Purpose-limited pharmaceutical product claims under the revised European Patent Convention: A camouflaged attack on generic substitution?

Abstract

While the commonly advanced justification for patents on pharmaceuticals –that without a period of monopoly to recoup research and development costs, no company would invest the sums necessary to bring a drug to market– may hold for new drugs or for old drugs to be used to treat new ailments, that justification is much less sustainable where an old drug is to be used to treat the same ailment but at a different dosage. Under European patent law, patents may not be granted for methods of therapy, apparently to ensure that the physician's freedom to select an appropriate treatment for her patient is not compromised by fear of being accused of patent infringement. Until recently, European patents for drugs could not be infringed by physicians or pharmacists by generic substitution. Now, however, the highest instance of the European Patent Office (EPO), the Enlarged Board of Appeal, is considering the extent to which that position has changed as a result of the 2000 revision of the European Patent Convention (EPC). The revised EPC, although officially intended to keep the legal status quo, actually extends the scope of patent protection for drugs, by introducing purpose-limited *product* protection in Art. 54(5). Although the Enlarged Board of Appeal –which currently has the task of interpreting the provisions of the EPC applying to patent protection of novel applications of old drugs– cannot undo the introduction of Art. 54(5), we argue that the Enlarged Board must construe this provision to minimise its potentially negative effects on physicians, veterinarians,

nurses and pharmacists, particularly in relation to generic substitution. We put forward a concrete proposal for this construction.

Keywords

European patents; generic substitution; Swiss type claims; dosage regime claims

1. Introduction: The creation of new ways of "evergreening" drug patent protection through the 2000 revision of the European Patent Convention

1.1. Different types of drug patent protection: the situation prior to the EPC revision

Once a drug has gone off patent, generic equivalents can enter the market, usually at a fraction of the price the patented drug was being sold for. This benefits patients who have to pay all or part of the drug price and national health systems which likewise may pick up all or part of the drug price.

Patented drugs however are the foundation of the profit base of the pharmaceutical industry and that industry uses whatever means it can to delay generic competition, e.g. by patenting "improved" formulations or the use of the drug for new applications. This may for example mean new ways of making the drug, new compound formats, new composition formulations, new administration routes, new dosage regimes, and new illnesses (new "indications") treatable with the drug.[1]

Outside the United States, methods of treatment with drugs are generally unpatentable and traditionally the only ways of "evergreening" drug patent protection were to patent new formulations of the drug, new forms of the drug (e.g. pure isomers rather

than racemates)[a], or new ways of manufacturing the drug. This meant that patent cover might be uncertain where a *known* drug was found to be useful for treating a *different* illness (a different "indication") or where an *improved* "dosage regime" is found for treating the *same* illness, especially when a generic version of the drug suitable for such use was already or would soon become available.

Thus, for example, the European Patent Convention, EPC 1973,[2] specified in Art. 52(4), that methods of treatment of the human or animal body by therapy could not be patented.[b] The EPC however makes it clear that, while methods of treatment are unpatentable, this exclusion does not apply to "products, in particular substances or compositions, for use in any of these methods".[c] Likewise, the EPC makes it clear that known substances or compositions which had no previous known medical use can be patented for use in medicine.[d] Accordingly, although patent protection was available for new drugs and for known compounds for their first medical use, the industry had a problem obtaining patent protection when a new use was found for an old drug. Such patent protection is of course particularly valuable as it may be relatively cheap to obtain marketing approval for the old drug.

However, in its very first decisions, all with the same text and exemplified by the three published versions G-1/83 *Bayer*,[4] G-5/83 *Eisai* [5] and G-7/83 *Pharmuka*,[6] the

[a] Many drug compounds exist in two or more forms, isomers, where one such form may be more active or have less side-effects than other(s). Mixtures of such forms may be referred to as racemates.

[b] The European Patent Convention, the law under which the European Patent Office may grant patents for most of the countries in Europe, dates from October 1973. It was revised, following a diplomatic conference in 2000, and is conveniently referred to as EPC 1973 (the original version)[2] or EPC 2000 (the revised version).[3]

[c] Art. 52(4) EPC 1973[2] and Art. 53(c) EPC 2000.[3]

[d] Art. 54(5) EPC 1973[2] and Art. 54(4) EPC 2000.[3]

Enlarged Board of Appeal (i.e. the highest instance) of the European Patent Office handed a treat to the pharmaceutical industry.

