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Patent Protection for Second and Further Medical Uses Under the European Patent Convention

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Abstract

It was only eleven years after the European Patent Convention (EPC) 1973 came into force that the Enlarged Board of Appeal (EBA) in EISA/Second medical indication finally settled the issue of whether patent protection should be provided for second or further medical uses of substances or compositions. This issue had divided the delegations during the drafting of the EPC, where the pharmaceutical industry lobbied tirelessly for patent protection. The EBA's decision did not sit comfortably with the text of Article 54(5) EPC 1973 and seemed contrary to the intentions of the drafters of the EPC. An examination of: (a) the intentions of the framers of the EPC; (b) the considerations that guided the EBA; and (c) the subsequent developments at the EPO, is poignant given the importance of patent protection for second and further medical uses in fuelling research and development in finding cures of illnesses. Consequently, the objectives of this paper are to: first, examine the travaux préparatoires of the EPC to see what light they shed on the interpretation of Article 54(5) EPC 1973; second, explore the origins of second medical uses and the decision of the EBA in EISA/Second medical indication; third, delineate the requirements of the Swiss-type claim, including the form of claim; fourth, examine the decisions applying EISA/Second medical indication to find out whether they have extended that decision beyond its original parameters; and, fifth, evaluate the recent changes heralded by the EPC 2000.

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1. Introduction

The drafters of the European Patent Convention (EPC) appreciated the importance of research and development to the pharmaceutical industry. However, for policy reasons, methods of medical treatment were excluded from patent protection.¹ The exclusion of methods of medical treatment from patent protection found in article 53(c) EPC 2000² relates to (a) methods for treatment of the human or animal body by: (i) therapy;³ and (ii) surgery;⁴ and (b) diagnostic methods practised on the human or animal body.⁵ Seemingly by way of compensation, the second sentence of article 53(c) provides that the methods of medical treatment exclusion shall not apply to products – in particular, substances or compositions – for use in any of these methods. In other words, substances used in treating patients remained patentable notwithstanding the medical treatment exclusion. A further and more important provision directly impacting upon the pharmaceutical industry was provided for in article 54(5) EPC 1973⁶ for medical uses of known substances and compositions. The inventive and innovative function of the patent system clearly is very pronounced in

¹ For a detailed consideration of the exclusions found in Article 52(4) EPC, see E Ventose, “Patent Protection for Surgical Methods Under the European Patent Convention” (2008) 39 *International Review of Intellectual Property and Competition Law*, 51-82; E Ventose, “Patent Protection for Diagnostic Methods Under the European Patent Convention” (2007) 38 *International Review of Intellectual Property and Competition Law*, 884-907; and E Ventose, “Patent Protection for Therapeutic Methods Under the European Patent Convention” (forthcoming).

² This article was previously Article 52(4) EPC 1973. With the entry into force of the EPC 2000 on 13 December 2007, Article 52(4) EPC has been replaced by Article 53(c) EPC 2000. The content of the exclusion of methods of medical treatment remains unchanged, but the juridical basis of the exclusion found in Article 52(4) EPC has been excised from the new formulation of the exclusion found in Article 53(c) EPC 2000. The drafters of the EPC 2000 made it clear that “[a] change in the EPO’s current practice regarding these inventions is not envisaged” as a result - The Basic Proposal for the Revision of the European Patent Convention, 13 October, 2000, Article 53 EPC, Explanatory Remarks, at para 3.

³ There has been no decision of the EBA considering this exclusion. For an examination of the jurisprudence relating to this exclusion, see Ventose, note 1 above. However, the EBA has considered the scope of Article 54(5) EPC relating to second (and further) medical uses of substances or compositions used in methods of medical treatment in G 05/83 *EISAI/Second medical indication* [1979-85] EPOR B241. For a consideration of the application of that decision to surgical methods, see E Ventose, “No European Patents for Second Medical Uses of Devices or Instruments” [2008] *European Intellectual Property Review*, 11-16.

⁴ See the decision of the TBA in T 0992/03 *MEDI-PHYSICS/Treatment by Surgery* [2007] EPOR 32 which has referred three questions relating to the scope of the exclusion of methods of treatment of the human or animal body by surgery to the EBA for its consideration. See also Ventose, note 1, at 51-82; E Ventose, “Exclusion of methods for treatment of the human or animal body by surgery from patent protection” (2007) *Journal of Intellectual Property Law and Practice*, 574-576.

⁵ See the recent decision of the EBA in G 01/04 *CYGNUS/Diagnostic method* [2006] EPOR 15. See also Ventose, note 1 above, at 884-907; E Ventose, “Making sense of the decision of the Enlarged Board of Appeal in *CYGNUS/Diagnostic method*” [2008] *European Intellectual Property Review*, 145-150.

⁶ This is now found in Article 54(4) EPC 2000. See also Article 54(5) EPC (2000).

this field.⁷ Research into further medicinal uses of current drugs and known substances will be enhanced, and any refusal to recognise second-use patents would deprive inventors of their just reward.⁸

When a product is newly discovered, it can be claimed as a product and for that particular use. When a product is old, the exclusion of methods of medical treatment assumes particular significance, because the claim would be for the product for use in a particular therapeutic method – i.e. a claim to a method of medical treatment using the particular substance or composition. In *EISAI/Second Medical Indication*,⁹ the Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) was faced with the question of whether article 54(5) EPC 1973 allowed second (and further) medical uses. This article aims to: first, examine the *travaux préparatoires* of the EPC to see what light they shed on the interpretation of article 54(5); second, explore the origins of second medical uses and the decision of the EBA in *EISAI/Second medical indication*; third, delineate the requirements of the Swiss-type claim, including the form of claim; fourth, examine the decisions applying *EISAI/Second Medical Indication* to find out whether they have extended that decision beyond its original parameters; and, fifth, evaluate the recent changes heralded by the EPC 2000.

