medical use claims may be used to protect the use of a known substance or composition in any method falling within the exclusion of Section 4A(1). For example, in T 655/92[67], 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.

106 Second medical use 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[83].

107 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 second medical use claims does not constitute added matter.

83 T 143/94 MAI/Trigonelline OJEPO 1996, 430

Determining novelty and inventiveness of second medical use claims

108 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 82), 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 second medical use 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 in T 241/95[84], where it was stated 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". While any document which "directly and unambiguously reflects such a therapeutic application" would clearly be a very strong inventiveness citation, to argue that such a document anticipates a second medical use claim if it does not actually disclose the medical use in question would appear to fail the test for novelty set by Lord Hoffmann in *SmithKline Beecham's (Paroxetine Methanesulfonate) Patent*[85]: "Anticipation requires prior disclosure of subject-matter which, when performed, must necessarily infringe the patented invention".

109 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, as discussed in T 1001/01[86].

"...it is common practice that a patent literature document, in order to be an enabling disclosure of a medical indication for pharmaceutically active compounds ... does not necessarily need to include either clinical tests (Phase I, II or even III) or in vivo human assays."

T 1001/01 SMITHKLINE BEECHAM

It would then be open to the applicant to challenge whether such a statement constitutes an enabling disclosure.

110 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*[87] 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[88]. 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[88].

111 It should be noted that the disclosure that an agent is being evaluated in clinical trials for a condition does not necessarily constitute evidence of therapeutic use[89]. It was pointed out in T 715/03[90] that successful completion of Phase I trials merely demonstrates an acceptable safety profile, and the mere disclosure that a compound is undergoing Phase II trials does not indicate any therapeutic effect unless results are provided. Clearly, however, such a disclosure would be very relevant for inventiveness.

84 T 241/95 ELI LILLY/Serotonin receptor OJEPO 2001, 103
85 SmithKline Beecham's (Paroxetine Methanesulfonate) Patent [2006] RPC 10
86 T 1001/01 SMITHKLINE BEECHAM
87 Bristol-Myers Squibb v Baker Norton Pharmaceuticals [2001] RPC 1
88 Pfizer's Patent [2001] FSR 16
89 T 158/96 PFIZER/Sertraline [1999] EPOR 285
90 T 715/03 PFIZER

112 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[91]. 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 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.

113 In relation to cancer treatments, the Board of Appeal in T 385/07[92] pointed out that different types of cancer have very different causes and characteristics, and there are no "magic bullets" which successfully treat all cancers. The disclosure that a particular treatment is effective against one or more cancer types would not normally indicate a "reasonable expectation of success" in the treatment of an unrelated form of cancer.

114 Following the decision of the Court of Appeal in *Actavis v Merck*[93], second medical use claims which are defined by a new dosage regime (where the substance or composition, and the disease treated, are both known in the prior art) are in principle allowable. The inventiveness of claims of this type should be very carefully scrutinised; there should be a general presumption that a new dosage regime will **not** be inventive unless there is a clear technical prejudice pointing away from the claimed dosage regime.

"…nearly always such dosage regimes will be obvious – it is standard practice to investigate appropriate dosage regimes. Only in an unusual case such as the present (where… treatment for the condition with the substance had ceased to be worth investigating with any dosage regime) could specifying a dosage regime as part of the therapeutic use confer validity on an otherwise invalid claim."

Jacob LJ*, Actavis v Merck* [2008] RPC 26

115 The earlier decision of the Hearing Officer in *Advance Biofactures of Curacao's Application*[94] illustrates some of the factors which might, exceptionally, lead to a new dosage form being considered both novel and inventive. The active agent was present at substantially higher concentration than the prior art, and it was impossible in practice to deliver the required dose with the prior art solutions. 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.

116 As discussed below (paragraphs 162-168), second medical use claims must be supported by evidence of the likely effectiveness of the claimed treatment, and so in the absence of any such evidence the claim should be objected to as being speculative. If this requirement is met (and the claim is novel), it must be decided whether the invention as defined in the claims is obvious. The examiner should not apply a different test depending on the amount of evidence provided in the specification, or determine the inventive concept on the basis of the supporting evidence rather than the claims. This follows from the decision of the House of Lords in *Conor Medsystems v Angiotech Pharmaceuticals*[95], which reversed the decision of the Patents Court[96] and the Court of Appeal[97].

91 T 913/94 EISAI/Medicament for gastritis [2001] EPOR 362
92 T 385/07 PHARMA MAR
93 Actavis v Merck [2008] RPC 26
94 Advance Biofactures of Curacao's Application BL O/303/04
95 Conor Medsystems v Angiotech Pharmaceuticals [2008] RPC 28
96 Angiotech Pharmaceuticals' Patent [2006] RPC 28
97 Angiotech Pharmaceuticals v Conor Medsystems [2007] RPC 20

117 This case concerned a drug-coated stent, and so was not a first or second medical use claim, but the case is relevant to medical use claims as it related to the choice of pharmaceutical agent used in the device, and the likely efficacy and safety of that drug for a specific therapeutic use. The case revolved around the question of whether it would be "obvious to try" to coat a stent with paclitaxel (TaxolRTM) to prevent restenosis (the proliferation of cells around the stent). The Patents Court[96] held that the technical contribution disclosed in the application was critical in determining the question to be asked; whether it was merely necessary to show that the substance was an obvious candidate for testing without any expectation of success, or whether it was necessary to show that the skilled person must have had an expectation of success sufficient to induce him to use it in practice. The House of Lords[95] rejected this distinction:

"But there is in my opinion no reason as a matter of principle why, if a specification passes the threshold test of disclosing enough to make the invention plausible, the question of obviousness should be subject to a different test according to the amount of evidence which the patentee presents to justify a conclusion that his patent will work."

