Is the Enlarged Board of Appeal of the European Patent Office authorised to extend the bounds of the patentable?
The G-3/85 Second medical indication/EISAI and G-2/08 Dosage regime/ABBOTT RESPIRATORY cases

JULIAN COCKBAIN[1] and SIGRID STERCKX[2]

> "Praetorian law ... is that which in the public interest the [judges] have introduced in aid or supplementation or correction of the [civil law]."[3]
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> "Quis custodiet ipsos custodes?"[4]

Abstract

The *European Patent Convention* (EPC), which governs the grant of European patents by the European Patent Office (EPO), forbids the grant of patents for methods of medical treatment. In 1984, in an attempt to find a manner in which European patents could be granted to those who found new medical treatments using existing drug compounds, the Enlarged Board of Appeal (EBoA) of the EPO sanctioned a novel form of patent claim, the "Swiss-type use claim", under which a known process for producing a known drug product was considered to acquire novelty by virtue of the new use to which the drug product was to be put. Following the revision of the EPC in 2000, in a 2010 decision, the EBoA has declared that the Swiss-type use claim is no longer to be permitted. In this article we explore the 1984 and 2010 decisions and their ramifications for the many European patents already granted with Swiss-type use claims. We conclude that the 2010 decision is both courageous and correct.

Introduction

European patent applications filed from 29 January 2011 and with no earlier priority date will no longer result in the grant of European Patents with Swiss-type use claims, i.e. claims of the format "Use of substance X for the manufacture of a medicament for use in the treatment of ailment Y". This was stipulated in the EBoA decision G-2/08 Dosage regime/ABBOTT RESPIRATORY[5] from February 2010 and in a notice from the EPO published in its Official Journal in October 2010.[6]

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[1] European Patent Attorney and partner of Dehns, Oxford, UK. The views expressed herein are those of the author and not of his firm or its clients.
[2] Professor of Ethics and Bioethics, Universiteit Gent and Vrije Universiteit Brussel, Belgium.
[3] According to Roman jurist and Praetorian Prefect AEMILIUS PAPINIANUS (PAPINIAN) (142-212 A.D.), Definitiones.
[4] Roman satirist DECIMUS IUNIUS IUVENALIS (JUVENAL), Satire VI.
[5] G-2/08 Dosage regime/ABBOTT RESPIRATORY, OJ EPO 456-494 (2010).
[6] OJ EPO 514-515 (2010).

The UK Patent Office acted even more quickly, stating on 26 May 2010 that Swiss-type use claims would be objected to with immediate effect.[7]

Swiss-type use claims[8] had been accepted by the EPO since the earliest decision of the EBoA in December 1984, G-5/83 Second medical indication/EISAI.[9] The "need" for such claims arose because of the prohibition in Art. 52(4) of the 1973 version of the EPC of the grant of European patents for methods of surgery, therapy or diagnosis.[10] Where a drug known for one treatment was found to be useful in another, for example against a different disease or in a different dosage regime, the "invention" could not be patented as the drug per se or as a method of using the drug, but the expense of regulatory clearance for the new treatment would still have to be incurred before the drug could be supplied for use in the new treatment. Swiss-type use claims offered a possibility of obtaining patent protection in such cases.

For known substances found to have a medicinal use *for the first time*, Art. 54(5) EPC 1973 provided an exception to the rules of novelty, allowing purpose-limited claims to the substance per se. Prior to the EISAI decision, in Germany[11] claims to a substance found to have a new medicinal use were allowed in the format "use of compound X for the treatment of ailment Y" and the Swiss Patent Office had come up with the Swiss-type use claim format.[12] The EBoA, in EISAI, decided that while the

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[7] UNITED KINGDOM PATENT OFFICE (2010), available at http://www.ipo.gov.uk/p-pn-medical.htm [last checked 8 December 2010].

[8] For a recent review, see: EDDY D VENTOSE, "Patent Protection for Second and Further Medical Uses Under the European Patent Convention", 6 SCRIPTed 57-74 (2009). For an early review explaining some of the concerns with Swiss-type use claims, see: JEAN M MILLER, "Patentability of a Second Indication of a Pharmaceutical in Europe", 26 IDEA 15-24 (1985-6). A memorable comment on the Swiss-type use claim format was made by Jacob J in the British Patents Court in Bristol-Myers Squibb v. Baker Norton in 1998: "I must now say something about the general structure of the [Swiss-type use claim at issue]. I daresay that an ordinary skilled man (to whom it is notionally addressed) would find it puzzling, unless he had been initiated in some of the Byzantine logic of patent law and jurisprudence." See Bristol-Myers Squibb Co. v. Baker Norton Pharmaceuticals Inc., RPC 253-281 (1999), at 271.