2. Legislative History

A limited exception for second medical use patents was made to the exclusion of methods of medical treatment.¹⁰ Some organisations – for example the European Industrial Research Management Association (EIRMA) and the *Fédération Internationale des Conseils en Propriété Industrielle* (PICPI) – proposed that “new therapeutic applications of known substances should not be excluded from patentability”,¹¹ and that rules should be adopted to encourage research into new therapeutic applications of known substances.¹² It was argued that “[w]ithout such incentive, the pharmaceutical industry might well concentrate its research efforts on entirely new products or compounds, which would be very costly to perfect.”¹³ At a Working Party meeting in 1971, it was pointed out that interested parties “had proposed that [the exclusion for methods of medical treatment] should not extend to

⁷ See T Scassa, “Patents for Second medical indications and their Potential Impact on Pharmacase in Canada” (2001) 9 *Health Law Journal* 23-59 for a detailed account of the law in Canada. See generally B Domeij, *Pharmaceutical Patents in Europe* (Kluwer Law International, 2000).

⁸ *Ibid.*

⁹ [1979-85] EPOR B241. See generally J Pila, “Article 52(2) of the Convention on the Grant of European Patents: What did the Framers Intend?” (2005) 36 *IIC* 755-787.

¹⁰ See the comments made at the 5th Meeting of the Inter-Governmental Conference for the Setting up of a European System for the Grant of Patents, Part II, Hearing of the Non-Governmental Organizations on the Second Preliminary Draft Convention establishing a European System for the Grant of Patents, Luxembourg, 26 January to 1 February 1972, at para 17.

¹¹ They also proposed that a method of interpreting the exclusion should be included in the Implementing Regulations: *ibid.*

¹² *Ibid.*

¹³ *Ibid.*

‘new therapeutic applications of known substances.’”¹⁴ The pharmaceutical industry, however, argued that “in the interests of humanity, it was desirable to include such applications as patentable.”¹⁵ The Working Party claimed that the reasons advanced were “not sufficient to justify the claims by the pharmaceutical industry and it would be contrary to the common practice in most countries.”¹⁶

When the question of “whether a new therapeutic use of a known substance should be included in the category of patentable inventions” was considered by the Working Party in 1972,¹⁷ a majority were “in favour of the Convention not specifying explicitly that such a thing was excluded.”¹⁸ From the discussions held, one suggestion – which the Working Party considered “more satisfactory”¹⁹ – was that patent protection might conceivably cover a substance for a specific indicated purpose.²⁰ The United Kingdom delegation expressed reservations on the very principle of patentability of new uses of known substances, and finally on the desirability of drawing a distinction between the first use and subsequent uses.²¹ The United Kingdom, Danish and Netherlands delegations suggested replacing paragraph 2(d) of article 50 with article 52, paragraph 5, which read as follows:

*Neither the provisions of this Article, nor those of Article 50, shall be interpreted as excluding the patentability of an invention consisting of a substance per se as a medicament provided that the state of the art does not include any such use of that substance.*²²

The word “substance” was thought to be too restrictive, especially in light of the fact that the text of article 50(2)(d) referred to “compounds”.²³ It was noted that in a system which allowed the patentability of new substances, it was indispensable that this provision should refer specifically to known substances.²⁴ Since there was no

¹⁴ Minutes of the 9th meeting of Working Party I held from 12 to 22 October, 1971, in Luxembourg, at para 92. The Working Party observed that the amendment was “based on the conception that, whereas new drugs were well protected by patents either in their processes or in respect of the products themselves, there was no economic incentive to invest in research involving new therapeutic uses of known substances as these are not patentable”.

¹⁵ *Ibid.*

¹⁶ *Ibid.*

¹⁷ Minutes of the 11th Meeting of the Working Party I held in Luxembourg from 28 February to 3 March, 1972, at para 9(a).

¹⁸ *Ibid.*

¹⁹ *Ibid.*

²⁰ *Ibid.* The first being the “use of the substance for the purposes indicated could form the subject of the patent protection, on the understanding that the proprietor would institute proceedings only against an intermediary infringer (competing producer) and not against the real infringer, who would be the doctor.”

²¹ *Ibid.*

²² Minutes of a 3rd Meeting of the Co-coordinating Committee, Luxembourg, 17, 23 and 24 June 1972, at para 5.

²³ *Ibid.*

²⁴ *Ibid.*

dispute as to the “justification for inserting a new provision of this nature in Article 52 on novelty”,²⁵ the Working Party wondered whether “a provision along the same lines be inserted in Article 50 on patentability, in order to avoid any possible doubt.”²⁶ In the end, the Working Party decided that it was preferable to suspend examination of that point to “enable the delegations to seek a solution”,²⁷ which would take into account all the points raised that might be submitted to the Conference.²⁸ Some interested parties proposed to allow the “patentability of a new therapeutic application of already-known substances”.²⁹ The Conference noted that other delegations proposed that the last suggestion should at least be adopted in the Convention, leaving it open to the jurisprudence of the EPO to decide on treatment by therapy other than physical and on new therapeutic applications of known substances.³⁰ Consequently, the Conference directed the Working Party to re-examine that proposal.³¹

Some delegations were of the opinion that they interpreted article 50(5) as not excluding the patentability of known substances or compositions, even if they are not used for the first time in an absolute sense for the purpose referred to in article 50(2)(d).³² Others made it clear that they would accept article 50(5) if it was “applicable only to the use for the first time in an absolute sense of any methods referred to in [Article 50(2)(d)].”³³ The Conference concluded the discussion by observing that extending the scope of Article 50(5) beyond instances of use for the first time in an absolute sense comprised a modification of the compromise proposal contained in Working Document No. 28.³⁴ The Netherlands delegation proposed a change in the wording of the provision, which by now was article 52(5), to read as follows:

*The provisions of par[a] 1-4 shall not exclude the patentability of any substance or composition, disclosed as such in the state of the art, for use in a method referred to in article 50 par[a] 2(d), provided that its use for no such method has been disclosed in the state of the art.*³⁵

²⁵ *Ibid.*

²⁶ *Ibid.*

²⁷ *Ibid.*

²⁸ *Ibid.*

²⁹ Minutes of the 5th Meeting of the Inter-Governmental Conference for the Setting up of a European System for the Grant of Patents, Parts I and III, Luxembourg, 24-25 January and 2-4 February 1972, at para 33.