Lord Hoffmann *Conor Medsystems v Angiotech Pharmaceuticals* [2008] RPC 28

118 In this case there was evidence provided in the application as filed that TaxolRTM was a particularly effective anti-angiogenic agent, and the invention was based on the principle that inhibition of angiogenesis could be used to prevent restenosis. The House of Lords accepted that the absence of any evidence to support a speculative claim could lead to an objection of lack of support or insufficiency (quoting the decision in *Prendergast's Applications*[80]), but held that this requirement should not be confused with the requirement for inventiveness[95].

119 Moreover, it cannot be argued that a prima facie obvious selection of a particular compound or treatment is rendered inventive by a surprising effect, in the absence of any evidence or disclosure of that effect in the application as filed. In assessing the inventiveness of any such selection invention, the following criteria (derived from the Court of Appeal's decision in *Dr Reddy's Laboratories v Eli Lilly*[98] and the EPO Board of Appeal decision in T 939/92[99]) should be used:

i) the selection must not be arbitrary but must be justified by a hitherto unknown technical effect;

ii) a technical effect which justifies the selection of the claimed group must be one which can be fairly assumed to be produced by substantially all the selected members;

ii) this technical effect can only be taken into account if it can be accepted as having been indicated in the specification as filed.

120 In this respect, we would take a different view from that of the EPO in T 36/04[100]. In this case, a second medical use claim relating to the administration of two agents in a specified order was granted on the basis of information obtained after filing showing an unexpected benefit of administration in that sequence, even though the specification as filed gave no hint that the order of administration was of importance, and so criterion (iii) would not appear to have been met. The examination of selection inventions is discussed in greater detail in MoPP 3.88-3.93 and the Examination Guidelines for Patent Applications relating to Chemical Inventions in the Intellectual Property Office.

98 Dr Reddy's Laboratories v Eli Lilly [2010] RPC 9
99 T 939/92 AGREVO/Triazoles OJEPO 1996, 309
100 T 36/04 SCHERING-PLOUGH

121 If the experimental evidence provided in support of the specified use is essentially the same as that provided in the prior art, then the application is likely to fail on grounds of either inventiveness or support. 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. 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[101] 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 (on grounds of inventiveness or support) even if a novelty objection cannot be made.

Second medical use claims - the new use

i) Treatment of a new disease or condition

122 The decisions of the EPO Enlarged Board of Appeal in G 05/83[8] 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" could (prior to G 02/08[10] and the release of our Practice Notice on 26 May 2010) be protected by a Swiss-type claim, while Section 4A(4) allows such a use to protected by the direct form of second medical use claim. Typically, second medical use 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.

123 It may be more difficult to determine whether a second medical use claim is novel if the new use is the treatment of a specific form of a disease, where the prior art discloses (or appears to disclose) the treatment of a wider class of diseases. Examples considered by the EPO Boards of Appeal include the use for treating pancreatic cancer of an agent known for the treatment of a variety of other cancers[92], adenocarcinoma of the ovary as opposed to ovarian cancer in general[86], and hormone refractory prostate cancer as opposed to prostate cancer in general[102]. As a general principle, a general disclosure of a class does not anticipate a claim to a specific member of that class. Nonetheless, a novelty objection should be made if the prior art disease class appears to encompass the specific disease claimed, and, **either** the specific disease is referred to in the prior art document as being treatable with the substance in question, **or** it may reasonably be implied that the prior art does disclose the treatment of the specific disease (for example, where the specific disease is the predominant form of the disease class). It would then be for the applicant to argue whether the prior art constitutes an enabling disclosure for the disease in question – in the three cases referred to above, the EPO decided that the specific use was in fact novel. Nevertheless, it should be emphasised that the mere discovery that a treatment is particularly effective in one particular sub-group of disease patients, does not render a claim novel if the substance has clearly been used to treat this sub-group (amongst others) in the prior art.

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

124 Second medical use claims which are distinguished from the prior art solely by the dosage regime used, or the mode of administration, are considered to be patentable if the claimed use is both new and inventive, with the proviso that if the claim is considered to be directed at the activity of the doctor rather than the manufacturer, it may be objectionable under Section 4A(1). This follows from the decision of the Court of Appeal in *Actavis v Merck*[93], which led to a significant change in Intellectual Property Office practice in this field.