[9] G-5/83 Second medical indication/EISAI, OJ EPO 64-66 (1985). The EBoA rendered the same judgement in six other cases, G-1/83 BAYER, G-2/83 DR KARL THOMAE, G-3/83 CIBA-GEIGY, G-4/83 DR KARL THOMAE, G-6/83 PHARMUKA and G-7/83 C H BOEHRINGER SOHN.

[10] EUROPEAN PATENT OFFICE, Convention on the Grant of European Patents (European Patent Convention), 70, 12th Ed. (European Patent Office, Munich 2006). References to Articles in this version, the first version, of the EPC have been supplemented in this paper by the year 1973. References to the current version of the EPC carry no year indicator.

[11] OJ EPO 26-41 (1984) - Hydropyridine. Here it should be borne in mind that, prior to the EPC coming into effect in 1978, the German courts had a somewhat "relaxed" attitude towards the wording of patent claims, an attitude that was addressed in the Protocol on the Interpretation of Article 69 of the Convention (see European Patent Office, *supra* note 10, at 84). To quote from the EBoA decision G-2/88 Friction reducing additive/MOBIL III: "In some countries, in particular Germany, in practice the protection conferred by a patent depended more upon what was perceived to be the inventor's contribution to the art, as disclosed in the patent, by way of the general inventive concept, than upon the wording of the claims." (See MOBIL III, *infra* note 24, at 98).

[12] SWISS FEDERAL INTELLECTUAL PROPERTY OFFICE, Legal advice dated 30 May 1984, OJ EPO 581-584 (1984).

German format was not acceptable under the EPC,[13] the Swiss-type use claim format was acceptable.

In the UK, in 1985, the Patents Court, somewhat reluctantly, decided to follow the EISAI decision and allow Swiss-type use claims in John Wyeth's and Schering's Applications.[14]

Problems with Swiss-type use claims

The major problem with the Swiss-type use claim format was of course that *the novelty of the claimed subject-matter derived entirely from the intended end use of the drug*, and, the first indications of Art 54(5) EPC 1973 aside, purpose-limitation has generally not been considered to confer novelty on a product. Product X for use Y is interpreted as covering product X *in a form suitable for* use Y, and if the old drug formulation could be used in the new treatment then the Swiss-type use claim would seem to lack novelty.

However, the claim format also poses problems when it comes to determining whether infringement has occurred. This may be illustrated by the drug acetyl salicylic acid (aspirin), which for decades has been available over the counter (i.e. not requiring a prescription) in tablet form as an analgesic. Recently, aspirin has been suggested to be useful in reducing the occurrence of cancers. In Swiss-type claim form, this could have been claimed as "The use of acetyl salicylic acid for the manufacture of a medicament for use in prophylactic treatment against cancer." Consider then three cases where a patient has taken aspirin tablets for this purpose: the first where the patient has bought the tablets over the counter in a package from company A labelled as for analgesic use, a packaged form that has been available from long before the new indication was found; the second where the tablets were made by company B, bought by company C in bulk and packaged as for analgesic or cancer prophylaxis use; and the third where the tablets were made by company D and packaged by the same company as for analgesic or cancer prophylaxis use.

[13] In EISAI, the EBoA was clearly tempted to follow the German Federal Supreme Court but drew back stating "It is ... difficult for the [EPO] to follow the practice of a superior court of only a single Contracting State in a matter which has a bearing on questions of infringement and which is regarded as controversial, however eminent that court may be. It is to be regarded as unfortunate that the appellant in the *Hydropyridine* case withdrew his appeal to the English Courts against a refusal of the United Kingdom Patent Office to grant a patent for the same invention. The decisions of the national courts of two Contracting States tending in the same direction might have had great weight." (EISAI, *supra* note 9, at 66). The English Patents Court responded to this in John Wyeth's and Schering's Applications (*infra* note 14, at 559): "we should, we think, make it clear that in our judgement, the reasoning and decision of the [Patent Office in the equivalent UK case] were correct and ... [the equivalent claims in John Wyeth's application] were rightly refused by the [Patent Office] as contrary to section 4(2) [the equivalent of Art. 52(4) EPC 1973]." More recently, in the 2006 Carvedilol II decision, the German Federal Supreme Court has diverged from the EPO's interpretation of the acceptability of second medical use claims, more particularly claims characterised by the dosage regime rather than by a treatment of a new disease. See for example Franz-Josef Zimmer and Steven Zeman, "Applicant Friendliness of the European Patent Office for Second Medical Use Claims: A Mixed Blessing", 26 Biotechnology Law Report 341-347 (2007).

[14] John Wyeth and Brother Ltd.'s Application and Schering A.G.'s Application, RPC 545-568 (1985).