³⁰ *Ibid.*

³¹ *Ibid.*

³² Minutes of a 6th Meeting of the Inter-Governmental Conference for the setting up of a European System for the Grant of Patents, Luxembourg, 19-30 June 1972, at para 31.

³³ *Ibid.*

³⁴ *Ibid.*

³⁵ Comments by the Netherlands Government on the proposed amendments concerning the draft convention and the draft implementing regulations, in particular, Article 52(5), Munich, 1 June 1973 at para 9.

There was no unanimity relating to the scope of the provision – some organisations supported the patenting of only the first medical use of substances or compositions.³⁶ Others, however, thought that the article could be clarified even further so as to emphasise that even a further new use of a substance or composition may be patented.³⁷

At the Munich Diplomatic Conference, the Netherlands delegation wanted the wording of paragraph 5 improved. They pointed out that on no account did they wish, with their proposal, to break away from the principle that only the first application in respect of the use of a known substance or composition in a method for the treatment of a human or animal body by surgery or therapy is patentable, and not the second and subsequent applications.³⁸ The Yugoslav delegation sought clarification on the meaning of the words “even when the substance or composition in question is disclosed in the state of the art.”³⁹ The Chairman replied as follows:

*[T]he aim in paragraph 5 was to make clear that a known substance (or a known composition) which, since it formed part of the state of the art, was no longer patentable, nevertheless could be patented for the first use in a method for treatment of the human or animal body by therapy; however, a further patent could not be granted if a second possible use were found for the same substance, irrespective of whether the human or animal body was to be treated with it.*⁴⁰

The Chairman noted that his views were shared by the various government delegations⁴¹ and did not wish to endorse the view that the provision applied for the first medical use of the human body, and the medical first use of the animal body.⁴²

The *travaux préparatoires* suggest that there was some controversy between member states concerning the meaning of the Article. The majority were in favour of a restrictive interpretation, thereby excluding patent protection for second and further medical uses. Others, for example, the pharmaceutical industry, argued for patent protection for foster continued research and development in finding new uses of known drugs.

³⁶ Comments by Standing Conference of the Chambers of Commerce and Industry of the European Economic Community on the proposed amendments concerning the draft convention and the draft implementing regulations, Munich, 1 June 1973, at para 4.

³⁷ Comments by the *Comite pour la Protection de la propriete industrielle dans la Communaute Economique Europeene* on the preparatory documents for the Munich Diplomatic Conference, 30 March 1973, at para 7.

³⁸ Minutes of the Munich Diplomatic for the Setting up of a European System for the Grant of Patents, Munich 10 September to 6 October 1973, at para 54.

³⁹ *Ibid*, at para 56.

⁴⁰ *Ibid*.

⁴¹ *Ibid*, at para 58.

⁴² *Ibid*, at paras 29-60.

3. The Origin of Second Medical Uses

3.1. Initial Exclusion

Initially, the EPO was reluctant to grant patents for second (or further) medical uses based on a literal reading of the relevant Articles. The Technical Board of Appeal (TBA) of the EPO consistently reiterated that only the first medical use was protected under article 54(5) EPC 1973. The issue first arose in *HOFFMAN-LA ROCHE/Pyrrrolidine derivatives*,⁴³ where the claims covered known pyrrolidine derivatives whose pharmaceutical uses were not known. It was later found out that the derivatives were suitable for combating cerebral insufficiency and improving intellectual ability. The TBA accepted that article 54(5) EPC 1973 introduced a special concept of novelty that was unknown in other technical fields⁴⁴ and that the history of the EPC did not reveal any uniform idea on the breadth of the claim for pharmaceutical inventions.⁴⁵ The TBA noted that it was “impossible to derive from the *travaux préparatoires* any arguments in favour of limiting claim scope.”⁴⁶ According to the TBA, the practice of the EPO indicated that claims for therapeutic compounds, not limited to specific indications, were allowed even though as a rule they were limited to only specific activities.⁴⁷ The principle of equal treatment, the TBA argued, meant that an inventor who had discovered a new therapeutic use of a known compound “should be rewarded with a purpose-limited substance claim under Article 54(5) EPC to cover the whole field of therapy.”⁴⁸ The TBA concluded that novelty was destroyed by the fact that the same therapeutic effect was already known in the prior art and the disclosure of any other specific therapeutic application.⁴⁹ This meant that the initial discovery of one therapeutic effect of a known substance or composition would give that patentee a monopoly over all future discoveries of new therapeutic effects. The term composition was to have a wider meaning which may legitimately cover a situation where the compounds are presented side-by-side, and not as a union.⁵⁰

Whether a claim for the use of a substance or composition for therapy was admissible given the prohibition in article 52(4) EPC 1973 was the issue for consideration in *BAYER/Nimodipin (I)*.⁵¹ The TBA observed that, in view of the exclusion found in article 52(4), it did not seem that use claims were allowable.⁵² The TBA therefore referred a question to the EBA in accordance with Article 112(a) of the EPC in the

⁴³ [1979-85] EPOR B591.

⁴⁴ *Ibid*, at para 9.

⁴⁵ *Ibid*.

⁴⁶ *Ibid*.

⁴⁷ *Ibid*, at para 10.

⁴⁸ *Ibid*.