101 T 1031/00 SEPRACOR
102 T 380/05 PRAECIS PHARMACEUTICALS

125 In this case, the disputed claim was as follows;

> The use of [finasteride] for the preparation of a medicament for oral administration useful for the treatment of androgenic alopecia in a person and wherein the dosage amount is about 0.05 to 1.0 mg.
>
> Finasteride was a known drug (used for treating prostate conditions), which had in the past been proposed as a treatment for alopecia, but at a dosage at least 5mg – the only new feature of the claim was thus the reduced dosage. The Court of Appeal held that the claim was valid, as it was novel, inventive and not excluded as a method of treatment by therapy[93]. This overturned the decision of the Patents Court[103] that this claim lacked novelty, and was a method of treatment excluded under Section 4(2) of the Patents Act 1977. These two grounds for invalidity both stemmed from the earlier decision of the Court of Appeal in the *Taxol* case (*Bristol-Myers Squibb v Baker Norton Pharmaceuticals*[87]), which had governed UK patent practice in relation to dosage regimes and similar second medical use claims prior to the more recent Court of Appeal decision in *Actavis v Merck*[93].

126 The claim in question in *Bristol-Myers Squibb v Baker Norton Pharmaceuticals*[87] 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/m2 up to 175 mg/m2 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 (TaxolRTM 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."

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

127 Following this decision, the practice of the Intellectual Property Office was to treat second medical use claims which defined the new use in terms of the mode of administration, or the quantity, frequency or timing of dosage, as being unpatentable methods of treatment, disguised by drafting in the second medical use format. Moreover, such claims were also considered to lack novelty over the prior use of the substance to treat the same disease at a different dosage or by a different method of administration.

128 This interpretation of the *Taxol*[87] decision was supported by the Patents Court in *Merck's Patents [Alendronate]*[104] (upheld by the Court of Appeal[105]). 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 considered to be an unpatentable method of treatment.

103 Actavis v Merck [2007] EWHC 1311
104 Merck's Patents [Alendronate] [2003] FSR 498
105 Merck's Patents [Alendronate] [2004] FSR 330

129 However, the Court of Appeal in *Actavis v Merck*[93] took the view that the *Taxol*[87] case provided no clear *ratio decidendi* that a second medical use claim lacks novelty if the only difference between it and the prior art is a new dosage regime. There was therefore no binding precedent to consider in respect of novelty, and the Court concluded that a second medical use claim solely distinguished by a new dosage regime is novel over the use of the substance to treat the same disease at a different dosage. Second medical use claims which define a new dosage regime or mode of administration should therefore be considered novel, even if this is the only new feature of the claim. This does not, of course, mean that such a claim will necessarily be inventive – see paragraphs 114-115.

130 The Court of Appeal in *Actavis v Merck*[93] accepted that there was a clear *ratio* from the *Taxol*[87] case that the claim at issue defined an unpatentable method of treatment. However, the dosage-specific claim of *Actavis v Merck* was considered to be directed at the manufacturer, and so was distinguished from the claim in *Taxol* which defined a series of steps performed by the doctor.

"So Aldous LJ decided the method of treatment point on a very narrow ground indeed. It was that if in essence the claim is merely to a method of treatment it is bad. The claim in the present case is far from that. It is in its essence directed at the manufacturer. The doctor's only involvement will be in prescribing for the treatment of aa the 1mg pill made by an alleged infringer. We do not regard Aldous LJ's ratio as binding in its effect so far as the general case of dosage specific Swiss form claims or so far as this case is concerned."

Jacob LJ, *Actavis v Merck* [2008] RPC 26

131 In addition to distinguishing the facts of the case from *Taxol*[87], the Court of Appeal in *Actavis v Merck*[93] decided (unusually) that it was not in any case bound to follow its own, earlier decision. The reason the Court of Appeal gave for departing from its own precedent was that the *Taxol* decision was inconsistent with the "settled view" of European patent law as interpreted in EPO Board of Appeal decisions.

132 The EPO has historically taken a more liberal view of what constitutes a "new therapeutic use" than the UK courts. Claims have been accepted in which the prescription regime of the treatment was specified[106] and where the distinguishing feature was mode of administration[107]. On the other hand, in T 56/97[108], a Swiss-type claim defined by an amount of thiazide diuretic "with the range of 7-25% by weight of the predetermined diuretic effective dose" was refused as a method of treatment. In this case, 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. However, in the later decision T 1020/03[109] it was held that the new therapeutic use may relate to **any** new and inventive use falling within Article 52(4) (equivalent to the now-repealed Section 4(2)). The claim in question was distinguished by the precise timing of an intermittent course of treatment over a period of several weeks, and this decision was followed in subsequent Technical Board of Appeal decisions.

133 As a result of this, the Court of Appeal in *Actavis v Merck*[93] held that the approach taken in T 1020/03[109] represented the "settled view" of the EPO on this issue. This was confirmed by the decision of Enlarged Board of Appeal in G 02/08[10]; which considered the following specific questions:

1. Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC 2000 for use in a different, new and inventive treatment by therapy of the same illness?

2. If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime?

106 T 570/92 BAYER
107 T 51/93 SERONO
108 T 56/97 TAKEDA
109 T 1020/03 GENENTECH/Method of administration of IGF-I OJEPO 2007, 204

3. Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?

