Applicant-friendliness of the EPO for second medical use claims: A mixed blessing

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Abstract: Technical Board of Appeal decision T1020/03 recently defined a policy of leniency toward the allowability of second medical use claims in the European Patent Office ("EPO"). Second medical use claims reciting *i.a.* administration steps were deemed allowable under Article 52(4) EPC, provided the claim adheres to the admissible format defined in Enlarged Board of Appeal decision G5/83. In contrast, the 2006 decision *Carvedilol II* of the German Federal Supreme Court ("FSC") denied the patentability of similar claims in Germany, maintaining that administration steps represent subject matter excluded from patentability under Article 52(4) EPC. These contradictory practices bear the dangerous potential for the regular grant of second medical use claims before the EPO which are *a priori* invalid in Germany. We discuss relevant details and legal implications of the above two cases, and provide suggestions to strengthen the validity of EPO-granted second medical use claims in Germany.

Few recent decisions of the EPO Boards of Appeal have generated as much discussion, or have been as enthusiastically received in pharma/biotech circles as the 2004 decision T1020/03[1]. This case considered the patentability of second medical use claims reciting, among other things, a specific administration pattern entailing intermittent administration of insulin-like growth factor I (IGF-I) in order to achieve a specified therapeutic effect. The format of the claims followed that deemed admissible in the landmark decision of the Enlarged Board of Appeal G5/83[2] in view of the patentability exclusion of Article 52(4) EPC[3].

According to the decision G5/83, a method of treatment claim of the form:

> *Use of substance Y for the treatment of disease X.*

was considered unallowable in view of Article 52(4) EPC. However a so-called Swiss-type claim:

> *Use of substance Y <u>for the preparation of a medicament</u> for the treatment of disease X*.

was found not to contravene Article 52(4) EPC (For brevity throughout the rest of this contribution, this formulation will be referred to as the "G5/83 form" and the corresponding claim a "Swiss-type claim"). The claims under consideration in T1020/03 were in the G5/83 form. According to G5/83, the intention of Art. 52(4) EPC is to free from restraint non-commercial and non-industrial medical and veterinary activities. The use of a substance or composition *for the manufacture of a medicament* for a *specified* new and inventive therapeutic application represents a commercial activity to which the intention, and therefore the notional lack of industrial applicability of Art. 52(4) EPC, does not apply. In its decision grounds, the Enlarged Board of Appeal noted that the novelty of such a claim derived from the

1 Official Journal of the European Patent Office 2007, 204

2 Official Journal of the European Patent Office 1985, 64

3 Article 52(4) EPC reads: „Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

new therapeutic use of the medicament, irrespective of whether or not a(nother) pharmaceutical use of the medicament was already known.

In the years following G5/83, the Appeal Boards of the EPO had to consider a variety of cases concerning the admissibility of second medical use claims, especially with regard to the question of which features may form the basis of novelty and/or inventive step. As stated above, in G5/83, the novelty of a second medical use claim was seen to derive from the new purpose, or medical indication, for which a known compound is used. In T19/86[4] it was held that a specific group of animals to be treated could form the basis of novelty, a notion which was later supported for a novel group of patients to be treated in T893/90[5]. In T290/86[6] it was held that a technical effect underlying the observed efficacy of a particular substance in treating a particular ailment could support novelty, even in light of a known use of the same substance to treat the same ailment by virtue of a different underlying technical effect (*e.g.* prevention of tooth decay by applying lanthanum salts to depress the solubility of tooth enamel was deemed novel over the disclosed prevention of tooth decay by applying lanthanum salts to remove plaque). It was later acknowledged in T51/93[7] that a particular mode of administration, e.g. subcutaneous rather than intramuscular, could render a second medical use claim novel. One decision (T570/92[8]) acknowledged that a claim reciting the timing of medicament administration once to twice daily did not contravene Article 52(4) EPC. While this suggested that such a feature may be admissible under Article 52(4) EPC (this was question was not definitively answered), the question of whether or not such a feature can be used to establish novelty was not addressed. In apparent contrast, the later decision T317/95[9] suggested that a claim feature relating to the timing of administration in a Swiss-type claim specifies a typical activity to be performed by the doctor in attendance and therefore represents medical activities excluded from patentability under Article 52(4) EPC. However here, as in T570/92, no explicit decision was made regarding this question.