The abovementioned Enlarged Board of Appeal decisions authorised acceptance of claims[e] to "the use of a known drug for the manufacture of a known medicament for use in the new method of therapy" as long as the new method of therapy was itself novel and inventive, i.e. the claim would cover a known activity, the manufacture of the medicament, but would derive its novelty and inventiveness from the *purpose* for which manufacture took place. Claims in this purpose-limited use format are normally referred to as second indication or "Swiss type" claims.[7-10]

Since in practice drugs are usually supplied with details of the purpose for which they are to be used, it should be relatively simple to distinguish infringing production from non-infringing production.

Nonetheless there was no formal basis in EPC 1973 for allowing novelty to derive from the intended use of a product, except in the provision in Art. 54(5) EPC 1973 relating to the *first* medical use, and generally patent law does not allow novelty of a product to derive from its intended purpose. There has always been some uncertainty as to whether the national courts, hearing infringement actions relating to Swiss type or second indication claims in European Patents would find them after all to lack novelty. Thus when EPC 1973[2] came up for revision in 2000, to create the version EPC 2000[3] now in force, the suggestion was made (*cf. infra*) that purpose-derived

[e] The monopoly granted by a patent is defined in the "claims" of the patent.

novelty could be accorded to second and further medical uses in much the same way as for first medical uses in EPC 1973.

1.2. The 2000 revision of the European Patent Convention: purpose-derived novelty for second and further medical uses

In paragraphs 2 and 3, Art. 54 EPC 2000 defines the criteria for novelty[f], specifying the subject matter against which novelty is to be judged, that is to say the "state of the art" or the prior art. The first and subsequent medical use provisions are found in paragraphs 4 and 5 respectively. Art. 54 (4) and (5) EPC 2000 thus read:

> (4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art [i.e. known], for use in a method referred to in Article 53(c) [i.e. a method of medical treatment], provided that its use for any such method is not comprised in the state of the art [i.e. compounds can be protected for medical use if no medical use was previously known].
>
> (5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.[3]

The *travaux préparatoires*, the documents detailing the negotiations in the revision of EPC 1973 to produce EPC 2000, made the following comments:

> The new **Article 54(5) EPC** eliminates any legal uncertainty on the patentability of further medical uses. It unambiguously permits purpose-related product protection for each new medical use of a substance or composition already known as a medicine. This protection is equivalent, as far as the further uses are concerned, to that offered by the "Swiss type claim". In contrast to previous Article 54(5) EPC, now Article 54(4) EPC, providing broad (generic)

[f] To be patentable under the EPC, an invention must be new, must involve an inventive step, must be susceptible of industrial application, and must not belong to any of the categories excluded from patentability (Art. 52 and 53 EPC 2000).[3]

> protection for use in a medical method for the inventor of such use for the first time, new Article 54(5) EPC is expressly limited to a **specific** use. This limitation is intended to match as closely as possible the scope of protection to the scope provided by a "Swiss type claim".[11]

It makes one wonder - if the scope was to be as close as possible, why not just specify that the Swiss type claim format was permitted?

This narrow nature of the extension to the scope of patentable subject matter was further commented on in the *travaux préparatoires* as follows:

> The present wording of Article 54(5) EPC should remain unchanged in respect of what was known as the first medical use; as regards the second or further medical uses, the case law evolved by the EPO Enlarged Board of Appeal should be enshrined in the Convention. For the sake of transparency and legal certainty the aim of the Basic Proposal [for the revised form of the EPC] was to keep the legal status quo for medical uses.[12]

This is where it gets interesting. For second indications, EPC 1973, interpreted in G-5/83 *Eisai*, allows purpose-limited patent claims to the *process* for making a drug; EPC 2000 now allows purpose-limited claims to the drug *itself*. Thus the status quo is *not* kept, for the actions which represent infringement are different and EPC 2000 specifically worsens the situation of the physician, nurse, veterinarian or pharmacist seeking to prescribe, administer or dispense generic drugs, especially for novel dosage regimes in the treatment of the same disease.

