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## Dosage regime claims in the EPO – the G-02/08 Dosage regime/Abbott hearing

On 5 November 2009 the EPO Enlarged Board of Appeal held its hearing on case G-2/08 Dosage regime/Abbott. Abbott's application<sup>1</sup> for a Swiss type dosage regime claim to “the use of nicotinic acid ... for the manufacture of a sustained release medicament for use in the treatment by oral administration once per day prior to sleep, of hyperlipidaemia ...” had been rejected by the Examining Division. Upon appeal, Technical Board of Appeal 3.3.02, in interlocutory decision T-1319/04 *Kos*,<sup>2</sup> had referred the following three questions to the Enlarged Board:

1. Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC 2000 for use in a different, new and inventive treatment by therapy of the same illness?
2. If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime?
3. Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?

Abbott and the President of the EPO were invited to make submissions and all other interested parties were given the opportunity to submit *amicus* briefs. Fifteen *amicus* briefs were submitted, *inter alia* by patent attorney associations, by pharmaceutical manufacturers and their associations and by a former member of the Enlarged Board. After setting the date for the hearing, the Enlarged Board advised Abbott and the EPO President, the only parties who would appear

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<sup>1</sup> The applicant, initially Kos Life Sciences Inc., has changed its name to Abbott Respiratory LLC.

<sup>2</sup> T-1319/04 Kos Life Sciences, Inc., Decision of the Technical Board of Appeal 3.3.02 of 22 April 2008, European Patent Office, Munich. Available at <<https://register.epoline.org/espacenet/regviewer>> under application number 94306847 [last checked 8 November 2009].

before the Board at the hearing, that discussion might be expected to focus on the following points:

- a) The meaning of the difference in language between question 1 and Art. 54(5) EPC;
- b) The identification of the change in the law brought about by the revision of EPC 1973<sup>3</sup> to create EPC 2000<sup>4</sup>;
- c) The consequences of that change, in particular in relation to Swiss type use claims and purpose-limited second indication product claims (so-called EPC 2000 claims);<sup>5</sup>
- d) The relevance of the prohibition, retained in EC 2000, on patenting methods of medical treatment;
- e) Whether there should be any difference in treatment between the cases where the dosage regime is characterised by the quantity of drug administered and where it is characterised by the activities involved in its administration; and
- f) A comparison between existing Enlarged Board decisions and decisions of the Technical Boards of Appeal relating to second or further *non*-medical uses.

On the first of these points, at the hearing Abbott<sup>6</sup> was of the view that the wording indicated that inventive step was not at issue in the present case, while the EPO President was of the opposite view, i.e. that inventive step was indeed at issue.

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<sup>3</sup> Convention on the grant of European patents (European Patent Convention), 12th Ed. (2006), European Patent Office, Munich.

<sup>4</sup> Convention on the grant of European patents (European Patent Convention), 13th Ed. (2007), European Patent Office, Munich.

<sup>5</sup> Swiss type claims are claims to a *process* for drug manufacture which derive their novelty from the purpose for which the drug is to be used, i.e. of the format “the use of compound X for the manufacture of a medicament for use in method of medical treatment Y”. EPC 2000 claims, a term that seems to have been coined by the Enlarged Board, are purpose-limited *product* claims of the format authorised by Art. 54(5) EPC 2000, i.e. of the format “Compound X for use in method of medical treatment Y”.

<sup>6</sup> References to statements by Abbott or the EPO President are of course to statements by their respective representatives at the hearing.