The problem faced by the Technical Board in T1020/03 was that while the claims under consideration were in the G5/83 form, they also recited process steps specifically relating to the *timing* of the medicament's administration[10]. In the grounds for the previous refusal of these claims by the Examining Division, such steps had been viewed as being part of

4 Official Journal of the European Patent Office 1989, 25

5 Available online at: http://legal.european-patent-office.org/dg3/pdf/t900893eu1.pdf

6 Official Journal of the European Patent Office 1992, 414

7 Available online at: http://legal.european-patent-office.org/dg3/pdf/t930051eu1.pdf

8 Available online at: http://legal.european-patent-office.org/dg3/pdf/t920570du1.pdf (in German)

9 Available online at: http://legal.european-patent-office.org/dg3/pdf/t950317eu1.pdf

10 Claim 1 at issue in T1020/03 read as follows: „1. Use of insulin-like growth factor-I (IGF-I) in the preparation of a medicament for administering to a mammal so as to sustain its biological response in the treatment of a chronic disorder in the mammal wherein the administration pattern of the medicament comprises **administering** a therapeutically effective amount of IGF-I to the mammal to provide an exposure to IGF-I that is continuous or at least once a day consecutively over a period of days that provides the maximum biological response in the mammal, **then discontinuing said administration** by means of a continual lack of treatment or a lack of treatment for consecutive days over a period of days equal to or less than the number of days during which the IGF-I was previously administered, **then administering** a therapeutically effective amount of IGF-I to the mammal to provide an exposure to IGF-I that is continuous or at least once a day consecutively over a period of days that provides the maximum biological response in the mammal, **then discontinuing said administration** by means of a continual lack of treatment or a lack of treatment or consecutive days over a period of days equal to or less than the number of days during which the IGF-I was just previously administered, and **repeating this pattern of administration and discontinuance of administration** for as long as necessary to achieve or maintain sustained biological response in the mammal." (with emphasis added to highlight intermittant administration timing)

the typical activities and duties of the doctor in treating an illness, *i.e.* those typically non-commercial and non-industrial medical activities which Article 52(4) EPC intended to free from restraint. Should the claims, then, be allowed since formulated in the G5/83 form, or rejected under Article 52(4) EPC due to their inclusion of additional steps reciting administration of the medicament? And if allowed under Article 52(4) EPC, may a feature relating to administration timing be relied on to establish novelty?

In answering these questions, the Board in T1020/03 referred to the implicit intent of the earlier decision G5/83. They focused on the following sentence from the grounds (and headnote) of this decision:

> *A European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a* ***specified*** *new and inventive therapeutic application*. (emphasis added).

Of particular importance to the Board was the word "specified", from which they drew the following conclusion:

> *[T]his Board understands the use of the word "specified" … to be merely by way of contrast to the unspecified therapy allowable in a claim for a first medical use, and not as imposing any special conditions that a further medical use had to fulfil. Rather any use to which Article 52(4) EPC first sentence applied … in circumstances where the composition had already been suggested for some therapeutic use, would allow a further medical use claim to the preparation of the composition for that further medical use,* ***irrespective of in what detail that use was specified****, subject to the use being novel and inventive.* (emphasis added)

It is important to reflect on the implications of the above passage. It means that as long as a claim is drafted in the G5/83 form, it is irrelevant what other features this claim recites – it will not fall under the patentability exclusion of Article 52(4) EPC. Practically, this reduces to the applicant-friendly interpretation that as long as a second medical use claim recites "Use of substance X for manufacturing a medicament for the treatment of [disease(s)]", no other features recited in addition to this passage will jeopardize the claim's allowability under Art. 52(4) EPC. This holds even if these additional features relate to activities which would normally be performed by a doctor such as, in the present case, administration timing.

The Board went further in T1020/03, interpreting the earlier decision G5/83 as allowing Swiss-type claims involving a novel and inventive therapeutic application, where the novelty of the therapeutic application might lie *only in the dose to be used or in the manner of application*. So as long as a claim adheres to the G5/83 form, features relating to typical activities of the doctor will not only be admissible under Article 52(4) EPC, but may even be relied upon to establish novelty and/or inventive step.

Applicant-friendliness, however can have a flipside. While the decision T1020/03 marks a shift toward increased leniency in the allowance of second medical use claims before the EPO, the applicant-turned-proprietor is hardly well served if the individual EPC contracting states do not share this leniency. It is here, in the EPC contracting states, that patents granted by the EPO will be enforced (Article 64(3) EPC[11]) and have to withstand the scrutiny of national invalidation proceedings. If patent practice at national invalidation courts diverges significantly from the criteria applied in examination proceedings before the EPO, proprietors may be forced to realize that

11 Article 64(3) EPC reads: „Any infringement of a European patent shall be dealt with by national law."

their costly intellectual property rights are not as valuable as originally thought.