1.3. Illustration of the implications of the EPC revision

Let us take the (fictional) example of "Exprin", a compound first known for its pretty colour, then found to be useful taken in 20mg tablets for curing malaria, then later

found to be useful in doses of 20mg for lowering blood pressure, then later still to be more useful in doses of 40mg for lowering blood pressure.

Under EPC 1973, the *inventor of the malaria application* could obtain a patent to "Exprin for use in medicine". The freedom of action of the physician or pharmacist is unaffected - Exprin had previously not been available in a medically approved form, so there is no generic to substitute with. After the patent expires, generic versions for the treatment of malaria could reach the market and be used legitimately.

Under EPC 1973, the *inventor of the first blood pressure application* could obtain a patent for "the use of Exprin for the manufacture of a medicament for use in treatment to reduce blood pressure". The physician treating blood pressure now has a new drug in her arsenal and her position is clearly improved. Generic Exprin might be available, but only from companies expressly advertising their product as for use in treating malaria. The physician or pharmacist does have the option to substitute without infringing (as, if the generic is manufactured for treating malaria and not blood pressure, the Swiss type patent claim in the patent of the inventor of the first blood pressure application is not infringed by her actions).

Under EPC 2000 however, the first blood pressure inventor could obtain a patent for "Exprin for use in treating blood pressure", i.e. for a *product* as such rather than for a *process* for its manufacture. If the physician or pharmacist substitutes generic Exprin under the new legal regime, she will infringe.

With the *second blood pressure invention* (i.e. the finding that Exprin in doses of 40mg is more useful for lowering blood pressure than in doses of 20mg), the question arises as to whether its inventor can obtain a patent with *dosage regime* claims, i.e. claims to either "the use of Exprin for the manufacture of a medicament to be given in 40mg doses in the treatment of blood pressure" or to "Exprin for use in 40mg doses for treating blood pressure". With the first of these claims, the Swiss type claim of EPC 1973, substitution with generic 20mg tablets for blood pressure would neither infringe nor be seen to be risky. With the second type of dosage regime claim, the product *per se* claim of EPC 2000, substitution *would* infringe.

2. Case law conflict and referral to the Enlarged Board of Appeal of the EPO

The grant of European Patents with Swiss type dosage regime claims was first denied by Technical Board of Appeal 3.3.2, e.g. in T-317/95 *Procter & Gamble* (a decision taken under EPC 1973 in 1999),[13] but then allowed by Technical Board of Appeal 3.3.04 in T-1020/03 *Genentech* (a decision taken under EPC 1973 in 2004).[14] The question of the allowability of dosage regime based *product* claims (i.e. of the type "Exprin for use in treating blood pressure") under EPC 2000 has been referred to the Enlarged Board of Appeal by Technical Board of Appeal 3.3.02 in April 2008 in decision T-1319/04 *Kos*[15] in which the relevant claim under consideration read as follows:

> 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 […][15]

This referral is now pending as case G-2/08 *Kos* with the following questions to be answered

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?[15]

The Enlarged Board of Appeal invited interested parties to comment, i.e. to file *amicus curiae* briefs, and both Kos and the President of the EPO were also invited to comment. Several *amicus* briefs have been filed, for example by pharmaceutical companies and by patent attorney associations. Nevertheless, despite the relevance to the day to day practice of physicians, nurses, veterinarians and pharmacists, none of the professional bodies representing medical practitioners have commented. It is to be hoped that this deficiency will be rectified.

3. The legal situation in the United Kingdom

In the United Kingdom, the Court of Appeal for England and Wales has given two decisions relating to Swiss type dosage regime claims, *Bristol-Myers Squibb v Baker Norton*[16] in May 2000 (i.e. after T-317/95 *Procter & Gamble* but before T-1020/03 *Genentech*) and *Actavis v Merck*[17] in May 2008, i.e. after T-1020/03 *Genentech*.