Asked to identify the change in the law brought about by the introduction of Art. 54(5) EPC 2000, Abbott argued that there was no substantive change. Abbott identified “two critical sections of the *travaux préparatoires*”, cited in paragraphs 12 and 13 of the EPO President’s submissions<sup>7</sup> of 28 January 2009 (citations respectively from the Swiss delegation’s proposal MR/18/00<sup>8</sup> and from paragraph 139 of the Minutes of the Munich Diplomatic Conference which decided the amendment to the EPC, MR/24/00<sup>9</sup>). According to the passage quoted in paragraph 12, the clear intention of the legislator in introducing Art. 54(5) EPC was to enshrine the case law of the Enlarged Board of Appeal. This raised the question, according to Abbott, as to whether this meant only decision G-5/83 *Eisai*<sup>10</sup> or also the Technical Board of Appeal case law that has evolved from that decision. In view of the statement in the *travaux préparatoires*, quoted in paragraph 13, that “the aim of the Basic Proposal was to keep the legal status quo”, for Abbott the conclusion had to be that the Technical Board case law should also be considered. In order to interpret the *Eisai* decision properly, Abbott submitted, it was necessary to look into the arguments against the type of claim Abbott was seeking in the present case, namely dosage regime claims. Abbott referred to the arguments put forward in the *amicus* brief<sup>11</sup> filed by Ratiopharm (a generic manufacturer) as to the proper interpretation of *Eisai* and labelled Ratiopharm’s position as “very radical” because it argued that second medical uses should be understood as only referring to using known drugs *to treat new illnesses*. This would make the Swiss type claims of several granted patents invalid, such as claims characterised by the selection of

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<sup>7</sup> Letter dated 28 January 2009 from the President of the European Patent Office. Available at <<https://register.epoline.org/espacenet/regviewer>> under application number 94306847 [last checked 8 November 2009].

<sup>8</sup> MR/18/00: Basic proposal - explanatory notes - Article 54(4) and Article 54(5) EPC, European Patent Office, Munich. Available at <<https://register.epoline.org/espacenet/regviewer>> under application number 94306847 [last checked 8 November 2009].

<sup>9</sup> MR/24/00: Conference of the contracting states to revise the 1973 European Patent Convention: Munich, 20 to 29 November 2000: Conference proceedings, European Patent Office, Munich. Available at <[http://documents.epo.org/projects/babylon/eponet.nsf/0/fa8da239660827a4c12572810041373f/\\$file/conf\\_proceed\\_mr0024\\_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/fa8da239660827a4c12572810041373f/$file/conf_proceed_mr0024_en.pdf)> [last checked 8 November 2009].

<sup>10</sup> G-5/83 *Eisai* Co., Ltd., Decision of the Enlarged Board of Appeal dated 5 December 1984 G 5/83, (1985) Official Journal of the European Patent Office 60.

<sup>11</sup> Letter dated 29 October 2008 from Ter Meer, Steinmeister & Partner GbR. Available at <<https://register.epoline.org/espacenet/regviewer>> under application number 94306847 [last checked 8 November 2009].

patient populations, by route of administration, or by the achievement of a new technical effect on the body. Such an interpretation was fundamentally wrong as, Abbott argued, the *Eisai* decision laid down that “second medical use” should be construed broadly and that the words “specific use” in Art. 54(5) EPC should therefore be understood to mean that claims to products should be allowed if limited to any novel specified use (in contrast to the more general restriction “for use in medicine” that is allowed under Art. 54(4) EPC for cases of first medical use).

The EPO President also commented on the change effected by EPC 2000, first clarifying that the exclusion from patentability of methods for medical treatment was initially based on a legal fiction (i.e. that such methods are not industrially applicable), but that in EPC 2000 they are simply listed with the other categories excluded from patentability. This exclusion, the EPO President emphasised, was based on ethical and social grounds. Nonetheless, Art. 53(c) EPC 2000, the current location of this exclusion, should be construed in exactly the same way as its predecessor Art. 52(4) EPC 1973. The President went on to explain that ‘Swiss type’ protection was not legally codified in EPC 1973 and that uncertainty existed in some Member States as to its validity. Meanwhile, however, this uncertainty had been eliminated by the introduction of Art. 54(5) EPC, and even though the words “specific use” in Art. 54(5) EPC 2000 are not defined, specific use should be understood broadly, i.e. *not* as being limited to new illnesses. The EPO President stated that “it was the clear intention of the legislator to improve protection in this field”, upon which the Chairman of the Enlarged Board, Dr Messerli, asked the EPO President to explain in which sense this was so. The EPO President replied: “in the sense of removing the legal uncertainty”.