⁴⁹ *Ibid*, at para 13. This was accepted by the TBA in T 43/82 *ROUSSEL-UCLAF/Tetrahydropyridinyl-Indole Derivatives* [1979-85] EPOR B448.

⁵⁰ T 09/81 *ASTA/Cytostatic Combination* [1979-85] EPOR B303, B306.

⁵¹ [1979-85] EPOR B320.

⁵² *Ibid*, at para B321.

following terms: “[c]an [a] patent be granted for the use of a substance or composition for the treatment of the human or animal body by therapy?”⁵³ The EBA answered the question in the negative, but sanctioned the use of claims in the Swiss form in its decision in *EISAI/Second Medical Indication*.⁵⁴

3.2. EISAI/Second Medical Indication

The question of whether article 54(5) EPC 1973 included second and further medical uses was answered in the affirmative by the EBA in *EISAI/Second Medical Indication*.⁵⁵ The EBA was of the opinion that a claim to the use of a compound or composition for the therapeutic treatment of the human body was no different from a claim to a method of treatment by therapy of the human body with the substance or composition⁵⁶ – the only difference was one of form and it would be in conflict with article 52(4) EPC 1973.⁵⁷ The EBA held that “use claims” were acceptable, but that the particular claimed use must not be directed at one of the excluded methods found in article 52(4) EPC 1973.⁵⁸ Such “use claims” are substantially equivalent to process claims.⁵⁹ The EBA opined that the inventor of a first medical use can obtain a purpose-limited product protection for a known substance or composition when the claim was in a form that was technically adapted to a specified therapeutic purpose.⁶⁰ This was contrary to the previous jurisprudence of the TBA, where the inventor of a first medical use would get a purpose-limited claim over the entire method in question. Claims that were directed to the use of a substance or composition for the treatment of the animal and human body by therapy were excluded from patent protection, because they were “in direct conflict with the provisions of Article 52(4).”⁶¹ This formulation, the EBA held, was no different from a claim directed to a method of medical treatment of the human or animal body by therapy with the substance or composition. The difference, the EBA asserted, was simply one of form.⁶²

To circumvent that problem, the EBA accepted the practice of the Swiss Federal Intellectual Property Office,⁶³ which had sanctioned claims that were directed to the “use of a substance or composition for the manufacture of a medicament for a

⁵³ T 17/81 *BAYER/Nimodipin (I)* [1979-85] EPOR B320, 322.

⁵⁴ T 80/96 *LONZA/L-Carnitine* [2000] EPOR 323.

⁵⁵ G 05/83, [1979-85] EPOR B241. See also E Ventose, “Patent Protection for Methods of Medical Treatment in the United Kingdom” [2008] *Intellectual Property Quarterly*, 58-81, at 71.

⁵⁶ G 05/83, *EISAI/Second medical indication*, at para 12; [1979-85] EPOR B241.

⁵⁷ *Ibid*, at para 13.

⁵⁸ *Ibid*, at para 12.

⁵⁹ T 0532/96 *LEO PHARMACEUTICALS PRODUCTS LTD/EDTA-free Heparins* at para. 2.2.3.

⁶⁰ G 05/83, *EISAI/Second medical indication*, at para 15; [1979-85] EPOR B241.

⁶¹ *Ibid*, at para 13.

⁶² *Ibid*. See also T 0532/96 *LEO PHARMACEUTICALS PRODUCTS LTD/EDTA-free heparins*, at para 2.2.2.

⁶³ [1984] OJEPO 581.

specified (new) therapeutic application.”⁶⁴ This method, the EBA emphasised, meant that there may be problems relating to the novelty of the invention. Nevertheless, it did not seem too concerned about this.⁶⁵ The claim, however, must be in the Swiss form to avail itself of such protection. As I have stated elsewhere, “the novelty of the medicament was derived from the new pharmaceutical use – not the product – since the product was old (the very reason for the origin of such use claims).”⁶⁶ The EBA pointed out that claims that were in the Swiss-type of claim did not conflict with article 52(4) of the EPC 1973 and that it was “justifiable by analogy”⁶⁷ with first medical uses to derive novelty for the new claim notwithstanding the existence of a known pharmaceutical use.⁶⁸ The EBA argued that this was possible because the exclusions existed to “free from restraint non-commercial and non-industrial medical and veterinary activities.”⁶⁹ This was an ingenious way around the exclusion for methods of medical treatment found in article 52(4), because the novelty of such claims was derived not in the *substance* or its *use* but in the *new purpose* that it was put to. This applied even if the manner of manufacture did not differ from what was applied before using the same substance or composition. The EBA observed that there was no intention to exclude second and further medical indications and none can be deduced from the terms of the EPC or the legislative history of the relevant articles.⁷⁰ Consequently, the EBA reasoned that it was legitimate *in principle* to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture does not differ from known processes using the same active ingredient.⁷¹

The EBA correctly pointed out that it was legitimate in principle to allow such patents given the rationale of the patent system to encourage research and development, in this instance to finding new uses of old substances and compositions. However, the question remained whether the rule articulated by the EBA was internally coherent. It was beyond doubt that article 54(5) EPC 1973 allowed first medical use patents – the claim would provide purpose-limited patent protection for a known substance or composition. If, however, the substance or composition already has a known medical use then the exception begins to bite.⁷² In the case of second medical use patents, the claim cannot be for the use of the substance or composition for any therapeutic purpose because it will offend against article 52(4). To circumvent this, the EBA accepted the Swiss-type form of claim directed to the use of a new substance or composition for the manufacture of a medicament for a specified (new) therapeutic application.

⁶⁴ G 05/83, at para 19; [1979-85] EPOR B241.

⁶⁵ *Ibid*, at para 18. See also Ventose, note 55 above, at 71.

⁶⁶ See also Ventose, note 55 above, at 71.