In the first case, the tablets only became "for use in prophylactic treatment against cancer" when they were purchased and consumed by the patient. Company A has no control over the intentions and actions of the purchaser and clearly could not be held to infringe. In the second case, bulk manufacturer B again has no control over the actions of its customer C or the intentions of the end user - it is simply continuing to do something (tablet manufacture) which it may have been doing for years and again seems unlikely to be found to infringe. Even in the third case, since the tablets are packaged for two alternative uses and since actual consumption can only be for one of these uses, the tablets again only become "for use in prophylactic treatment against cancer" when they are purchased and consumed by the patient. If an action can only become infringement when a drug is consumed, it would seem that the process covered by the claim would have to be interpreted as including the act of consumption, which would make the process unpatentable as a method of medical treatment. Thus it would appear that the Swiss-type use claim is only infringed if the *manufacturer* of the tablets, at the time of manufacture, intended (all) the tablets to be used for the new indication.

Philip Grubb has commented:

> "At best, a patent containing a Swiss-type claim may be used to prevent a competitor from actively promoting the compound for the new use, by advertisements, package inserts, etc., but it cannot prevent doctors from prescribing for the patented new use a generic product which is already on the market for an earlier indication."[15]

Besides direct infringement, there may be contributory infringement of a patent claim, where the infringer supplies something which can be used by the recipient to put the invention into effect. However, since, in the case of a Swiss-type use claim, the "invention" claimed is the process for manufacturing the tablets, a bulk manufacturer such as company B cannot be guilty of contributory infringement as it supplies the product of the process and not a means for putting the process into effect.

The 2000 revision of the EPC

The situation concerning patent protection for *second and further* medical indications changed with the revision of the EPC in 2000,[16] when a new clause, Art. 54(5) EPC, was added, allowing purpose-limited product per se claims for drugs found to be useful in new treatments. This clause reads as follows:

> "[The provisions mandating novelty for claimed subject matter] shall ... not exclude the patentability of any substance or composition, comprised in the state of the art [i.e. not novel], for use in a method [for

[15] PHILIP W GRUBB, Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy, 243, 4th Ed. (Oxford University Press, Oxford 2004).
[16] EUROPEAN PATENT OFFICE, Convention on the Grant of European Patents (European Patent Convention), 13th Ed. (European Patent Office, Munich 2007).

> treatment of the human or animal body by surgery or of diagnosis practised on the human or animal body], provided that such use is not comprised in the state of the art."[17]

Interestingly, Art. 54(5) EPC was introduced at the suggestion of Switzerland.[18] Even more interestingly, the submissions made by the Swiss delegation in support of the new clause, to the effect that it did no more than transpose into statute law the effects of the *EISAI* decision, were misleading and incorrect. This was apparently not picked up by the other delegates to the Munich Conference at which the adoption of Art. 54(5) EPC was approved. We have discussed the misleading nature of the Swiss submissions elsewhere.[19] It was also discussed in an amicus curiae brief[20] filed in ABBOTT RESPIRATORY, and, at length, at the EBoA oral proceedings in ABBOTT RESPIRATORY.[21] Put briefly, the position regarding patent infringement by medical practitioners at least is worsened by the adoption of Art. 54(5) EPC.

In ABBOTT RESPIRATORY, the EBoA did acknowledge that Art. 54(5) EPC went beyond simply codifying the result of the EISAI decision:

> "It appears that the rights conferred on the patentee by the claim category under Article 54(5) EPC are likely broader, and could, in particular, lead to possible restrictions on the freedom of medical practitioners to prescribe or administer generics."[22]

More to the point, however, in ABBOTT RESPIRATORY the EBoA decided that Swiss-type use claims were no longer necessary, and should no longer be allowed, in view of the adoption of Art. 54(5) EPC:

> "Article 54(5) EPC now permits purpose-related product protection for any further specific use of a known medicament in a method of therapy. Therefore ... the loophole existing in the provisions of the EPC 1973 [whereby there was no clear basis in the EPC for allowing patent protection for drugs found to have a second (or further) medical use] was closed.
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> In other words "*cessante ratione legis, cessat et ipsa lex*", when the reason of the law ceases, the law itself ceases.
>
> The cause of the praetorian approach ceasing, the effect must cease."[23]

Nonetheless, in the revision of the EPC in 2000, no amendment was made which specifically accorded or denied patentability to Swiss-type use claims.