G5/83 was handed down in 1984. The previous year, the German FSC had handed down the landmark decision *Hydropyridine*. In standing with G5/83, *Hydropyridine* had held that a claim directed to the use of a known substance for the treatment of a new disease does not contravene §5(2), S.1 German Patent Act, corresponding to Art. 52(4) EPC. But in contrast to G5/83 the FSC held in *Hydropyridine* that a use claim need not be drafted in G5/83 form in order to be admissible. Rather, it is admissible even if drafted as a direct use, *i.e.* "Use of substance X for the treatment of disease Y".

Despite the fact that G5/83 and *Hydropyridine* differed in their view of the specific language which may be used for an admissible second medical use claim, the two decisions are based on similar considerations. Each decision is based on the common premise that a second medical use claim may entail commercial as well as non-commercial activities, and only the non-commercial activities are intended to be excluded from patentability by Art. 52(4) EPC or §5(2) S.1 German Patent Act. Conversely, to the extent that such claims are directed to commercial activities, they are admissible. While G5/83 addressed this problem by requiring that a second medical use claim be drafted in G5/83 form, *Hydropyridine* allowed the claim to be drafted as a direct use, but stated explicitly that the scope of a second medical use claim includes all commercial activities prior to actual administration of the medicament, *e.g.* formulation and packaging with a package insert indicating the indication to be treated.

If European and German views on the admissibility of second medical use claims were essentially similar 24 years ago, the recent EPO decision T1020/03 taken together with a recent decision by the German FSC nullifying certain EP-granted Swiss-type claims suggests that significant divergence may have taken place in the interim In this regard, it is ironic that the same decision used by the Board in T1020/03 as a basis for developing a lenient interpretation of second medical use claims, G5/83, also described the EPO as having "*… the task of granting patents which have the same effect as national patents in all Contracting States, even though, at the present time, not all of them have completely harmonised patent laws or outlooks on patent matters.*"

In its decision of December 19, 2006, *Carvedilol II*[12] (official reference X ZR 236/01), the case before the FSC concerned EP 808162 B1. This patent had been granted in the EPO with effect for Germany. The patent claimed uses of the substance carvedilol for the treatment of congestive heart failure, and had previously been nullified by the German Federal Patent Court. On appeal to the FSC, the patent was defended with one main request and two auxiliary requests, the relevant differences of which may be summarized as shown in the following table:

12 Available online in German at: http://www.bundesgerichtshof.de/

Preamble	Additional features	Request
Use of carvedilol for the manufacture of a medicament for decreasing mort	Medicament *is administered* in particular doses at particular times	Main[13]
	None	Auxiliary 1[14]
	Medicament is *prepared for administration* in particular doses at particular times	Auxiliary 2[15]

According to the interpretation of Article 52(4) EPC developed in EPO decision T1020/03, the main request on appeal should have been allowable, since it was drafted in G5/83 form. In particular, the inclusion of features relating to the act of administering particular doses of the medicament at particular times should not render the claim unpatentable under Article 52(4) EPC. Further, the assessment of the claim's novelty in light of the cited prior art should have taken these additional features into consideration.

The interpretation of the FSC in *Carvedilol II* was quite different, their conclusions not at all in standing with the conclusions reached in T1020/03. In the FSC's view, a substantive assessment of the main request was unnecessary since it recited steps of administering a medicament and was therefore excluded from patentability *a priori* as a method of treatment in the sense of Art.52(4) EPC. A relevant passage of the decision reads as follows (authors' translation):

> *The administration of a medicine intended for the treatment of a particular disease is, per se, a therapeutic method for the treatment of the human body. It is not an*

13 Claim 1 (main request, authors' translation): „Use of carvedilol for the preparation of a medicament for reducing the mortality due to congestive heart failure in human patients in combination with an angiotensin-converting enzyme inhibitor, a diuretic and a digitalis glycoside, wherein the medicament **is administered** in an initial dose of 3.125 mg or 6.250 mg carvedilol per day over a time period of 7 to 28 days, followed by dosage increases, each in intervals of 14 days, up to a maximum dose of 2 x 25 mg carvedilol per day." (emphasis added)

14 Claim 1 (first auxiliary request, authors' translation): „ Use of carvedilol for the preparation of a medicament for reducing the mortality due to congestive heart failure in human patients in combination with an angiotensin- converting enzyme inhibitor, a diuretic and a digitalis glycoside."