⁶⁷ G 05/83, *EISAI/Second medical indication*, at para 21; [1979-85] EPOR B241.

⁶⁸ *Ibid*.

⁶⁹ *Ibid*, at para 22. See also Ventose, note 55 above, at 71.

⁷⁰ G 05/83, *EISAI/Second medical indication*, at para 23; [1979-85] EPOR B241.

⁷¹ *Ibid*.

⁷² W Cornish and D Llewelyn, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 6th ed (Sweet and Maxwell, 2007), at 223.

4. Requirements of the Swiss-type claim

To secure patent protection, the Swiss-type claim must satisfy two criteria: (a) the manufacture of a medicament; and (b) a new therapeutic application.⁷³ They are indispensable requirements of the Swiss-type claim and both have the functions of identifying novelty and defining the scope of the claim in question.

4.1 Manufacture of a Medicament

The use of the Swiss-type claim arguably enabled patentees to circumvent the exclusion of methods of medical treatment in article 52(4) EPC 1973 by claiming the manufacture of the medicament. The claim for the preparation of a medicament is an invention for a process, which means that the exact manner of manufacture must be clearly delineated in the claims.⁷⁴ If the patent merely teaches how the invention is to be used, it will be a use claim and an excluded method of medical treatment.⁷⁵ This aspect of the Swiss form of claim has not been subject to detailed examination by the TBA. Usually, that requirement does not get mentioned at all. This has, however, changed with the decision of the TBA in *Kanegafuchi Kagaku Kogyo Kabushiki Kaisha*⁷⁶ (KKKKK), which focussed on that aspect of the claim. The claim in KKKKK related to the use of an adsorbent which was claimed in the Swiss-type form. The question for the TBA was whether the different medical indications (the differences in the intended use of the adsorbent, characterised by the different proteins to be removed) could confer novelty on the claims in which further medical indications were stated.⁷⁷ The appellants argued that the claim for the adsorbent was directed at a new therapeutic application, because it consisted of removing at least one cytokine selected from a group from a patient's body fluid, which treated one of the diseases specified in the claims.⁷⁸ The TBA considered the decision of the EBA in *EISAI/Second Medical Indication*, and was of the opinion that the structure of the Swiss-type claim contained three elements, namely: (a) the use of a compound or composition; (b) for the manufacture of a medicament; and (c) for a therapy.⁷⁹ The TBA was of the opinion that conditions (a) and (c) were "doubtlessly satisfied in the claims under examination"; however, it was "not convinced that condition b) [was] met and, more specifically, that the claims indeed relate to the manufacture of a medicament."⁸⁰ The TBA thought it unnecessary to entertain all possible definitions

⁷³ T 0787/00 *KIRIN-AMGEN/Erythropoietin*, at para 8.

⁷⁴ *Monsanto & Company v Merck & Co Inc* [1999] RPC 77, at 92.

⁷⁵ T 0138/95 *GENENTECH INC/Intrapulmonary delivery*.

⁷⁶ T 0138/02.

⁷⁷ *Ibid*, at para 2.1.

⁷⁸ *Ibid*, at para 2.4.

⁷⁹ *Ibid*, at para 2.5.

⁸⁰ *Ibid*, at para 2.6.

of the term ‘medicament’, but was convinced that its use in the application did “not meet at least one essential characteristic of a medicament”,⁸¹ namely:

*[T]hat it be administered to a patient’s body in order to treat a disease. This means that the medicament is brought into contact with the body in order to deliver and apply a substance or composition in an effective form and dose for it to develop its therapeutic effects within the patient’s body.*⁸²

The TBA held that the porous adsorbent did not and could not be administered or applied directly to the human body.⁸³ The adsorbent was actually used in a cartridge (which is located in a circulation cycle outside the body) provided with a filter when the body fluid is passed through it.⁸⁴ The application resembled a membrane for blood dialysis.⁸⁵ The TBA argued that there was no analogy with an active carbon, which is taken orally to adsorb toxic species in their passage through the gastrointestinal ducts, because “the active carbon is administered to the patient and develops its therapeutic effect within the patient’s body, contrary to the present adsorbent.”⁸⁶ A change in the wording of the claim from “adsorbent” to “adsorbent medicament” did not change the substance of the claim, because “the adsorbent does not become a medicament simply by calling it so.”⁸⁷ The claimed method was therefore not a medicament, so the appellant could not rely on the jurisprudence of the EPO relating to second and further medical uses.

4.2 New Therapeutic Application

The other distinct feature of the Swiss-type claim is that the claim must indicate a new therapeutic application. In other words, the claims must, first, provide for a therapeutic application; and, second, indicate that the therapeutic application is new.⁸⁸ This meant that the novelty of the claim should not reside in the *manner of use* but in the *new therapeutic purpose* that the substance was put to.⁸⁹ The manner of use would effectively be the method of treatment which can be evidenced by showing that there is no connection between the new use and any old uses.⁹⁰ As the EBA put it in *EISAI/Second Medical Indication*, the claim must be directed to a known medicament to treat an illness *not previously treated* by means of that substance, in order for it to

⁸¹ *Ibid.*

⁸² *Ibid.*

⁸³ *Ibid.*

⁸⁴ *Ibid.*

⁸⁵ *Ibid.*

⁸⁶ *Ibid.*

⁸⁷ *Ibid.*, at para 2.8.

⁸⁸ See T 81/84 *RORER/Dysmenorrhea*, [1988] EPOR 297 and T 584/88 *REICHERT/Anti-snoring means* [1989] EPOR 449.

⁸⁹ G05/83 *EISAI/Second Medical Indication*, at para 17; [1979-85] EPOR B241.