In patent law in general, the applicant is free to define her invention as she wishes. The claim chosen is examined for patent-eligibility under Art 52(2) and Art 53 EPC, and then for novelty, inventive step, susceptibility to industrial application,

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[17] *Ibid*., at 82.
[18] EUROPEAN PATENT OFFICE, MR/18/00: Basic Proposal - explanatory notes - Article 54(4) and Article 54(5) EPC (European Patent Office, Munich 2000).
[19] SIGRID STERCKX and JULIAN COCKBAIN, "Purpose-Limited Pharmaceutical Product Claims under the Revised European Patent Convention: A camouflaged Attack on Generic Substitution?", Intellectual Property Quarterly 88-107 (2010).
[20] JULIAN COCKBAIN (2009), Amicus curiae brief dated 21 May 2009, available at https://register.epoline.org/espacenet/application?documentId=EOVYKLSM8034154&number=EP94306847&lng=en&npl=false&seql=false [last checked 14 December 2010].
[21] SIGRID STERCKX, "Dosage regime claims in the European Patent Office", European Intellectual Property Review 294 - 298 (2010).
[22] ABBOTT RESPIRATORY, *supra* note 5, at 490.
[23] *Ibid*., at 492.

sufficiency of disclosure, and clarity. Apart from the addition of Art. 54(5) EPC, these gate-keepers to the patentability of further medical indication inventions were essentially unchanged in the 2000 revision. Why then should an applicant no longer be free to use Swiss-type use claims? The key, we feel, is to be found in the EBoA's references to "praetorian" law in the ABBOTT RESPIRATORY decision.

As is clear from the opening quote of this article, praetorian law is judicially-made law and can go beyond the simple "interpretation" of the statute law which courts are required to do. The EPC, however, is an international treaty for which amendment to the definitions of what is and is not patentable requires ratification by all the member states (as was done with EPC 2000). The following questions thus arise: (i) did the EBoA, in EISAI, extend the scope of the subject-matter for which European patents could be granted beyond the scope permitted by EPC 1973? (ii) if it did not, then why are Swiss-type use claims no longer to be permitted? (iii) if it did, then are the European patents which have been granted with Swiss-type use claims invalid? and finally (iv) are the days of the much-reviled Mobil use claim[24] also numbered?

Before commenting on these issues, we must draw attention to the breathing space that EPO Boards of Appeal have to create new law. First, we must quote Paul Van den Berg, the erstwhile chairman of EPO Technical Board of Appeal (TBoA) 3.5.1 and for a long time a member of the EBoA:

> "[EPO] boards of appeal cannot assume the role of legislator. They have to apply the law as it stands and cannot strive to meet wishes which are incompatible with the provisions of the European Patent Convention."[25]

Further, we would draw attention to the powers of the Boards of Appeal to "interpret" the EPC as set out in the EPC:

> "In their decisions the members of the Boards ... shall comply ... with the provisions of the [EPC]."[26]

Finally we would refer to the minutes of the Munich Diplomatic Conference of 1973, the conference at which the wording of EPC 1973 was agreed, and in particular to two comments relating to Art. 54(5) EPC 1973, the clause which permitted purpose-

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[24] G-2/88 Friction reducing additive/MOBIL OIL III, OJ EPO 93-113 and 469 (1990); MOBIL III confirmed that in the EBoA's opinion a known product, found to have a new use or effect which may have been implicit but was unrecognised, could be validly claimed in a purpose-limited use claim format. This was said to apply even to products which were not medicaments. This decision deprived the public of the freedom to carry out an act described in the prior art in the way described in the prior art and with the only difference being that the previously unrecognised effect was now both recognised and intended. *MOBIL III* was commented on, with extreme care to avoid the suggestion that it was bad law, by the UK House of Lords in Merrel Dow Pharmaceuticals Inc. and Anr. v. H.N. Norton & Co. Ltd., RPC 76-93 (1996).

[25] PAUL VAN DEN BERG, "Patentability of computer-software related inventions", in Members of the Enlarged Board of Appeal of the EPO, The Law and Practice of the Enlarged Board of Appeal of the European Patent Office during its first ten years, 45 (Carl Heymanns, Cologne 1996).

[26] EUROPEAN PATENT OFFICE, *supra* note 16, Art. 23(3) EPC, at 50.

limited claims to a known compound which has been found for the first time to have a medicinal use:

> "The Netherlands delegation proposed that the wording of [Art. 54(5) EPC 1973] ... should be improved. It said that on no account did it wish, with its proposal, to break away from the principle that only the first application of the use of a known substance or composition in a method for treatment of the human or animal body by surgery or therapy is patentable, and not the second and subsequent applications. ...
>
> The Chairman replied to the Yugoslav delegation and said that, in his opinion, the aim in [Art. 54(5) EPC 1973] was to make it 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 the treatment of the human or animal body by surgery or 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. ... The Chairman noted that his views were shared by the Government delegations"[27]

From this, it seems clear that the intention of the legislators of EPC 1973, unlike that of the legislators of EPC 2000, was to provide a loophole (to the exclusion from patentability of inventions which were methods of medical treatment) *only* for compounds found for the *first* time to have a medicinal use. *EISAI* went against this intention by allowing claims (Swiss-type use claims) to second and subsequent indications.

For answers to the four questions we posed above, we must turn to the texts of the EISAI and ABBOTT RESPIRATORY decisions.