The position of both Abbott and the EPO President on the effect of the introduction of Art. 54(5) EPC was thus clear: for second and further medical uses, purpose-limited product claims

should be allowed and the new use need not be the treatment of a new disease but might be a new dosage regime for the treatment of the same disease.

Turning to the consequences of the introduction of Art. 54(5) EPC, discussion point (c) above, Abbott stated that EPC 2000 was intended to maintain the status quo, albeit with a shift to a different claim format. Abbott stressed, however, that Swiss type claims must remain valid, as *Eisai* had not been overruled and as so many Swiss type claims had already been granted. Guidance from the Enlarged Board on the equivalence of Swiss type and EPC 2000 claims was urgently needed, however, not least because recently issued guidelines for EPO examiners state that the claim scope of both types of claims must be regarded as identical.

The Chairman of the Enlarged Board asked Abbott whether in their view, the claim scope was identical. Abbott said yes. The Chairman then referred to the *amicus* brief<sup>12</sup> of Julian Cockbain, and asked Abbott to consider an example given therein. The example relates to a known compound (compound X) which is found to be useful taken in one dosage (dosage Y) for treating disease A, then later found to be useful in the same dosage for treating disease B, then later still found to be more useful in a different dosage (dosage Z) for treating disease B.

Cockbain had argued that under EPC 1973 the inventor of the application of compound X to treat disease A could obtain a patent to "compound X for use in medicine". The grant of such a patent leaves the freedom of action of the physician or pharmacist unaffected as the compound had previously not been available in medically approved form, so there was no generic to substitute with. After the patent expired, generic versions of compound X for the treatment of

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<sup>12</sup> Letter dated 21 May 2009 from Julian Cockbain. Available at <<https://register.epoline.org/espacenet/regviewer>> under application number 94306847 [last checked 8 November 2009].

disease A could reach the market and be used legitimately. Also under EPC 1973, the inventor of the application of the compound to treat disease B could obtain a patent for "the use of compound X for the manufacture of a medicament for use in treatment of disease B". The physician treating disease B would then have a new drug in her arsenal and her position was clearly improved. A generic version of compound X might be available, but only from companies expressly advertising their product as for use in treating disease A. The physician or pharmacist would thus have the option to substitute without infringing (for, if the generic was manufactured for treating disease A and not disease B, the Swiss type claim would not be infringed by her actions). Under EPC 2000 however, Cockbain argued, the inventor of the first treatment of disease B with compound X could obtain a patent for "compound X for use in treating disease B", i.e. for a *product* as such rather than for a *process* for its manufacture. If the physician or pharmacist substituted generic compound X, she would be infringing such a claim. With the second disease B invention (using dosage Z to treat disease B), the question arose as to whether its inventor could obtain a patent with dosage regime claims to "the use of compound X for the manufacture of a medicament to be given in dosage Z in the treatment of disease B" or to "compound X for use in dosage Z for treating disease B". With the first of these claims, the Swiss type claim of EPC 1973, substitution by making up dosage Z using the generic available for disease B in dosage Y would neither infringe nor be seen to be risky. With the second claim, the product *per se* claim of EPC 2000, however, such substitution *would* infringe. Thus, with Swiss type claims, the physician cannot infringe by her use of any legitimately available medical supplies while, with EPC 2000 claims, the physician's use of a legitimately available generic *can* infringe – *a situation which does not occur with claims to new pharmaceuticals or to first indications* since no generic equivalent can then legitimately be available on the physician's shelves.

The Chairman asked Abbott whether a physician would indeed infringe under the EPC 2000 claim format. Abbott noted that this had to do with infringement and hence fell under national law. On being pressed for an answer, Abbott stated that the amendment of the law implied no change as to whether the physician would infringe.