⁹⁰ *John Wyeth & Brothers Ltd’s Application and AG’s Schering Application* [1985] RPC 545, at 566.

be patentable.⁹¹ The first point was emphasised by the TBA in *ELI LILLY/Serotonin Receptor*⁹² where the claims related to the use of (R)-fluoxetine for the preparation of a medicament for the treatment of certain conditions in mammals. The TBA reiterated that the applicant “needed to find a *practical* application in the form of a defined, real treatment of a pathological condition for their discovery in order to make a technical contribution to the art” (emphasis added).⁹³ This reason is correct because one cannot determine whether or not the therapeutic application is new if one cannot first determine the exact nature of the treatment.⁹⁴ Therefore, the claims must define the subject matter specifically before it can claim protection under this method. So, for example, where claims merely stated that the use of hydroxyl sine or lysine when used in the preparation of medicaments could treat certain specified conditions, but did not provide the evidence of the effectiveness of this in the claims, they were denied patent protection.⁹⁵ Similarly, to be patented, it must be shown that an invention had actually been made, not a mere possibility that it could be made.⁹⁶

The decision of the TBA in *LONZA/L-Carnitine*⁹⁷ has, however, cast doubt on the approach mentioned above. In that decision, the claim was for the use of L (-) carnitine, but the claims did not contain any specific therapeutic use. The substance was known to have therapeutic applications for a variety of illnesses. Therefore, in accordance with the received learning of the TBA, the claims should have been rejected on the basis that there was no specific therapeutic treatment. However, the TBA held that the use of a substance to make a new pharmaceutical product *without delimitation as to indication* does not contravene the requirements of articles 57 and 52(1) of the EPC.⁹⁸ A closer reading of the decision showed that the claim was not actually based on the Swiss-type claim alone, but also consisted of a claim for the product itself. Where two diseases share a similar origin or causative factors, the second therapeutic application would be a reason to not find inventive step.⁹⁹ Where, however, the medical effect of the substance is uncertain, the claim will not amount to a second medical use in accordance with *EISAI/Second medical indication*. For example, in *STERLING/S(+)-ibuprofen*,¹⁰⁰ the claim was for a pharmaceutical composition containing S(+)-ibuprofen substantially free of its R(-)antipode. The appellant argued that, in light of the decision of the EBA in *EISAI/Second medical*

⁹¹ G05/83 *EISAI/Second Medical Indication* [1979-85] EPOR B241, B248. The determination of whether a claim satisfied the conditions of the Swiss-type formula meant that it was sensible to distinguish between methods of medical treatment by therapy and surgery: T 775/97 *EXPANDABLE GRAFTS/Surgical device* [2002] EPOR 24, 30. See generally Ventose, note 3 above, at 11-16.

⁹² T 241/95, [2001] EPOR 292. See also T 0385/07 *PHARMA MAR/Apilide*, at para 12.

⁹³ T 241/95, at para 3.1.2; [2001] EPOR 292 (emphasis added)

⁹⁴ See also T 0292/99 *NIPRO/Combined anti-inflammatory agent*, at para. 3.3.

⁹⁵ T 80/96, *LONZA/L-Carnitine* [2000] EPOR 322. See, generally, T 0825/94 *SQUIBB/Prostaglandin analogs*.

⁹⁶ *Hoerrmann's Application* [1996] RPC 341, at 345. This decision was applied in *Mc Manus Application* [1993] FSR 558 and *Consultants Suppliers Ltd's Application* [1996] RPC 348, 352.

⁹⁷ T 80/96 [2000] EPOR 323.

⁹⁸ *Ibid*, at para 2.

⁹⁹ T 913/94 *EISAI/Medicament for Gastritis*, at para 3.3.6; [2001] EPOR 362.

¹⁰⁰ T 315/98 [2000] EPOR 401.

indication, the achievement of hastened onset of analgesia was novel, because it was not made available to the public before the filing date.¹⁰¹ The TBA held that it could agree that the achievement of an analgesic response in a human by using a specific pharmaceutical composition may represent a medical indication, but that it had:

Strong doubts whether the mere reference in a claim to hastened onset of analgesia, the analgesic effect of that composition is known the prior art, can be regarded as a second or further medical indication within the meaning of [EISAI/Second medical indication].¹⁰²

Claims would not be acceptable to the EPO if they simply provide increased information about an old therapeutic application or treatment. This was the case in *VERICORE/Sea Lice Infestation*,¹⁰³ where the TBA clarified that increased information about the pathology would not render the claims patentable. The TBA argued that the mere explanation of an effect obtained when using a known substance – even if the explanation relates to a pharmaceutical effect which was not known to be due to that substance – could not confer novelty on a known treatment if the skilled person was already aware of the occurrence of the desired effect when applying the known treatment.¹⁰⁴ The TBA therefore concluded that the finding that cypermethrin was not only effective on the mature developmental stages of sea lice but also on immature developmental stages, such as the chalimus and copepodid phases, did not result in a different pathology being treated.¹⁰⁵

5. Acceptable Form of Claim

The TBA has emphasised that since Swiss-type claims do not conflict with Article 52(4) and 57 EPC 1973 and irrespective of the purpose they serve, “no prior evidence of further medical use need to be submitted for this form of claim to be included in the patent application.”¹⁰⁶ In *Therapeutic Substitutes/Anti-tumoural Agent*,¹⁰⁷ the claim was for the use of a dextran derivative to manufacture an agent for inhibiting the growth of tumour cells. The derivative also had known uses as an anticoagulant and anti-inflammatory agent. The TBA emphasised that the EBA in *EISAI/Second medical indication* referred “not to the formal aspect of the category of the claim but rather its substance, i.e. the definition of the claimed invention in terms of its essential characteristics.”¹⁰⁸ This was because: first, such inventions could be claimed as either the application or use of a substance or composition to achieve a certain result or a method or process to achieve the same (both types of claim involve a sequence of

¹⁰¹ *Ibid.*, at para 8.6.