In *Bristol-Myers Squibb v Baker Norton*[g], the Court of Appeal was addressing a Swiss type dosage regime claim relating to the known anti-cancer drug paclitaxel (also known as Taxol) reading as follows:

> Use of taxol[h] and sufficient medications to prevent severe anaphylactic reactions, for manufacturing a medicamentation for simultaneous, separate, or sequential application for the administration of from 135 mg/m^2 up to 175 mg/m^2 taxol over a period of about 3 hours or less as a means for treating cancer and simultaneously reducing neutropenia.[16]

Lord Justice Aldous, commenting on the decision under appeal, stated

> The judge [Justice Jacob] was right to conclude that it [the claim recited above] was not a claim for a second therapeutic use [i.e. a claim permissible under G-5/83 *Eisai*]. The medicaments in question were known to be suitable for treating cancer. The remainder of the claim relates to the way that such a medicament was to be used. A similar conclusion was reached by the Dutch Court of Appeal in Bristol-Myers Squibb v Yew Tree of 25th June 1998. It follows that the reasoning in *Eisai* [i.e. the reasoning permitting grant of a Swiss type claim] does not apply.[16]

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[g] Bristol-Myers Squibb's European patent, EP-B-584001, was opposed by Nycomed Pharma, Yew Tree Pharmaceuticals, NaPro BioTherapeutics, Boehringer Ingelheim and Baker Norton Pharmaceuticals and was revoked by the EPO Opposition Division for lack of novelty. Although Bristol-Myers Squibb did not appeal the decision by the Opposition Division, NaPro BioTherapeutics did. The EPO Technical Board of Appeal 3.3.2, in its decision T-854/02 *Bristol-Myers Squibb*[18] rejected that appeal as inadmissible since, among other things, NaPro Biotherapeutics was not adversely affected by the Opposition Division's decision to revoke the patent. Interestingly, neither Nycomed Pharma nor Yew Tree Pharmaceuticals alleged that the Swiss type dosage regime claims of EP-B-584001 should be rejected as being claims to methods of therapy.

[h] Paclitaxel, a compound found in the bark of the Pacific yew tree *Taxus brevifolia*, was found by the US National Cancer Institute and Department of Agriculture to have cytotoxic activity in 1964 and was named "taxol" in 1967 by Monroe Wall. After clinical trials had begun, rights to taxol were transferred in 1989 to Bristol-Myers Squibb which in 1990 successfully applied to register Taxol as a trademark. The story of the discovery and development of taxol is told by Goodman and Walsh[19] who comment on page 2 on the trademark controversy as follows "[since 1992] Bristol-Myers Squibb have insisted that the molecule be referred to as paclitaxel and that the drug is called Taxol ®, even, as the excerpt from their report shows, when it means rewriting history." In these circumstances, it is remarkable that the claims in Bristol-Myers Squibb's patent referred to taxol rather than paclitaxel or Taxol®.

Accordingly, the position of the English Court of Appeal in 2000 was that Swiss type claims were acceptable for new indications (new illnesses treatable with the known drug) but *not* for new dosage regimes for the treatment of the same illness.

Swiss type dosage regime claims however came back before the Court of Appeal in *Actavis v Merck* where the decision was handed down by Lord Justice Jacob (the very judge responsible for the decision under appeal in *Bristol-Myers Squibb v Baker Norton*). In this case, the claim under consideration read as follows:

> The use of [finasteride] for the preparation of a medicament for oral administration useful for the treatment of androgenic alopecia in a person and wherein the dosage amount is about 0.05 to 1.0 mg.[17]

In his judgement, Lord Justice Jacob stated

> [*Eisai*] is saying that the novelty of the process (i.e. use of X in manufacture of a medicament for Y) comes from the "new therapeutic use".Does this mean only treatment of a different disease ("second medical indication" in a narrow sense), or does it also extend to a different method of using a compound for treatment of a particular disease when it was already known for use in treating that disease but by a different method?
>
> We think that the latter should be the answer is fairly clear from policy. The Enlarged Board [in *Eisai*] clearly had policy in mind for it went on to say: […] The intention of Article 52(4) EPC [...] is only to free from restraint non-commercial and non-industrial medical and veterinary activities.
>
> So the method of treatment exception to patentability should be construed restrictively. […] Accordingly on the basis of Eisai alone we would hold that Swiss form claims are allowable where the novelty is conferred by a new dosage regime or other form of administration of a substance. […]

> The EPO takes the same view about the effect of *Eisai* as us. For there is now clear Board of Appeal authority [T-1020/03 *Genentech*] holding, as we do, that it follows from *Eisai* that a novel dosage regime can confer novelty to a Swiss form claim.[17]