134 The Enlarged Board's decision on the third question is discussed above (see paragraph 95). In answer to the first two questions, the Board decided that a medicament could be protected under Art. 54(5) EPC for use in a different method of treating the same disease as the prior art, and this could include uses where the dosage regime is the only new feature.

"Thus, the new use within the meaning of Article 54(5) EPC need not be the treatment of another disease."

G 02/08 ABBOTT RESPIRATORY/*Dosage regime* [2010] 10 OJEPO 456

135 In view of the decisions in *Actavis v Merck*[93] and G 02/08[10], second medical use claims defined by a new dosage forms, or new modes of administration (for example, intramuscular as opposed to intravenous injection) should therefore not generally be objected to under Section 4A(1) as being an unpatentable method of treatment. It was pointed out in *Actavis v Merck* that manufacturers have to provide detailed information relating to uses and dosages with their medicines, and so such a claim can fairly be said to be directed at the manufacturer, rather than the doctor. Moreover, a new dosage regime may necessarily result in the use of a wholly different composition, for example, where the active agent is present at a different concentration compared with the prior art[94].

136 However, the Court of Appeal in *Actavis v Merck*[93] took care to identify the narrow *ratio* in the *Taxol*[87] case and distinguish the claim in question (and typical dosage regime claims in general) from it, and so it is not clear that the Court considered that the *ratio* in *Taxol* was no longer relevant. Second medical use claims defined by features of the method by which the patient is treated should therefore still be scrutinised to determine whether they are (as in the *Taxol* case) solely directed towards the doctor, rather than the manufacturer. If the claim is considered to impinge directly on the doctor/patient interaction, and thereby potentially impact on the doctor's professional skill and judgement, then an objection under Section 4A(1) should be considered. In addition, objection may be raised if the claimed use includes a surgical, therapeutic or *in vivo* diagnostic step which is not in fact directly connected to the administration of the agent in question. In T 566/07[110], the Technical Board of Appeal rejected a claim to the use of a dye "for staining a retinal membrane ... in a method for performing retinal membrane removal" on the grounds that the claimed use of the dye solely related to staining the retina, and not to the surgical removal of the retina. This was considered to be an entirely separate surgical method step (even though it was worded as part of the second medical use) and so the claim was rejected under Art. 53(c) as defining a method of treatment by surgery.

137 Notwithstanding the settled view of the EPO that a new use can relate to a new method of administering the same agent to treat the same disease, the Technical Board of Appeal in T 174/07[111] held that a negative feature of the method of administration (that the substance be administered and nature left to take its course) did not provide novelty over prior art in which further steps were taken following administration.

iii) New patient group

138 A second medical use claim may, in 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[2]. 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[112], the use of a composition to treat bleeding in non-haemophiliac humans was not anticipated by its use in treating bleeding in haemophiliac patients.

110 T 566/07 MELLES
111 T 174/07 GENVEC
112 T 893/90 QUEEN'S UNIVERSITY KINGSTON

139 The Technical Board of Appeal in T 233/96[113] 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. More recently, the EPO have held that the new patient group **can** overlap with, or be a subset of, the patients treated in the prior art. In T 1399/04[114] a known treatment for hepatitis C virus (HCV) was used to treat patients infected with a high titre of the HCV-1 subtype. This claim was considered new and inventive, despite the fact that over half of HCV-infected patients fell within this category.

140 UK Office practice is that a second medical use claim to an agent for use in the treatment of a disease in a specific patient group is not new if the agent **has already been used** to treat the same group of patients **amongst others**, with the same disease. Insofar as this may depart from EPO practice, this is based on the decision of the Patents Court in the *Taxol* case (*Bristol-Myers Squibb v Baker Norton Pharmaceuticals*[115]), that a new piece of information about an advantage, or how a treatment worked, did not constitute an invention if it did not lead to a new use. This aspect of the decision was upheld at appeal[87] and was not challenged in later cases such as *Actavis v Merck*[93]. The discovery that the treatment works particularly well for a group of patients does not therefore render such a claim novel if that same group of patients has already in fact been treated for the disease with the same agent. This is merely the discovery of an advantageous property of a known treatment. Nonetheless, a general disclosure that an agent may be used to treat a disease does not necessarily anticipate a specific claim to the treatment of a subgroup of patients with the disease, unless it can be shown that treatment of this subgroup is explicitly or inherently disclosed in the prior art (see paragraph 123).

iv) New mechanism or technical effect

141 Second medical use 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.

142 This question was considered by the Patents Court in the *Taxol* case (*Bristol-Myers Squibb v Baker Norton Pharmaceuticals*[115]). 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 aspect of the decision was upheld by the Court of Appeal[87].

"All you have is more information about the old use. In due course no doubt more information about the exact mode of action of Taxol will emerge. No-one could obtain a patent for its use simply by adding "for" at the end of the claim and then adding the newly discovered details of the exact mode of action."

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

This decision was followed by the Patents Court in *El-Tawil's Application*[116], where a claim was considered to relate to a combination of newly discovered technical effects, and newly discovered advantages of a known treatment, neither of which conferred novelty.