The EISAI Decision

In EISAI, the justification given for accepting Swiss-type use claims was as follows:

> "As is rightly recognised ... Article 52(1) EPC [1973] expresses a general principle of patentability for inventions which are industrially applicable, new and inventive and it is clear that in all fields of industrial activity other than those of making products for use in surgery, therapy and diagnostic methods, a new use for a known product can be fully protected as such by claims directed to that use.
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> This is in fact the appropriate form of protection in such cases as the new and non-obvious use of the known product constitutes the invention and it is the clear intention of the European Patent Convention that a patent be granted for the invention to which a European patent application relates ... Article 54(5) EPC [1973] provides an exception to this general rule, however, so far as the first use of medicaments is concerned, in respect of which the normal type of use claim is prohibited by Art. 52(4) EPC [1973]. In effect, in this case the required novelty for the medicament which forms the subject-matter of the claim is derived from the new pharmaceutical use."[28]

Thus far, nothing much new or groundbreaking: where an invention resides in a new use for a known thing, that invention can be claimed as a method ("A method of doing new thing X using known thing Y"). Where the method is a medical treatment with a drug, however, such claims are not allowed and an alternative claim format is required. Where the drug is new, the claim can be to the drug as such. Where the drug is a known substance, but not a substance known to have medicinal properties,

[27] GOVERNMENT OF THE FEDERAL REPUBLIC OF GERMANY, Minutes of the Munich Diplomatic Conference for the Setting Up of a European System for the Grant of Patents (Munich, 10 September to 5 October, 1973), 29 (Bundesdruckerei Berlin, Berlin 1973).
[28] EISAI, *supra* note 9, at 66.

Art. 54(5) EPC 1973 provided a special exception, allowing the alternative format to be a purpose-limited product claim.

Art. 54(5) EPC 1973 states that the provisions of the rest of the Article, which say that an invention will be considered to be new if it does not form part of the state of the art, "shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method [of treatment] ... provided that its use for any method [of treatment] ... is not comprised in the state of the art." Since the drug compound as such is comprised in the state of the art, the first indication *invention* (Compound Y for use in medicine) is novel because "for use in medicine" provides novelty, i.e. in some way distinguishes over the drug as such and in some way is limitative. Art. 54(5) EPC 1973 thus provided a special exception to the general rule that a purpose limitation does not provide novelty over a known product *in a form suitable for that purpose* - the special exception however was relatively limited for, as a matter of fact, medicines do have to be made under special conditions and a compound that is known, but not known to have any medicinal use, would rarely be in a form suitable for use as a medicine. The same logic would *not* apply to a second or further medical indication, as the drug would very likely form part of the state of the art in a form suitable for the new use.

The EISAI Board continued:

> "It seems justifiable by analogy to derive the novelty for the process which forms the subject-matter of the type of use claim now being considered from the new therapeutic use of the medicament and this irrespective of the fact whether any pharmaceutical use of the medicament was already known or not."[29]

The analogy however is not so direct. In the Swiss-type use claim, which is directed to a *process* for preparing a product, the *invention* as claimed is a process but the purpose limitation is not on the process (the subject-matter of the claim) but on the product. The process claimed may be identical to a known process in all process aspects. In other words, strictly speaking, the invention forms part of the state of the art and therefore lacks novelty according to Art. 54 EPC 1973. The EISAI Board itself does mention in relation to Swiss-type use claims that "there may be a problem concerning the novelty of the invention."[30] The UK Patents Court, in John Wyeth's and Schering's Applications, felt similarly:

> "there can be no objections to the patenting in the Swiss form of claim of an invention directed to a second or subsequent medical use of a known pharmaceutical if the statutory requirement of novelty can be met.
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> However, that stated, had the matter to be considered on the wording of sections 1 to 4 of the UK statute (the 1977 Act) and without regard to the position, as it has developed, under the corresponding provisions of [EPC 1973], we think the better view would be that a claim in the Swiss form to an invention directed to the use of a known pharmaceutical to manufacture a medicament, not in itself novel, for a second or subsequent and novel medical use would not be patentable as lacking the required novelty. It has to be recognised that it would have been a simple matter to provide for the patenting of such an invention directed to a second medical use by the omission of the word "any" in section 2(6) [i.e. the section corresponding to Art. 54(5) EPC 1973], if it had been the intention of the legislature that a novel second or further use of a known pharmaceutical should be patentable."[31]

[29] *Ibid*.
[30] *Ibid*.
[31] John Wyeth's and Schering's Applications, *supra* note 14, at 565.