The analysis by the English Court of Appeal squarely pins down the fact that any basis for dosage regime claims must be findable in G-5/83 *Eisai* and the policy it embodies. This is also the clear conclusion from the *travaux préparatoires* for EPC 2000 quoted above. Nonetheless, the reasoning in the conflicting decisions of EPO Technical Boards of Appeal 3.3.02 (*Procter & Gamble*) and 3.3.04 (*Genentech*) must be considered carefully. First however the policy reason quoted above must be repeated:

> The intention of Article 52(4) EPC [...] is only **to free from restraint** non-commercial and non-industrial medical and veterinary activities. (emphasis added)[5]

4. The conflicting positions of the EPO Technical Boards of Appeal: the *Genentech, Procter & Gamble* and *Kos* Boards on the 'true implications' of the *Eisai* decision

As mentioned earlier, the grant of European Patents with Swiss type dosage regime claims was first denied by Technical Board of Appeal 3.3.2, e.g. in T-317/95 *Procter & Gamble*, but then allowed by Technical Board of Appeal 3.3.04 in T-1020/03 *Genentech*.

To quote from Board of Appeal decision T-1020/03 *Genentech*:

> It appears to this Board that the issue to be decided in this case depends critically on what was [...] decided by the Enlarged Board [in *Eisai*] in relation to Articles 52(4) and 54(5) EPC [...]

> The third paragraph of point 4.5 of decision T 317/95 [*Procter & Gamble*] by emphasising only that the typical activities of a doctor (physician) consist in the determination of the best individual treatment schedule, in particular the prescribing and modification of drug regimens for administering a particular medicament, simply ignores that it is equally part of the physician's role to choose the particular medicament. Patients would certainly be surprised to learn that this is not part of their physician's function, as who else would be competent to make this critical choice? Yet the manufacture of the medicament may be patented because its composition is absolutely new, because its therapeutic use for any purpose is new, or because the particular process of manufacture is new. But not even in these situations does the EPC (see point 1 of the Enlarged Board of Appeals order [in G-5/83 *Eisai*] point 1) allow a claim to the method of therapy as such, so the physician is protected in his own field (as are nursing staff) whereas patent protection for manufacture is not considered to be interference in this forbidden area. It is not, certainly nowadays, part of the ordinary task of a physician to manufacture his own medicaments: these are bought from suppliers. The Enlarged Board decision [in G-5/83 *Eisai*] merely allows obtaining of a patent covering the manufacture of a medicament for a further medical use. Even if the proprietor of such a patent can enforce it against a competing manufacturer or dealer, by proving that it was manufactured for the purpose of being used in the further medical indication, the patent will still not allow the patentee to interfere in the excluded [area] of the medical treatment itself, anymore than in the case of a first medical indication.[14]

This passage shows some misunderstanding and in any event is not directly transferable to purpose-limited *product* claims (rather than Swiss type claims). Infringement is defined in the national laws of the EPC member states rather than in the EPC itself. In the United Kingdom, Section 60 of the Patents Act 1977[20] defines the following as infringements of product and process claims:

> a person infringes if [...] he does any of the following things [...]
>
> (a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise; [...]

> (c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.[20]

Certain things are excluded from being infringements. Thus Section 60(5) of the United Kingdom Patents Act specifies:

> An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if -
>
> (a) it is done privately and for purposes which are not commercial; [...]
>
> (c) it consists of the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared [...][20]

It will immediately be appreciated that, as far as the UK is concerned, no exclusion from infringement occurs for veterinarians, for pharmacists providing ready-made medicaments, or for physicians and nurses in the commercial sector. Where the veterinarian, pharmacist or the commercial sector physician or nurse is substituting a generic, then there is no infringement of the Swiss type claim - *however they would infringe equivalently worded purpose-limited product claims*. Regarding the final statement, that "the patent will still not allow the patentee to interfere in the excluded [area] of the medical treatment itself, anymore than in the case of a first medical indication", we would repeat that the situation is different - quite simply because with the first medical indication there are no generics available to substitute.

One must also consider the situation where the patentee of a second or subsequent indication is not herself manufacturing the medicament (e.g. because the drug is still under patent) and has no licensee. Where the drug is commercially manufactured for

another indication, Swiss type claims do not prevent the physician, etc., from using that commercially available product to treat their patients - purpose-limited product claims however *would* interfere with their freedom of action.