The Chairman asked Abbott to explain why this was the case, to which Abbott replied that, under UK law, the physician would not infringe. The Chairman referred to Cockbain's *amicus* brief again, repeating the example given and his earlier question as to whether a physician would infringe under the new EPC 2000 claim format. Abbott said they might have misunderstood the Chairman's question, upon which the Chairman explained the example again and repeated his question again. Abbott indicated that they had now understood the question and repeated that this related to questions of infringement under national law, but that they would nevertheless attempt to give an answer. If the dosage form is novel, Abbott said, whether there is infringement will depend on the regulatory environment, more particularly on the surrounding circumstances of distribution and use of the drug. Abbott added that it was not helpful to think about this issue in terms of the physician. The Chairman replied that methods of medical treatment are excluded from patentability and that, although during the process leading up to the amendment of the EPC, attempts were made to delete this exclusion, it was maintained. He then once more repeated his question whether a physician would infringe claims in the EPC 2000 format. Abbott repeated its reply that this regarded infringement and noted that there might be provisions in national laws to ensure freedom of operation for the physician.

The Chairman then asked the EPO President to comment on the same question. The EPO President said that it was clear from EPC 2000 that the legislator had chosen the EPC 2000 claim format, and at the same time to keep the legal status quo - this implied that the legislator



did not intend to introduce a broader scope of protection than that offered by Swiss type claims and so that the scope of protection of both claim formats was identical. It was added by the EPO President that in the future there was no need to maintain Swiss type claim protection, as the legislator had wanted to abolish this. As to Swiss type claims in existing granted patents, the EPO President considered that these should be replaced by EPC 2000 claims.

The Chairman asked Abbott to consider a claim of the type “substance X manufactured for use in a method of treatment” and to explain who would infringe such a claim. Abbott said that they could not assist the Chairman with the question posed, as the claim type in question was a hybrid claim form which had elements of a Swiss type claim as well as being a product claim. As no case law existed on such claims, Abbott could not answer the Chairman’s question.

Abbott subsequently noted, with regard to physicians’ freedom to operate, that it should not be forgotten that ‘first medical use’ claims also impact on the freedom of physicians, as they are also in danger of infringing such claims (rather than just being at risk of infringing second or further medical use claims).

The Chairman asked Abbott whether it was the case that the remaining freedom of physicians is shrinking further and further. Abbott asked whether they could come back to that later.

Enlarged Board member Dr Günzel then put a question to the EPO President: why, she asked, does the President say the claim scope of both types of claim is identical? The President replied that the *travaux préparatoires* showed that the claim scope must be considered to be identical because both types of claim derive their novelty from the new use. Moreover, the EPO President

added, instructions had been given to the EPO examiners that they must regard the claims as being identical in scope.

Enlarged Board member Dr Schachenmann, addressing the EPO President, noted that the scope of patent protection is defined by the claims and that in the EPC 2000 claim there is no reference to “manufacture”. Therefore, he said, one could envisage a physician using a generic drug and thereby potentially infringing such an EPC 2000 claim. That is why it is crucial to bear in mind Art. 53(c) EPC, he explained. Also according to the UK Court of Appeal Actavis decision,<sup>13</sup> he added, the manufacture aspect is decisive. He wanted to know what the President’s view on this issue was. The President did not give a reply. The Chairman then asked Abbott whether they would like to comment on the Actavis case. Abbott argued that, contrary to some of the assumptions made in some of the *amicus* briefs there was no inconsistency in the UK case law. However, Abbott did admit that in some EPC member states uncertainty exists as to the comparability of scope of Swiss type claims and EPC 2000 claims and that the guidance of the Enlarged Board was therefore needed.

The Chairman asked Abbott: assuming that EPC 2000 claims would be accepted, what would remain of the physician’s freedom, or put differently: what would be left under Art. 53(c) EPC? In reply, Abbott provided two examples of what physicians would still be free to do: to take a patient’s blood pressure and to use surgical methods. Abbott contended that drug products are not methods of treatment and that the EPC 2000 claim format would not limit the freedom of operation of physicians.