The UK Patents Court then reviewed the EISAI approach to the novelty of Swiss-type use claims and concluded that:

> "[the EBoA's] approach to the novelty of the Swiss type of use claim directed to a second, or subsequent, therapeutic use is equally possible under the corresponding provisions of the [UK] 1977 Act and, notwithstanding the opinion expressed earlier [i.e. the opinion quoted immediately above in this article] as to the better view of the patentability of such a Swiss type claim under the material provisions of the [UK 1977] Act considered without regard to the position, as it has developed, under the corresponding provisions of the [EPC 1973], having regard to the desirability of achieving conformity, the same approach should be adopted to the novelty of the Swiss type of claim now under consideration under the material provisions of the [1977 UK] Act."[32]

Put differently, the EBoA was wrong, but for the sake of uniformity its decision must be followed, at least until it is overturned by a higher court or by the EBoA itself.

Turning back to EISAI, the EBoA commented on the exclusion from patentability of methods of medical treatment and, reassuring itself that its view was also held by the German Federal Supreme Court, stated that: "The intention of Article 52(4) EPC [1973 - now replaced by its equivalent Art. 53(c) EPC] is only to free from restraint non-commercial and non-industrial medical and veterinary activities."[33]

Since medical practitioners may be involved in commercial activity and so be constrained by patents, for example on surgical devices or covering generic substitution,[34] this seems an all too convenient interpretation of the legislators' intention. Had the legislators' intention actually been to free medical practitioners from constraint by patents it would have been simple to add to the EPC an Article specifying that no act by a medical practitioner in the performance of her professional duties could constitute patent infringement. Instead, the EPC seems simply to have enshrined the earlier practice of the member states of just not allowing patents for methods of medical treatment.[35] Nonetheless, if the EISAI Board's interpretation is accepted, then it might have been expected that the EBoA would avoid expanding the range of patentable subject-matter the patenting of which could further add to the restraints on such practitioners.

The EISAI Board minimised the reach of the exclusion: "To prevent the exclusion from going beyond its proper limits, it seems appropriate to take a special view of the concept of the "state of the art" ... Article 54(5) EPC [1973] alone provides only a partial compensation for the restriction on patent rights in the industrial and commercial field resulting from [the exclusion]."[36]

At the Munich Diplomatic Conference in 1973, the French and German delegations had made it abundantly clear[37] that the scope of what was or was not patentable subject matter was too important to be left to the EPO's Administrative Council to decide, in other words it was only for the EPC Member States to agree that scope.

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[32] *Ibid.*, at 567.
[33] EISAI, *supra* note 9, at 66.
[34] SIGRID STERCKX and JULIAN COCKBAIN, *supra* note 19.
[35] See JUSTINE PILA, The Requirement for an Invention in Patent Law, 138 (Oxford University Press, Oxford 2010).
[36] EISAI, *supra* note 9, at 66.
[37] GOVERNMENT OF THE FEDERAL REPUBLIC OF GERMANY, *supra* note 27, at 28.

One wonders whether the delegations would have been comfortable with the scope of the patentable being broadened by the EBoA.

The EISAI Board then left credibility behind:

> "It should be added that the Enlarged Board does not deduce from the special provision of Article 54(5) EPC [1973] that there was any intention to exclude second (and further) medical indications from patent protection other than by a purpose-limited product claim. The rule of interpretation that if one thing is expressed the alternative is excluded ..., is a rule to be applied with very great caution as it can lead to injustice. No intention to exclude second (and further) medical indications can be deduced from the terms of the European Patent Convention: nor can it be deduced from the legislative history of the articles in question."[38]

As mentioned above, at the Munich Diplomatic Conference in 1973, the delegates had clearly taken a different position:

> "The Netherlands ... said that on no account did it wish, with its proposal, to break away from the principle that only the first application of the use of a known substance or composition in a method for treatment of the human or animal body by surgery or therapy is patentable, and not the second and subsequent applications. ...
>
> "The Chairman ... said that, in his opinion, the aim in [Art. 54(5) EPC 1973] was to make it 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 the treatment of the human or animal body by surgery or 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. ... The Chairman noted that his views were shared by the Government delegations"[39]

The EISAI Board then approved the use of Swiss-type use claims, i.e. found that purpose limitation could render an otherwise anticipated claim novel. This was praetorian law, i.e. the EBoA deciding that it was entitled to *supplement* or *correct* the EPC.