143 This contrasts with the decision in T 290/86[35] 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 Patents Court in *Taxol*[115] considered the precedent of T 290/86 and specifically rejected this approach. Second medical use claims based solely on a new technical effect when treating the same condition should not therefore be allowed.

113 T 233/96 MEDCO RESEARCH
114 T 1399/04 SCHERING
115 Bristol-Myers Squibb v Baker Norton Pharmaceuticals [1999] RPC 253
116 El-Tawil's Application [2012] EWHC 185

144 In a later decision[117] 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.

"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

145 This was reinforced by the EPO Board of Appeal in T 486/01[118], 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

Similarly, in T 406/06[119], the "stimulation of beta cell proliferation" was considered to merely an explanation of the known anti-diabetic effects of GLP-1. However, in T 509/04[120], a claim relating to the use of botulinum toxin to promote normal muscle growth in juvenile cerebral palsy patients was held to be novel over the previous successful use of the toxin to treat the same disease, in the same patient group. The prior art document did not suggest any activity in promoting muscle growth – it was instead known to act as a muscle relaxant – but the Opposition Division considered that the muscle promotion activity was inherent in the prior art treatment. Nonetheless, the claim was considered to be both new and inventive on the basis that the claimed technical effect (promoting muscle growth) was not disclosed or suggested in the prior art. This case, like T 290/86[35], was based on the decision of the Enlarged Board of Appeal in G 02/88[121], which held that a claim to the use of a known substance to achieve a new technical effect is novel if the technical effect has not previously been disclosed, even if it may have inherently taken place in a prior art method. The UK courts have interpreted G 02/88 narrowly, such that a use claim based on a newly discovered technical effect can only be considered novel if it leads to a new use which is clearly different from the old use – this interpretation was applied to second medical use claims by the Patents Court in *Taxol*[115] and also in *Actavis v Janssen Pharmaceutica*[122]. Similarly, in a non-medical case (*Tate & Lyle Technology v Roquette Frères*[123] – upheld at appeal[124]) a claim to "the use of maltotriitol to modify or control the form of maltitol crystals", was held to lack novelty over a number of prior art documents which disclosed crystallisation of maltitol in the presence of maltotriitol at levels at which it would control crystal formation, even though this effect was not recognised (see MoPP 2.14-2.14.1). We do not therefore consider that a newly discovered technical effect can confer novelty to a second medical use if the prior art discloses the use of the same agent for the same purpose, notwithstanding G 02/88 and the Technical Board of Appeal decisions cited above which rely on it.

117 T 254/93 ORTHO PHARMACEUTICAL/Prevention of skin atrophy OJEPO 1998, 285
118 T 486/01 GENENTECH
119 T 406/06 NOVO NORDISK
120 T 509/04 ALLERGAN
121 G 02/88 MOBIL/Friction reducing additive III OJEPO 1990, 93
122 Actavis v Janssen Pharmaceutica [2008] FSR 35
123 Tate & Lyle Technology v Roquette Frères [2010] FSR 1
124 Tate & Lyle Technology v Roquette Frères [2010] EWCA Civ 1049

146 In T 836/01[125], 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. If this argument is made in relation to an application, then it will need to be considered whether the patient group is genuinely different from those treated in the prior art (see above, paragraphs 138-140) and the clarity of the claimed use needs to be considered carefully – this is discussed further below (see paragraphs 148-149).

v) New advantage to known use

147 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*[87 115] 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

Similarly, the identification of symptoms which are alleviated by a known treatment does not in itself confer novelty[116]. 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[126].

vi) Functional definition of the new medical use

148 Section 4A(4) allows the protection of a **specific** new and inventive therapeutic application of a substance or composition. The scope of the claimed use must be clear to the person skilled in the art. In cases where the disease or diseases to be treated are clearly defined in the claim, then this requirement is met. However, this may not be the case where the use is only defined in mechanistic terms; and so if the examiner is in any doubt that the skilled person would know what the claimed use means in terms of the treatment of specific conditions then an objection of lack of clarity should be raised. It is then for the applicant to show that the skilled person would be able to determine the scope of the claim without an undue burden of research. As held in T 241/95[84], a second medical use claim in which the new use is defined in functional terms can only be regarded as clear if means (in the form of experimental tests or other testable criteria) for assessing whether or not a condition falls within the scope of the claim are available to the skilled person from the specification or the common general knowledge. In this decision the Board of Appeal 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_{ic} 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

Definitions of therapeutic uses based on molecular activities (such as inhibition of the activity of a receptor, as in T 241/95) may be particularly problematic from a clarity point of view. Although it may be relatively straightforward to determine whether an agent binds or inhibits a receptor, it is likely to be much more complex to definitively determine the role of the receptor in a given pathology.

125 T 836/01 YEDA
126 T 315/98 STERLING/S(+) ibuprofen [2000] EPOR 401

149 Nevertheless, functional or mechanistic definitions of the therapeutic use are not necessarily unclear. In *Regeneron Pharmaceuticals v Genentech*[127] the Patents Court considered whether a claimed use for the treatment of "a non-neoplastic disease or disorder characterised by undesirable excessive neovascularisation" was so ambiguous and unclear as to be insufficient. Floyd J rejected this allegation:

"There was no evidence that the skilled addressee would have any difficulty in determining whether a given disease would fall within the terms of the claim as I have construed them."