¹⁰² *Ibid.*, at para 8.7.

¹⁰³ T0708/02 (dated 4 April 2006).

¹⁰⁴ *Ibid.*

¹⁰⁵ *Ibid.*

¹⁰⁶ T 143/94 *MAI/Trigonelline*, at para 3.2; [1996] EPOR 613.

¹⁰⁷ T 958/94 [1997] EPOR 417.

¹⁰⁸ *Ibid.*, at para 3.3.

steps giving rise to the final effect); second, a claim to the use of a substance or composition for therapeutic purposes is no different in substance from a claim to a method of medical treatment or manufacturing a medicament. The TBA emphasised that, under *EISAI/Second Medical Indication*, both the use and method type of claim circumscribe in the same way as the activity of formulating the medicament's active substance which constituted the process for obtaining the medicament. As a result, the TBA held that there can be no argument that the scope of protection conferred by use or method claims under Article 64(2) EPC could be invoked solely in order to draw an *artificial substantive* distinction between the two.¹⁰⁹ This means that the form of claim can fall within any of those identified by the EBA in *EISAI/Second Medical Indication* as sufficient for protecting second and further medical uses.

In *ZAIDAN/Benanomicin A*,¹¹⁰ the TBA considered the decision in *Therapeutic Substitutes/Anti-tumoural Agent* wherein the TBA accepted that Swiss-type claims may be claimed as either: (a) the use of the compound for the manufacture of a medicament for the therapeutic application; or (b) a process for the manufacture of a medicament for the therapeutic application characterised in the use of the compound.¹¹¹ In *ZAIDAN/Benanomicin A*, the claim related to the use of benanomicin A as an agent for inhibiting infection with a virus causative of acquired human immunodeficiency syndrome or for inhibiting syncytium formation of human T-cells induced by the same virus.¹¹² The TBA accepted the statement in *Therapeutic Substitutes/Anti-Tumoural Agent* that there was no difference in substance between where the subject-matter of the claimed invention is defined in accordance with the form and wording mentioned under (a) above, or in accordance with the wording and form mentioned under (b) above.¹¹³ The TBA, therefore, concluded that there was no reason why these principles should not equally apply to the first and second sets of claims, noting that it considered these two sets of claims as equivalent. This meant that “the subject matter of the second set of claims [was] also novel”,¹¹⁴ because “of the hitherto undisclosed therapeutic application of benanomicin A.”¹¹⁵

6. Extending the reach of the EISAI principle

Unsurprisingly, the TBAs were burdened with considering which claims satisfied the requirements of the Swiss-type claim sanctioned by the EBA in *EISAI/Second medical indication*. As mentioned above, the Swiss-type claim must consist of a manufacture of a medicament and a new therapeutic application of the medicament. However, the TBA in *DUPHAR/Pigs II* allowed claims that were directed at the administration of a vaccine to sero-positive pigs where the vaccine was not previously

¹⁰⁹ *Ibid*, at para 3.4.

¹¹⁰ T 0853/94.

¹¹¹ *Ibid*, at para 3.3.

¹¹² *Ibid*, at para 3.2.

¹¹³ *Ibid*, at para 3.3.

¹¹⁴ *Ibid*, at para 3.4.

¹¹⁵ *Ibid*, at para 3.2.

applied to that class of pigs.¹¹⁶ The TBA observed that in the case before it there was no new therapeutic application of the vaccine of the kind that was before the EBA in *EISAI/Second medical indication*, namely an application to a different ailment.¹¹⁷ Indeed, the novelty of the invention was that the known vaccine was effective on a new class of pigs – sero-positive pigs – that are maternally immune.¹¹⁸ In the TBA’s opinion, the question was whether the application of the vaccine to this new class of pigs can be considered a new therapeutic application from which novelty for the claims can be derived, in accordance with the principles enunciated by the EBA in *EISAI/Second medical indication*.¹¹⁹ The TBA noted that:

*The concept of patentability of the use of a substance or composition for the manufacture of a medicament for a new and inventive therapeutic application in accordance with the decision of the [EBA in EISAI/Second medical indication] even for a substance or composition, the use of which in therapy is known, should be broadly construed.*¹²⁰

The TBA clarified that such a new use was not only valuable in cases where a novel area of therapeutic use (i.e. a novel medical indication) was provided but also in those cases where a novel class of animals – which previously did not respond to a medicament – was cured or protected against a disease.¹²¹ This meant that:

*The question whether a new therapeutic use is in accordance with the decision [EBA in EISAI/Second medical indication] should not be answered exclusively on the basis of the ailment to be cured but also on the basis of the subject (in the present case the new group of pigs) to be treated. A medical indication is incomplete if the subject to be treated is not identified; only a disclosure from which both the disease and the subject to be treated are clear represent a complete technical teaching.*¹²²

This reasoning is dubious indeed. The *EISAI/Second medical indication* principle demanded that the medical purpose be novel. The fact that the class of animal treated was different is immaterial to the proper scope of the enquiry.¹²³ The TBA only had to find a *new* therapeutic application, *not* a new class of subject to which the substance or composition could *then* be applied.¹²⁴

¹¹⁶ T 19/86 *DUPHAR/Pigs II* [1988] 1 EPOR 10. See also E Ventose “‘Farming’ out an Exception to the Exclusion of Methods of Medical Treatment under the European Patent Convention” [2008] *European Intellectual Property Review*, 509-514.

¹¹⁷ T 19/86 *DUPHAR/Pigs II*, at para 6; [1988] 1 EPOR 10.

¹¹⁸ *Ibid.*

¹¹⁹ *Ibid.*

¹²⁰ *Ibid.*, at para 8.

¹²¹ *Ibid.*

¹²² *Ibid.*

¹²³ See T 0469/94 *MIT/Perception of fatigue*, at para 5.2.