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<sup>13</sup> *Actavis UK Limited and Merck & Co Inc*, [2008] EWCA Civ 444.

On the same topic, the EPO President stated that medical practice should not be hindered by patent law as public health must be guaranteed, and noted that when the EPC was revised in 2000 the legislator explicitly refrained from deleting the exclusion from patentability of methods of treatment. However, according to the EPO President, Art. 53(c) EPC, last sentence (which allows drugs to be patented) already limits the freedom of physicians in order to encourage research and development of medicaments. Articles 54(4) and 54(5) EPC had to be seen as providing compensation for the exclusion from patentability of medical methods and the purpose of this compensation was to encourage R&D. In this regard the President endorsed the approach expressed in decision T-1020/03 *Genentech*.<sup>14</sup>

Abbott expressed its agreement with the views of the President and referred to the principle that exceptions to patentability must be construed narrowly. Enlarged Board member Dr Günzel asked Abbott where such a principle could be found in the Vienna Convention on the Law of Treaties. Abbott replied that they did not know. The Chairman noted that, for the sake of consistency, if one advocates narrow construction for the purposes of Art. 53(c) EPC, one must also advocate narrow construction for the purposes of Articles 54(4) and 54(5) EPC, but that apparently the latter was not advocated by Abbott.

The discussion then moved to Question 2 of the referral. Asked by the Chairman to make observations on Question 2, Abbott argued that there was no reason to treat claims characterised by dosage regime (i.e. dosage quantity or timing) differently, for they represented R&D expenditure which might deliver medical benefits. The EPC did not allow differentiation in the field of “specific uses”. Abbott argued that claims for new routes of administration of drugs provided an example of a category of second medical use claims which has been permitted by

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<sup>14</sup> T-1020/03 *Genentech, Inc.*, Decision of Technical Board of Appeal 3.3.04 dated 29 October 2004, (2007) Official Journal of the European Patent Office 204-257.

the EPO and which lay closer to what physicians do in the clinic than do dosage regime claims. In Abbott's view, there was no way to draw a line between dosage regimes and other second medical uses and, moreover, there is no basis in the EPC to draw a line. In this regard they too endorsed decision T-1020/03 *Genentech*. Thus, Abbott concluded, it was much simpler not to draw a line and to allow claims to *all* kinds of second medical uses.

On the same topic, the EPO President began by referring to paragraph 20 of decision G-5/83 *Eisai*: "Where the medicament itself is novel ... the ordinary requirements of Article 54(1) to (4) EPC will be met and there will in principle be no difficulty over the question of novelty, whether the claim be directed to the medicament *per se* or to the use of the active ingredient to prepare the medicament. The critical case is, however, that in which the medicament resulting from the claimed use is not in any way different from a known medicament." The EPO President added that the role of the physician was not limited to the administration of medicaments, but also included the selection of the medicament and, therefore, it was not justified to distinguish between these types of activities. Moreover, according to the President, a physician would almost never say "take 5mg of this drug prior to sleep", so there was no reason to single out dosage regimes. Abbott expressed its agreement with this view.

The Chairman asked Abbott whether in order for patentability there has to be a functional technical feature. Enlarged Board member Dr Schachenmann joined the Chairman in asking this question and, with reference to decision G-2/88 *Mobil*,<sup>15</sup> asked Abbott what ought to be the *nature* of the "specific use" of Art. 54(5) EPC in order to achieve patentability. Abbott replied that it was better to deal with this issue under the heading of inventive step rather than novelty. They appreciated the reference to the *Mobil* decision, but noted that *Mobil* concerned *non-medical*

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<sup>15</sup> G-2/88 Friction reducing additive/MOBIL III, (1985) Official Journal of the European Patent Office 64.

second use claims, claims which, unlike *medical* second use claims, do not get special treatment by the legislator.

Before closing the hearing and announcing that a decision would be issued in writing, the Chairman obtained Abbott's confirmation that the answers to the questions before the Enlarged Board should, in Abbott's opinion, be yes, yes and no.

The written decision is awaited with great interest.