Floyd J, *Regeneron Pharmaceuticals v Genentech* [2012] EWHC 657

Although (being a post-grant revocation case) Floyd J was addressing sufficiency (s.14(3)) rather than clarity (s.14(5)(b)), this decision (upheld at appeal[128]) does show that mechanistically-defined uses are not considered to be inherently so unclear as to be insufficient by the UK courts.

150 In addition to considering clarity, the examiner should also consider whether a functional or mechanistic definition is merely the identification of a mechanism or additional advantage of a known treatment (see above, paragraphs 141-146). A novelty objection should be raised if the functional definition includes diseases which have already been treated by the drug in question in the prior art. A common mechanistic feature, if new and inventive, may nevertheless provide the common subject matter between second medical use claims for different diseases (see below, paragraph 160).

vii) Use in association with another agent

151 Second medical use claims to the use of a composition comprising two or more agents together for the treatment of a disease 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 176-179 below. A claim to the use of an agent for the manufacture of a medicament to reduce the side effects[117], or to potentiate the effects[122], 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 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. For example, in *Actavis v Janssen Pharmaceutica*[122], the use of one stereoisomer to potentiate the blood-pressure reducing effects of other agents – including one of the other stereoisomers – was held to be anticipated by the use of a racemic mixture of the isomers for the treatment of hypertension. The fact that the synergistic effect of the isomers was not recognised in the prior art did not render the claim novel.

viii) Use in treatments performed outside the body

152 As discussed in paragraph 41, therapeutic treatments such as dialysis where blood or tissue is treated outside of the body and returned to the patient are considered to be methods of treatment by therapy and so are unpatentable under s.4A(1). It therefore follows that an invention relating to the use of a known substance or composition for such an *ex vivo* treatment method could be protected using a second medical use claim. This is notwithstanding the decision of the Technical Board of Appeal in T 138/02[129], where it was held that Swiss-type claims could only protect the use of the substance or compound as a "medicament" (based on the wording of the decision in G 05/83[8]), and it was an essential feature of a medicament that it was administered to the body. This case related to an adsorbent composition used to remove blood proteins in a dialysis system. It was considered not to be a medicament as it was not taken into the body, and so a Swiss claim was rejected. This decision (unusually) does not appear to be relevant for the new form of second medical use claim – Section 4A(4) and Article 54(5) make no reference to "medicaments". In view of this, and the UK case law[4 44] which establishes that such methods are excluded under s.4A(1), we would allow second medical use claims for new and inventive uses of substances in ex vivo treatments.

127 Regeneron Pharmaceuticals v Genentech [2012] EWHC 657
128 Regeneron Pharmaceuticals v Genentech [2013] EWCA Civ 93
129 T 138/02 KANEGAFUCHI

153 As discussed in paragraph 41, this applies only to treatments where the blood or tissue is returned to the patient – treatment of stored blood is not regarded as therapy and so could not be protected by a second medical use claim.

Second medical use claims - the substance or composition

i) Assessing novelty and inventive step

154 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*[130], 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. It was also held in this case that the presence of the compound in question as an impurity in a medicament does not fall within the scope of a second medical use claim.

155 A prior art citation showing the use of a substance produced by a chemical reaction from the compound in question does not anticipate a second medical use claim (though it may be relevant for inventiveness). This question was particularly relevant to Swiss-type claims: the wording of Swiss-type claims (but not the new form of second medical use claims) could suggest that they encompass derivatives produced from the substance in question. The Court of Appeal in *Monsanto v Merck*[131] 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*[130] decided that if this was the case this would require a wide construction of the term "medicament" in the claim (that is, to mean a medicament not restricted to one comprising compound X), and this would leave the claim hopelessly broad. This question was also addressed in relation to infringement in *Ranbaxy v AstraZeneca*[132]. In this instance the Patents Court also held that a Swiss-type claim would be construed as being restricted to the use of the substance as a medicament, rather than as an intermediate in the production of a medicament, though Kitchin J emphasised that he had interpreted with reference to the description in this patent, rather than providing an absolute rule of construction of Swiss claims. The patent in question included both Swiss-type medical use claims and second medical use claims in the form "Substance X for use in the treatment of disease Y". It was accepted by all parties that the latter claim clearly does not encompass any derivative produced from substance X, and so this ambiguity does not arise with the new format of second medical use claim. As we no longer allow Swiss-type claims, this issue of construction no longer arises in pre-grant patent applications at the Office.

ii) Assessing support when the substance is defined by chemical structure or class

156 Second medical use 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*[130] (see above, paragraph 154) 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.