15 Claim 1 (second auxiliary request, authors' translation): „Use of carvedilol for the preparation of a medicament for reducing the mortality due to congestive heart failure in human patients in combination with an angiotensin-converting enzyme inhibitor, a diuretic and a digitalis glycoside, wherein the medicament **is prepared for administeration** in an initial dose of 3.125 mg or 6.25 mg carvedilol per day over a time period of 7 to 28 days, followed by dosage increases, each in intervals of 14 days, up to a maximum dose of 2 x 25 mg carvedilol per day." (emphasis added)

16 Claim 1 (main request, authors' translation): „Use of carvedilol for the preparation of a medicament for reducing the mortality due to congestive heart failure in human patients in combination with an angiotensin-converting enzyme inhibitor, a diuretic and a digitalis glycoside, wherein the medicament **is administered** in an initial dose of 3.125 mg or 6.250 mg carvedilol per day over a time period of 7 to 28 days, followed by dosage increases, each in intervals of 14 days, up to a maximum dose of 2 x 25 mg carvedilol per day." (emphasis added)

17 Claim 1 (first auxiliary request, authors' translation): „ Use of carvedilol for the preparation of a medicament for reducing the mortality due to congestive heart failure in human patients in combination with an angiotensin- converting enzyme inhibitor, a diuretic and a digitalis glycoside."

18 Claim 1 (second auxiliary request, authors' translation): „Use of carvedilol for the preparation of a medicament for reducing the mortality due to congestive heart failure in human patients in combination with an angiotensin-converting enzyme inhibitor, a diuretic and a digitalis glycoside, wherein the medicament **is prepared for administeration** in an initial dose of 3.125 mg or 6.25 mg carvedilol per day over a time period of 7 to 28 days, followed by dosage increases, each in intervals of 14 days, up to a maximum dose of 2 x 25 mg carvedilol per day." (emphasis added)

> *element of the preparation of a substance for the use in the treatment of a disease … but rather follows this. The specification of a suitable therapy plan for a patient including the prescribing and the administration of medicaments is a characteristic part of the activity of the doctor in attendance and, as such, a method excluded from patentability by Art. 52(4) EPC and §5(2) German Patent Act. A use claim is possible for the preparation of a particular substance for the treatment of a disease …, however this does not imply patent protection for pure dosing recommendations independent of the preparation of the substance. … To come to any other conclusion would be incompatible with the wording of Art. 52(4) EPC and would deprive this provision of a significant part of its intended area of application.*

For the FSC – in stark contrast to the Board in T1020/03 – simple adherence to the G5/83 form does not render a Swiss-type claim admissible under Article 52(4) EPC, irrespective of any other features which may be recited. Rather, all features of the claim are to be considered on their own respective merits in light of the original intent of Article 52(4) EPC.

Nor was this the FSC's only divergence from T1020/03. The FSC in *Carvedilol II* also maintained that claim features relating to activities excluded under Article 52(4) EPC as falling within the freedom of medical therapy could not be taken into account in considering novelty and inventive step. This view was applied to the administration steps recited in the main request with the result that, after having been stripped of its non-admissible features, the only features remaining to be considered for novelty and inventive step was the preamble in the G5/83 form. As the above table shows, removal of the administration-related steps from the main request results in a claim corresponding exactly to the first auxiliary request.

The FSC rejected the main request as contravening Article 52(4) EPC and §5(2) German Patent Act, leaving the question open as to whether the main request as a whole was admissible. While deemed to be in compliance with the requirements of Art. 52(4) EPC and §5(2) German Patent Act, the first auxiliary request was rejected as lacking an inventive step over the cited prior art.