The *Genentech* Board unwittingly drew attention to this in its discussion of "other considerations"

> Physicians in ordinary practice are not likely to be put off from using new methods of therapy by fear of patent infringement, but rather by fear of being sued for medical malpractice by their patients if something should go wrong, or even losing their licence to practice. It is the very responsible task of physicians to treat their patients according to the best method known to the physician [...][14]

As we mentioned earlier, the avowed intention of the legislator in introducing Art. 54(5) EPC 2000 was to leave the situation essentially as it was as a result of G-5/83 *Eisai*. Nonetheless, despite this *intention*, the legislators of EPC 2000 actually achieved a quite different effect, *extending the scope of patent protection of known drugs* by introducing purpose-limited *product* protection in Art. 54(5) EPC 2000. The introduction of Art. 54(5) EPC 2000 cannot be undone by the Enlarged Board in G-2/08 *Kos* but must be construed to minimise the effect on the physicians, veterinarians, nurses and pharmacists.

Before turning to G-5/83 *Eisai*, and eventually to the *travaux préparatoires* for EPC 2000, we must examine the reasons Technical Board of Appeal 3.3.02 has given in its *Procter & Gamble* decision for doubting whether Swiss type and purpose-limited product claims for dosage regimes might not be patentable.

In T-317/95 *Procter & Gamble*, the EPO Technical Board of Appeal 3.3.2 stated

> In the context of the question of law referred to the Enlarged Board for appeal ... the Enlarged Board of Appeal considered as a **further medical indication** the use of a substance, already known as a medicament, to treat an illness or disease not previously treated by means of that substance [...] While the treatment of a different illness or disease, was specifically recognised in decision G 5/83 [*Eisai*] to represent a new therapeutic application (further medical indication) of a medicament known per se, this does not yet exclude the possibility of deriving a second or further medical indication (a new therapeutic application) of a substance or composition, already known as a medicament, likewise from some other, previously unknown feature or embodiment (than treatment of a different illness or disease) associated with the use of that substance or composition in a method for the medical treatment of the human or animal body. […]
>
> The invention as such which forms the subject-matter of claim 10 in fact involves treatment of exactly the same category of patients by separately administering to them exactly the same two commercial drugs in the same concentration, dosage and formulation [...] for the treatment of **entirely the same illness or disease**, with the sole exception that the prescribed regimen for this treatment is slightly modified [...] It appears therefore difficult to recognise in the present invention a new field of therapeutic application or any further medical indication in general associated with the claimed combined use [...][13]

In T-1319/04 *Kos*, the decision which led to the referral of 3 questions to the EPO Enlarged Board of Appeal (cf. section 2 above), EPO Technical Board of Appeal 3.3.02 took note that *the travaux préparatoires* indicated that the function of Art. 54(5) EPC 2000 was to enshrine the case law of the Enlarged Board of Appeal, i.e. as expressed in G-5/83 *Eisai*, and provided a basis for disagreeing with the *Genentech* decision T-1020/03:

> A contrary view to that expressed in decision T 1020/03 [*Genentech*] can be stated in two alternative ways. One way of stating it is that for a therapy to be recognized as new for the purposes of Article 53(c) and 54(5) EPC 2000 over a known therapy using the same substance

> or compound to treat the same disease, there must be some difference other than the dosage regime. The other way of stating it, is that a known therapy for using a substance to treat a disease must for the purposes of Article 53(c) and 54(5) 2000 be deemed to make known all possible dosage regimes using that known substance for treating that disease. The justification for either alternative way of expressing the view would be that *assessing the right dosage is so much a question between physician and patient that preservation of the physician's freedom to assess the right dosage must take precedence over any right to obtain a patent*. (emphasis added)[15]

Does the *Eisai* decision indeed provide a basis for disagreeing with the *Genentech* decision? The reasoning of the Enlarged Board of Appeal in *Eisai* is set out in points 21 to 23 as follows:

> As is rightly recognised by the [German] Federal Court of Justice, Article 52(1) EPC 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 case as the new and non-obvious use of the known product constitutes the invention [...] Article 54(5) EPC [i.e. Article 54(4) EPC 2000] 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 such use claim is prohibited by Article 52(4) EPC [the exclusion from patentability of methods of medical treatment, now in Article 53(c) EPC 2000]. 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.
>
> It seems justifiable by analogy to derive the novelty for the process which forms the subject-matter of the type of use claim [i.e. Swiss type] now being considered from the new therapeutic use of the medicament and this is irrespective of the fact whether a pharmaceutical use of the medicament was already known or not. It is to be clearly understood that the application of this special approach to the derivation of novelty can only be applied to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC.