¹²⁴ A similar argument was rejected in T 0486/01 *GENTECH INC/IGF-1*, at para 11; [2006] EPOR 9.

The issue was also considered in *MEDCO RESEARCH/Adrenaline*¹²⁵ where the claim related to the administration of adenosine to a human who was unable to exercise adequately. The TBA observed that the purpose of this feature was to confine the use of the diagnostic agent to an allegedly novel sub-group of patients as compared to the patients referred to in the closest prior art.¹²⁶ The TBA applied *DUPHAR/Pigs II* noting that, in its view, the position was that if the use of a compound was known in the treatment of a disease, the treatment of the same disease with the same compound could nevertheless represent a novel therapeutic or diagnostic application, provided that two conditions were satisfied.¹²⁷ The first was that the treatment must be carried out on a novel group of subjects which is clearly distinguishable with respect to its physiological or pathological status from and does not overlap with the group previously treated.¹²⁸ In relation to the second, the TBA pointed out that:

[T]he choice of the new group, if distinguishable from the known one, must not be arbitrary, which means that there must exist a functional relationship between the particular physiological or pathological status of this new group and the therapeutic effect obtained. In other words, the peculiar feature identifying the new group of patients must have a real impact on the result of the treatment, since it is able finally to “change” the treatment itself.¹²⁹

The TBA noted that these considerations applied to the use of a substance as a diagnostic agent, but that none of the above mentioned conditions were satisfied in the case before it. In relation to the first condition, the TBA found that the limitation to patients who were unable to exercise adequately was too vague and general.¹³⁰ In respect of the second, the TBA held that no evidence or argument was produced by the appellant to show any interaction between the physical hindrance and the hyperaemic effect cause by adenosine.¹³¹

7. Reform of the European Patent Convention

The EPC 2000 has put the issue of second medical use patents beyond doubt. Article 54(5) EPC 1973 has become article 54(4) EPC 2000 because of the deletion of the Article 54(4) EPC 1973. Article 54(4) EPC 2000 remains substantially the same as before, except that instead of providing that “the provisions of paragraphs 1 to 4 shall not exclude the patentability of...”, the new provision reads: “the provisions of

¹²⁵ T 0233/96. See also T 893/90 *QUEEN’S UNIVERSITY KINGSTON/Controlling bleeding*, at para 4.3.

¹²⁶ T 0233/96, at para 8.6.

¹²⁷ *Ibid*, at para 8.7.

¹²⁸ *Ibid*. This decision was applied in T 0708/02 *VERICORE/Sea lice infestation*, at para 3.1.2.

¹²⁹ *Ibid*.

¹³⁰ *Ibid*, at para 8.8.

¹³¹ *Ibid*. See, also, T 1031/00 *SEPRACOR INC/Method and composition for treating hypertension*, at para 2.3.

paragraphs 2 and 3 shall not exclude the patentability of...” This does not change the substance of the provision. A new provision was added, however. The new article 54(5) EPC 2000 provides that, notwithstanding paragraphs 2 and 3, the provisions of this article shall not exclude the patentability of any substance or composition referred to in paragraph (4) for any specific use in any method referred to in article 53(c), provided that such use is not comprised in the state of the art. This removes any doubt that second and further medical uses are patentable. The use that is now patentable must not have formed part of the prior art. This confirms *EISAI/Second Medical Indication* and reaffirms the salient principle found therein that it is only the new use that must be novel, although the substance or composition need not be.¹³²

The Swiss delegation at the Revision Conference stated succinctly that:

*The new 54(5) EPC eliminates any legal uncertainty on the patentability of further medical uses. It unambiguously permits purpose-related product protection for each further new medical use of a substance or composition already known as a medicine. This protection is equivalent, as far as the further uses are concerned, to that offered by the “Swiss type claim”. In contrast to previous Article 54(5), now Article 54(4) EPC, providing broad (generic) protection for use in a medical method for the inventor of such use for the first time, new Article 54(5) is expressly limited to a specific use. This limitation is intended to match as closely as possible the scope of protection to the scope provided by a “Swiss type claim”.*¹³³

Interestingly, the TBA in *KOS LIFE SCIENCES INC/Dosage regimen* has recently referred three questions to the EBA relating to the scope of article 54(5) EPC 2000 for its consideration. In particular, it asked whether dosage or treatment regimes are patentable under article 53(c) and 54(5) EPC 2000.¹³⁴

8. Conclusion

The demands of the pharmaceutical industry held sway and the EPO interpreted the EPC in light of the needs of the industry. The decision of the TBA *EISAI/Second medical indication* to allow patent protection for second (and further) medical uses was a watershed in the jurisprudence of the EPO. Even if the decision was criticised because it did not result from the wording of Article 54(5) EPC – and was contrary to the intentions of the drafter of the EPC – the result was a practical one. It provided patentees with the much-needed incentive of the patent system to justify continued research and development in finding new and further uses of substances and compositions. In the process, the EPO arguably carved a major exception to the exclusion for methods of medical treatment. Subsequent decisions of the TBA have

¹³² See T 0385/07 *PHARMA/Aplidine* (dated 5 October 2007), at para 21.

¹³³ Basic Proposal – Explanatory notes – Article 54(4) and Article 54(5) EPC – drawn up by the Swiss delegation, Munich, 21 November 2000.

¹³⁴ T 1319/04 dated 28 April, 2008. See also, E Ventose, Patenting treatment or dosage regimes under Article 53(c) and 54(5) EPC 2000” (2008) *Journal of Intellectual Property Law and Practice*, 540-542.

extended the *EISAI/Second medical indication* principle beyond its known parameters. If there was any doubt as to the need of that incentive provided for by *EISAI/Second medical indication*, article 54(5) EPC 2000 means that there is now a statutory basis for second (and further) medical uses under the EPC. It will therefore no longer be necessary to resort to the Swiss form of claim.