It is worth noting that the FSC did not view the second auxiliary request as contravening Article 52(4) EPC and §5(2) German Patent Act. Here, the steps of the main request relating to administration of the medicament had been reformulated to recite that the medicament is *prepared for administration*[19]. In standing with its earlier landmark decision *Hydropyridine*, the FSC noted (authors' translation):

> *Auxiliary request 2 provides in both claims that the carvedilol-containing medicament is prepared for administration in certain doses over certain time spans. As such the subject matter to be protected is the use of a chemical substance in the therapeutic treatment of the human body, said substance being prepared for this use by, for example, a purposive confectioning of tablet sizes, printing on the package or on the accompanying package insert. According to the case law of the Senate [reference to Hydropyridine decision], such a use is not excluded from patent protection under §5(1) German Patent Act. The same applies for §5(2) German Patent Act, the wording of which corresponds exactly to Article 52(4) EPC. The prohibition of patenting methods for the surgical and therapeutic treatment of the human or animal body does not preclude the claims of the second auxiliary request.*

In *Carvedilol II* the FSC did not specifically highlight the reasons for their different

19 *Supra*, footnote 15

assessment of the main and second auxiliary requests. However, taken in the overall context of the decision, it is clear that the pivotal point in these differing assessments was the distinction between commercial and non-commercial activities. Activities relating to the formulation or confectioning of a substance so as to obtain an administrable medicament all take place prior to the actual administration as such and fall within the sphere of commercial activities which, due to this commercial nature, reside outside of the exclusion of Article 52(4) EPC. For the FSC, non-commercial activities encompassed by Article 52(4) EPC commence only after completion of a commercial formulation. For the FSC the dividing line between commercial and non-commercial activities – and therefore between admissibility and non-admissibility of features in a Swiss-type claim under Article 52(4) EPC – is thus to be drawn between preparation of a substance as a medicament and administration of this medicament to a subject.

Carvedilol II is disturbing for a number of reasons. From a strictly legal perspective, it is deeply dissatisfying that the highest appeal instance in Europe's largest pharmaceutical market and the central European patent granting authority interpret the admissibility of Swiss-type claims, so important for pharmaceutical patent protection, in such fundamentally incompatible ways. Indeed, while the EPO in T1020/03 will allow any (novel and inventive) Swiss-type claim with administration steps as long as the claim adheres to the G5/83 form, in Germany the view is exactly converse: even if drafted in the G5/83 form, the German FSC will not allow a Swiss-type claim if it includes at least one administration step. Further, the novelty of a Swiss-type claim before the EPO may be established – even solely – by steps relating to administration and dosing, whereas the assessment of novelty and inventive step in Germany must proceed ignoring such steps. To add to the frustration, in reaching their respective conclusions, both the EPO Technical Board of Appeal and the German FSC refer to the intention of the same legal provision: Article 52(4) EPC.

But abstract legal considerations aside, this divergence is so troubling because the real loser is the applicant for and, later, proprietor of European patents designating Germany. The applicant who has already absorbed the substantial cost of grant and validation and proceeds to enforce his German patent is likely to suddenly find himself caught between the contradictory views of two legal systems, holding a worthless piece of paper. *Carvedilol II* has binding effect only within German territory. However, it is possible that other EPC contracting states besides Germany may interpret Article 52(4) EPC in line with the FSC rather than with the EPO Board of T1020/03, especially now that the FSC has shown the way with *Carvedilol II*. It should not be forgotten that the German FSC is one of the most highly reputed courts in all of Europe, to which, if not officially, other courts in Europe turn for guidance. Initial informal inquiries with our colleagues in other EPC contracting states (Great Britain, France and Italy, for instance) have indicated that national courts in these countries may well follow the FSC's interpretation. On the other hand, a colleague in Holland expected that Dutch national courts would likely follow the interpretation of the EPO in T1020/03.

EP 808162 B1, the basis of the *Carvedilol II* decision, was granted in May 1999 and nullified in Germany by the Federal Patent Court in September 2001. On appeal, the FSC upheld this ruling in December 2006. Only recently published in the Official Journal of the EPO, T1020/03 is dated late October 2004 and has been available online at least since the beginning of 2006. It is unknown when the FSC's deliberations leading to *Carvedilol II* took place, *i.e.* whether the decision *Carvedilol II* was rendered in knowledge of T1020/03, but one must suspect this was the case. The deliberations for *Carvedilol II* were still

open and amendable prior to pronouncement on December 19, 2006, at which time T1020/03 had been available online for months. One would have hoped that the FSC would have addressed their divergence from T1020/03, if only by way of *obiter dictum*, but *Carvedilol II* contains no reference to the earlier EPO decision.