> *The intention of Article 52(4) EPC*, again as recognised by the [German] Federal Court of Justice, *is only to free from constraint non-commercial and non-industrial medical and veterinary activities.* 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" defined in Article 54(2) EPC.
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> Article 54(5) EPC alone provides only a *partial* compensation for the restriction on patent rights in the industrial and commercial field resulting from Article 52(4) EPC, first sentence. It should be added that the Enlarged Board of Appeal does not deduce from the special provision of Article 54(5) EPC that there was any intention to exclude *second (and further) medical indications* from patent protection other than by a purpose-limited product claim. […]
>
> No intention to exclude second (and further) medical indications generally from patent protection can be deduced from the terms of the European Patent Convention: not can it be deduced from the legislative history of the articles in question. [...]
>
> For these reasons, the Enlarged Board considers that it is legitimate in principle to allow claims to the use of a substance or composition for the manufacture of a medicament *for a specified new and inventive therapeutic application,* even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient. (emphasis added)[5]

Thus the Enlarged Board in *Eisai* saw the intention of Art. 52(4) EPC 1973 as being "*only to free from constraint non-commercial and non-industrial medical and veterinary activities".* This must be understood in the context of the legal fiction of Art. 52(4) EPC 1973 that methods of medical treatment were excluded from patentability by being considered not to be industrially applicable. This legal fiction has disappeared from EPC 2000 which now excludes methods of medical treatment in Art. 53(c) EPC 2000 as simply being subject-matter for which European patents shall not be granted.

The practice of the German Federal Court of Justice had been to allow claims to the "use of compound X for the treatment of the human or animal body by therapy". Such claims were deemed to cover commercial or industrial therapy but not non-commercial and non-industrial acts of therapy. By refusing to follow the line of the German Federal Court of Justice, the EPO Enlarged Board in *Eisai* made it clear that it was the purpose of Art 52(4) EPC 1973 to avoid causing a physician or veterinarian to have to consider patent infringement when considering whether or not to treat her patient. This meaning was clearly accepted by the *Genentech* Board as quoted above. Hence the *Eisai* decision does *not* in our view provide a basis for disagreeing with the *Genentech* decision to allow Swiss type dosage regime claims, even though it *does* provide a basis for disagreeing with the view that purpose-limited product claims are allowable.

For a *novel drug*, product *per se* claims (and purpose-limited product claims) are available; for a *first indication*, purpose-limited product claims are available. Why then did the *Eisai* Board not simply state that, for a *second or further indication*, purpose-limited product claims were available? Perhaps because unlike the first indication, the freedom of action of the physician and veterinarian would then be compromised? The result was that the decision of the *Eisai* Board allowed the inventors of second and further indications to patent their inventions using Swiss type *use* claims, but unlike the inventors of first indications did not allow them purpose-limited *product* claims, i.e. gave them a more limited freedom to patent.

Even though the cases the *Eisai* Board was reviewing related to new diseases or to illnesses treatable with a drug known for the treatment of a different disease, the

reasoning the *Eisai* Board gave applies equally to new dosage regimes for the treatment of the same disease. Thus, since a Swiss type claim is not infringed by the normal actions of the medical practitioner, whether the new application of the drug involves treatment of a new disease or treatment of the same disease at a different dosage, the allowability of Swiss type dosage regime claims would seem to be covered by the reasoning of the *Eisai* Board. To that extent, in our opinion, the *Genentech* Board was correct in differing from the earlier decisions of Technical Board of Appeal 3.3.02 and allowing Swiss type dosage regime claims.