Interestingly, Technical Board of Appeal 3.3.4, in a decision in June 1994, rejected a process claim in the form "A process for the manufacture of a medicament for use in treatment X comprising mixing Y with a carrier and/or diluent" as lacking novelty while at the same time accepting that under EISAI the equivalent Swiss-type use claim ("Use of Y for the manufacture of a medicament for use in treatment X") was novel. Since the use claim is a process claim, this decision would seem bizarre without the following justification given by the Board:

> "[T]he novelty of the intended use of the product can only be taken into account as a technical feature limiting the claim where the claim takes the form of a use claim as approved of in decision G 5/83".[40]

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[38] EISAI, *supra* note 9, at 66.
[39] GOVERNMENT OF THE FEDERAL REPUBLIC OF GERMANY, *supra* note 27, at 29.
[40] T-51/93 HCG/SERONO (1994), available at http://legal.european-patent-office.org/dg3/pdf/t930051eu1.pdf [last checked 15 December 2010], at 7. Technical Board of Appeal 3.3.2 disagreed, however, and considered that formulation of a claim explicitly as a process was equally acceptable as formulation as a Swiss-type use. See: T-958/94 Anti-tumoral agent/THERAPEUTIQUES SUBSTITUIVES, OJ EPO 241-250 (1997); and T-853/94 Benanomicin A/ZAIDAIN (1998) available at http://legal.european-patent-office.org/dg3/pdf/t940853eu1.pdf [last checked 15 December 2010]. This disagreement between the two Boards on second indication claims is reflected in the ABBOTT RESPIRATORY case which resulted from the disagreement on dosage regime claims

This seems to be a statement that the Swiss-type use claim is in a category apart from other process claims, one to which the normal rules of novelty do not apply, i.e. that EISAI represented praetorian law which the Technical Board of Appeal was bound to follow.

The answer to the first of the questions posed above —whether the EBoA, in EISAI, extended the scope of the subject-matter for which European patents could be granted beyond the scope permitted by EPC 1973— is clearly yes. This is confirmed by the ABBOTT RESPIRATORY Board's references, discussed below, to EISAI as representing praetorian law. The second question, as to why Swiss-type use claims should no longer to be permitted, is thus redundant.

The ABBOTT RESPIRATORY decision

In ABBOTT RESPIRATORY, the EBoA revisited the topic of the Swiss-type use claims and argued as follows:

> "It has been established practice under the EPC 1973 that a patent related to a further medical indication of a known medicament could only be granted for a claim directed to the use of a substance or composition for the manufacture of a medicament for a specified therapeutic application ...
>
> Since the medicament *per se* was not new the subject-matter of such a claim was rendered novel by its therapeutic application ... This **praetorian** approach was a "special approach to the derivation of novelty" ... and therefore constituted a narrow exception to the principles governing the novelty requirements which was not intended to be applied in other fields of technology".[41]

Sadly, the EBoA's special approach to the derivation of novelty had become more broadly applied outside the field of medicine in G-2/88 Friction-reducing additive/*MOBIL III,* a decision that has been widely criticised. We should note however that this "special approach to the derivation of novelty", an approach under which something that lacks novelty under the normal approach, and hence would be unpatentable, is deemed novel and patentable, is described by the ABBOTT RESPIRATORY Board as a *praetorian* approach, i.e. one which goes beyond the law as agreed by the EPC 1973 legislators. This appears to be a clear admission that EISAI's acceptance of Swiss-type use claims was bad law which should be followed no longer. The ABBOTT RESPIRATORY Board proceeded first to explain how the "praetorian" approach had come about, before explicitly stating that it no longer had its place in European patent law:

> "That **praetorian** ruling found its cause in the fact that a claim directed to the use of the substance or composition for the treatment of the human body by therapy had to be regarded as a step of treatment ... A claim of that kind was forbidden. On the other hand only the first medical indication of a known composition in the form of a medicament was by virtue of Article 54(5) EPC 1973 (Article 54(4) EPC 2000) entitled to be drafted in the form of a purpose-related product claim. And since the intention of the legislator was clearly not to exclude second therapeutic indications of a known medicament from the field of patentability the so-called Swiss-type claim constituted the adequate but exceptional solution.

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between decisions from the same two Boards, with Board 3.3.4 in that instance being more generous than Board 3.3.2.

[41] ABBOTT RESPIRATORY, *supra* note 5, at 491 (emphasis added).

> Article 54(5) EPC now permits purpose-related product protection for any further specific use of a known medicament in a method of therapy. Therefore, as mentioned in the preparatory document (MR/24/00, point 139)[42] the loophole existing in the provisions of EPC 1973 was closed.
>
> In other words "*cessante ratione legis, cessat et ipsa lex*", when the reason of the law ceases, the law itself ceases.
>
> The cause of the **praetorian** approach ceasing, the effect must cease. ...".[43]

Note, however, that the ABBOTT RESPIRATORY Board merely *repeated* the EISAI Board's incorrect statement that "the intention of the legislator was clearly not to exclude second therapeutic indications of a known medicament from the field of patentability", without this time stating that it had studied the *travaux préparatoires*.

The Mobil use claims

According to the EBoA in MOBIL III, Mobil use claims are *not* process claims (unlike Swiss-type use claims. Hence, they must be purpose-limited product claims. They have to be one or the other after all, since inventions can only be claimed as products or processes.

This little piece of "Byzantine logic" is explained, if that is an appropriate word for it, in MOBIL III.