130 American Home Products v Novartis [2001] RPC 8
131 Monsanto v Merck [2000] RPC 77
132 Ranbaxy v AstraZeneca [2011] EWHC 1831

157 However, if the specification discloses a general principle capable of general application, a claim in correspondingly general terms may be acceptable – in *Regeneron Pharmaceuticals v Genentech*[127] (upheld at appeal[128]), this test was applied and the claim was considered to be a fair generalisation. In this case it was pointed out that in the pharmaceutical industry a period of trial and error, sometimes extending over months or even years, is entirely normal, and so the need for such experimentation does not render the claim insufficient. There is no need to 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 second medical use 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

The decisions in *American Home Products v Novartis*[130] and *Regeneron Pharmaceuticals v Genentech*[127 128], together with other decisions concerning claim breadth and sufficiency, are discussed further in MoPP 14.76.1-3.

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

158 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*[88], 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*[88] that a second medical use claim relating to, for example, the use of an inhibitor of A 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.

159 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

160 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. 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 150).

Second medical use, apparatus and devices

161 Second medical use claims, like first medical use claims, 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[72] and T 227/91[71], and by the Hearing Officer in *National Research & Development Corporation's Application*[70]. The EPO have allowed a claim to the use of a substance in the manufacture of a "device" for intrapulmonary administration[133]. The device in question was a piece of apparatus for storing, dispersing and delivering the substance to the lungs, and so, given the clear precedent set in previous EPO and UK Office decisions, such a claim would not be considered to be a valid second medical use claim under UK Office practice.

Support for the medical use in second medical use claims

162 Second medical use 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[81], 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*[134] and *McManus's Application*[135].

"...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*[136] 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*[80] confirmed that speculative second medical use 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.

"...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."

Prendergast's Applications [2000] RPC 446

163 The requirement for some experimental support for second medical use claims was confirmed by the Patents Court decision in *El-Tawil's Application*[116]. The evidence provided does not need to meet the standard required of, for example, a peer-reviewed journal[94]. 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[16 81]. However, a claim to a broader class of diseases may be justified if the applicant can show that it could reasonably be predicted from the demonstrated activity that the agent will treat the diseases in question. In *Regeneron Pharmaceuticals v Genentech*[127 128], it was held, on the facts of the case, that it was reasonable to predict that an anti-angiogenic effect demonstrated in tumours would also extend to non-neoplastic diseases characterised by excessive angiogenesis (growth of new blood vessels into a tissue).

133 T 138/95 GENENTECH
134 Hoerrmann's Application [1996] RPC 341
135 McManus's Application [1994] FSR 558
136 Consultant Suppliers' Application [1996] RPC 348

164 The judge in *Prendergast's Applications*[80] 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.

165 In T 609/02[137], the EPO also concluded that second medical use claims must be supported by some evidence, filed in the specification, of the likely efficacy of the compound in question. The objection was phrased in terms of sufficiency rather than support, but the effect is the same.

"If the description of the patent specification, like in the present case, provides no more than a vague indication of a possible medical use for a chemical compound yet to be identified, later more detailed evidence cannot be used to remedy the fundamental insufficiency of such subject matter."

T 609/02 SALK INSTITUTE

A similar conclusion was reached in T 491/08[138], where it was emphasised that post-filed evidence could only be used to back up the findings provided in the patent application, and not in itself to establish sufficiency of disclosure

166 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 MoPP 18.43).

Claims to Pharmaceutical Compositions

Compositions adapted to a particular use

167 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 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[139]. 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.

137 T 609/02 SALK INSTITUTE
138 T 491/08 GOVERNMENT OF USA
139 T 289/84 WELLCOME/3-Amino-pyrazoline derivatives [1987] EPOR 58

168 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[140] and T 401/90[141], 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 second medical use claims, although this would not normally be appropriate for methods of contraception as they are not excluded under Section 4A(1).

169 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

170 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[142]) 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[142].

171 Terms such as "therapeutically effective amount" of an active ingredient are generally considered to be clear. However, if such a term is used to distinguish the composition from the prior art, then this is open to objection unless the specification teaches how this is tested, or there is a standard test in the art[143]. The purity of a product cannot be defined merely by defining the substance "as a pharmaceutical product"[144].

Compositions with a new non-medical purpose or property

172 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. 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. 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. In this respect, the Intellectual Property Office has not followed the decision of the EPO Enlarged Board of Appeal in G 02/88[121], where it was held that novelty could be derived from a new technical effect (see MoPP 2.14-2.14.1).

140 T 303/90 VICTORIA UNIVERSITY MANCHESTER
141 T 401/90 VICTORIA UNIVERSITY MANCHESTER
142 T 80/96 LONZA/L-Carnitine OJEPO 2000, 50
143 T 151/01 INSITE VISION
144 T 226/98 RICHTER GEDEON/Famotidine OJEPO 2002, 498

Claims to unit dosage forms

173 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.

174 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.

175 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 patient's body weight have been rejected as lacking in support, as have claims derived from the amounts of active ingredient fed to experimental animals.

Combined preparations and packs of medicaments

176 It is common in the pharmaceutical field for inventions to relate to the combined 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*[145] the first question that must be addressed is whether – for the purpose of assessing inventive step – 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.

177 Moreover, synergistic effects between the components must be identified **in the specification**[146]. Evidence of synergy provided after the filing date cannot be used to demonstrate inventiveness, if there is no indication of such synergy in the specification as filed[147].