Ways out

In time, case law will likely indicate which interpretation of Article 52(4) EPC – that of the EPO in T1020/03 or that of the German FSC in Carvedilol II – will prevail in each of the individual EPC contracting states. For the present, given the incompatible interpretations of the EPO and Germany, applicants currently pursuing second medical use claims including administration steps at the EPO would be well advised to pursue multiple versions of these claims reciting both "**administration of the medicament**" and "**preparation of the medicament for administration**". While the EPO Examining Division may allege that the applicant lacks a legitimate interest for pursuing multiple claims of essentially identical scope, this could possibly be traversed by referring to the divergent legal interpretations discussed above and the applicant's legitimate interest in obtaining a patent which is valid and enforceable in all EPC contracting states designated as already stated in G5/83 (see above). Should the EPO maintain such an objection, the applicant may be prompted to assess its competitive situation in each of the designated states, and to limit itself to a single Swiss-type claim formulated as admissible in the contracting state where enforcement is most likely. However, given the typical uncertainty as to later enforcement in the early application stage as well as, often, the strategic importance of a broadly enforceable patent portfolio for the applicant's partnering, licensing and/or financing activities, it will generally be preferable to pursue variously formulated Swiss-type claims in parallel.

The proprietor of a patent with Swiss-type claims comprising administration steps which has already been granted before the EPO and validated in Germany is faced with a different problem. He may well know that he needs to enforce his claim in Germany, but since examination is now concluded in the EPO and the claim language no longer amendable, he finds himself bound to claim language inappropriate for enforcement in the country needed.

One possible solution may be to request limitation of the German patent under §64 German Patent Act prior to enforcement. To be admissible, a limitation request must truly entail a restriction of claim scope, rather than a mere reformulation. The Proprietor seeking to limit its Swiss-type claim must therefore demonstrate that amendment from "administration of the medicament" to "preparation of the medicament for administration" truly represents a limitation in claim scope.

For this, it may be possible to refer to the arguments applied by the FSC in *Carvedilol II* to their assessment of novelty and inventive step of second medical use claims reciting "administration of a medicament" (see above). Recall that the FSC had held that any administration-related step must be ignored for the assessment of novelty and inventive step. Given that a correlation must ideally exist between the standards to be applied in assessing patentability on the one hand and claim scope on the other (the purpose of patent examination being to endow the applicant with an enforceable prohibitive right only for that subject matter which is novel and inventive over the prior art), then the effective scope of a Swiss-type claim reciting administration steps must be defined only by the language obtained after subtracting all administration-related language. Referring to the above table summarizing the requests in the *Carvedilol II* decision, subtraction of the administration-related language effectively converts the main request to the first auxiliary request. The comparison to be

made for a limitation request under § 64 German Patent Act may therefore be between a Swiss-type claim lacking all administration-related language (as in the first auxiliary request in *Carvedilol II*) and a Swiss-type claim including this language, except formulated as "preparation of the medicament for administration" (as in the second auxiliary request in *Carvedilol II*). The scope of the second auxiliary request in *Carvedilol II* is obviously narrower than the first auxiliary request. Analogously, a claim for which limitation is requested under §64 German Patent Act should be narrower in the form reciting "preparation of the medicament for administration" than in the form reciting "administering the medicament".

Once a limited form of the German patent is secured, the patent may be enforced against the putative infringer.

In this context, it is worth mentioning that with the entry into force of the EPC-2000 on December 17, 2007, the EPC will provide, in Articles 105a, 105b and 105c (in conjunction with the Implementing Regulations) a centralized procedure for limitation of EP-granted patents at the EP-level.

Whether the Board interpreted Art.52(4) EPC too leniently in T1020/03 or the FSC interpreted it too strictly in *Carvedilol II*, is not considered at present. Also not considered is whether the coming into force of the EPC-2000 with its new Articles 53(c)[20] and 54(5)[21] is likely to alleviate or further complicate discord between EP-regional and national interpretations of second medical use claims. The important point is that differing views on the patentability of Swiss-type claims involving administration steps have evolved between the EPO and (at least) the contracting state Germany. The increasing crowding of the pharmaceutical patent space is requiring incorporation of ever finer levels of detail, often in the form of specific treatment regimens, to establish the novelty of Swiss-type claims. Given this, it is expected that the issues discussed above will increase rather than diminish in importance. Maintaining the ability to enforce EP-granted Swiss-type claims in EPC contracting states will require that one appreciates and reacts to these differences sufficiently early in the patent acquisition process.

20 Article 53(c) EPC-2000 reads: „European patents shall not be granted in respect of: ... methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

21 Article 54(5) EPC-2000 reads: „Paragraphs 2 and 3 [definition of prior art] shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any **specific** use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art." (emphasis added to show that under the EPC-2000 purpose-bound product protection will be available for both the second and first medical indications. The present EPC allows purpose-bound product protection only for the first medical indication.)