> "The recognition or discovery of a previously unknown property of a known compound, such property providing a new technical effect, can clearly involve a valuable and inventive contribution to the art.
>
> In countries such as Germany, such inventions have for many years commonly been sought to be protected by "use" claims".[44]

Thus far, nothing problematic for the EPC. The MOBIL III Board then commented on the purpose and features of the patent claims:

> "The purpose of claims under the EPC is to enable the protection conferred by the patent ... to be determined ...
>
> It follows that the technical features of the invention are the physical features which are essential to it".[45]

Again, so far, so good. Then the Board stated that for process claims "the technical features of a claim ... are the physical steps which define such activity [i.e. the process]" and that for product claims "the technical features of a claim to a physical entity are the physical parameters of the entity".[46]

The conclusion from this is mind-blowing:

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[42] EUROPEAN PATENT OFFICE, Conference of the Contracting States to Revise the 1973 European Patent Convention - Munich, 20 to 29 November 2000 - Conference Proceedings, 71, MR/24/00 e (European Patent Office, Munich 2003).
[43] ABBOTT RESPIRATORY, *supra* note 5, at 491-492 (footnote and emphasis added).
[44] MOBIL III, *supra* note 24, at 99. That "use", "process", and "method" claims are all of the same type was confirmed by the EBoA in MOBIL III. *Ibid*., at 98-99.
[45] *Ibid*., at 100.
[46] *Ibid*., at 100.

> "It ... follows that a claim to a particular use of a compound is in effect a claim to the physical entity (the compound) only when it is being used in the course of the particular physical activity (the use), this being an additional technical feature of the claim".[47]

> "Thus, provided that a use claim in reality defines the use of a particular physical entity to achieve an "effect", and does not define such a use to produce a "product", the use claim is not a process claim".[48]

This little piece of Byzantine logic is fatally flawed as can be seen if it is applied to the second medical indication of a known drug, e.g. aspirin to achieve a prophylactic effect against cancer. Expressed in a Mobil use claim form (rather than as a Swiss-type use claim), the "use" claim would read "Use of aspirin to achieve a prophylactic effect against cancer". The EISAI Board had, reluctantly, accepted that this was a claim to a *method* of medical treatment, and thus unpatentable. Even if the logic of MOBIL III is followed and this is read as a product claim, i.e. "Aspirin for use to achieve a prophylactic effect against cancer", the position of the claim does not improve - this claim format was explicitly rejected in the *travaux préparatoires* as quoted above.

Conclusion

Thus if the EBoA decides that something previously thought to be patentable is not, do the owners of patents or applicants for patents claiming such subject-matter have a "legitimate expectation" that their patents be held to be valid or that their applications be granted, despite the new decision? Normally, one would expect not - it is the interests of the public that must be guarded against the grant of unwarranted monopolies and not the interests of the investors and patentees who may have benefited for many years from an unjustified monopoly. Monopolies are an exception to business practice in Europe and one which requires justification to the public which, as a result of such monopolies, must pay prices for goods and services which are higher than those which might apply were there to be free and open competition. In a decision in December 2010, in G-1/08 Tomato/ISRAEL, the EBoA addressed this very point:

> "There can be no "legitimate expectation" that an interpretation of a substantive provision governing patentability given in a decision of the boards of appeal will not be overruled in the future by the Enlarged Board of Appeal, since recognising such an expectation as legitimate would undermine the function of the Enlarged Board of Appeal".[49]

It seems therefore that European patent claims which derive their novelty from purpose limitations, when subject-matter suitable for that purpose was known, might be invalid. The answer to the third question posed above, whether European patents which have been granted with Swiss-type use claims are invalid, seems to be yes.

Finally, to answer the fourth question, regarding the status of the Mobil use claim: if the EBoA's extension of the scope of what was patentable under EISAI was

[47] *Ibid.*, at 104.
[48] *Ibid.*, at 105.
[49] G-1/08 Tomato/ISRAEL (2010), available at http://documents.epo.org/projects/babylon/eponet.nsf/0/E72204692CFE1DC3C12577F4004BEA42/$File/G1_08_en.pdf [last checked 9 December 2010], at 32.

praetorian law, i.e. an action going beyond the powers of the EBoA, then so too was the MOBIL III decision. Few will regret its demise if our analysis is correct.

With a refreshing willingness to revisit its earliest decision, in ABBOTT RESPIRATORY the EBoA has laid to rest a claim format which should probably never have been permitted. Unlike the EISAI decision, the ABBOTT RESPIRATORY decision honours the law agreed to by the legislators. By recognising that Swiss-type use claims arose out of praetorian law, "the cause of [which] ceasing, the effect must cease",[50] the EBoA has courageously wiped its own slate clean.

[50] ABBOTT RESPIRATORY, *supra* note 5, at 492.