"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 [2004] RPC 43

178 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*[146] and *Richardson-Vicks' Patent*[147] 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[148].

145 SABAF v MFI Furniture Centres [2005] RPC 10
146 Glaxo Group's Patent [2004] RPC 43
147 Richardson-Vicks' Patent [1995] RPC 568
148 T 492/99 NIPRO

179 In *Richardson-Vicks' Patent*[147] 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. On the other hand, if there is a **technical** prejudice that would point away from the combination in question, then inventiveness may be acknowledged, even if the combination is superficially obvious[149].

180 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 Board of Appeal in T 09/81[75]. It was held in this case that the combination was novel and inventive, but needed to be "purpose limited" - ie in the first or second 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 Intellectual Property 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.

181 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)[150]. However, the acceptance of second medical use claims has now made such claims redundant in the medical fields.

182 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 Application*[151], 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.

149 Norbrook Laboratories' Patent [2006] FSR 18
150 Bayer's (Meyer's) Application [1984] RPC 11
151 Organon's Application [1970] RPC 235

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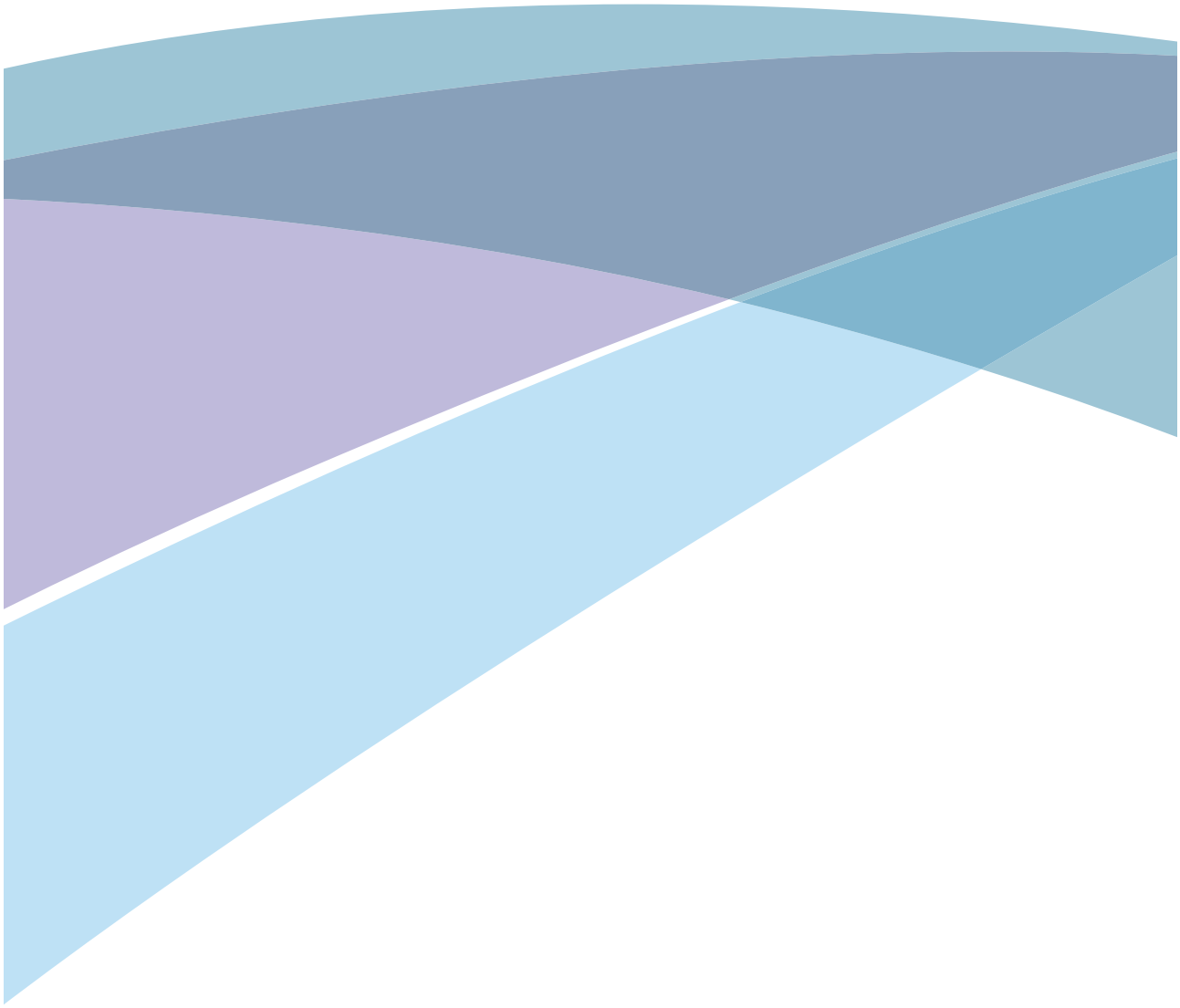

Concept House
Cardiff Road
Newport
NP10 8QQ

Tel: 0300 300 2000
Minicom: 0300 0200 015
Fax: 01633 817 777
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Published: May 2013

DPS/P500/05-13