5. At the Enlarged Board of Appeal

In an *amicus curiae* brief[i] to the Enlarged Board of Appeal in *Kos*,[21] Actavis (which is party to the abovementioned case *Actavis v Merck* which is yet to be heard by the highest British court, the House of Lords) reviewed the *travaux préparatoires* for EPC 1973 (i.e. the initial version of EPC) in relation to the possible protection for first, second and further medical indications, drawing attention to the minutes of the proceedings of Main Committee I (M/PR/I) and to Section 2 of Annex I to the Minutes of the Main Committee I[22] arguing that any exception to the exclusion of methods of medical treatment should only apply to the first indication and quoting these minutes as follows:

> "(The Netherlands delegation) said that on no account did it wish, with its proposal, to break away from the principle that only the first application in respect of the use of a known

[i] Interestingly, a portion of the letter accompanying Actavis' *amicus* brief has been deleted from the EPO file and replaced with the comment "blacked out to comply with Rule 144(a) EPC - The Registrar of the EBA". Rule 144(a) EPC states that "The parts of the file excluded from inspection ... shall be... the documents relating to the exclusion of or objections to members of the Boards of Appeal or of the Enlarged Board of Appeal"

> substance or composition in a method for treatment of a 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 [of Art. 54(5) EPC 1973] was to make clear that a known substance (or a known composition) which, since it formed part of the state of the art, was no longer patentable, nevertheless could be patented for the first use in a method of treatment... ...; however a further patent could not be granted if a second possible use were found for the same substance...." […]
>
> "In this connection the Main Committee was also of the opinion that only a first use, irrespective of whether it is with regard to humans or animals, fulfils the requirements of this provision (which became Article 54(5) (emphasis added)[21]

In their *amicus* brief, Actavis continued:

> Prior to ***Eisai*** therefore the basic policy consideration underlying the exclusion from patentability from methods of medical treatment lay in the recognition that it was wrong to circumscribe the freedom of a medical practitioner to treat his patient in any way that the medical practitioner considered best without restriction by reason of a patent monopoly.[21]

The discussions quoted by Actavis however related to the availability of purpose-limited *product* claims under Art. 54(5) EPC 1973. The Enlarged Board of Appeal in G-5/83 *Eisai* on the other hand had neatly sidestepped the question of whether the medical practitioner's freedom of action would be circumscribed by claims to second and further medical indications, by permitting *not* purpose-limited *product* claims but Swiss type *use* claims, that is claims which would not be infringed by the actions of a medical practitioner in treating her patient or prescribing drugs for the patient.

Both Actavis and Merck have asked the *Kos* Enlarged Board of Appeal to be able to present their arguments at the hearing which the Enlarged Board will probably hold. It would be most unusual if the Enlarged Board would agree to this, as in a similar

hearing in 2008, in G-2/06 *WARF*,[23] only the patent applicant WARF and the President of the EPO were heard with the Enlarged Board specifically stating that it would not hear parties who had filed *amicus* briefs.

It is time to return to the current wording of Art. 54 EPC 2000. The relevant provisions relating to first, second and further indications read as follows:

> (4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c) [the provision excluding methods of medical treatment from patentability], provided that its use for any such method is not comprised in the state of the art.
>
> (5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.[3]

Paragraph 4 is essentially unchanged in comparison with its wording in EPC 1973 – purpose-limited product claims to "compound X [known but not for medical purposes] for use in medicine" are permitted by this paragraph. But what does paragraph 5 of Art. 54 EPC 2000 permit? Clearly, claims to "compound X [known for a *medical* use] for a specific use in a new method of medical treatment". Terms in international treaties are construed to have their clear meaning, if there is a clear meaning. However, that the question arises whether the new method of medical treatment referred to in paragraph 5 may be one wherein the *same drug*, in the *same dosage form* is used to treat the *same disease*, but under a *new dosage regime*. If there is doubt, then reference may be had to the *travaux préparatoires* for EPC 2000. Clearly there is such a doubt, since otherwise the *Kos* Board would not be referring the case to the Enlarged Board of Appeal. Thus one must turn to the *travaux*

préparatoires for EPC 2000, the wording of which was finally decided at the Munich Diplomatic Conference in November 2000.

6. The *travaux préparatoires* for EPC 2000

6.1. The introduction of new Article 54(5) as proposed by the organisation of European patent attorneys and supported by the Swiss delegation

New Art. 54(5) EPC 2000 was introduced by the Swiss delegation following its proposal[24] by *epi*, the organisation of professional representatives before the EPO, i.e. of European patent attorneys, and was commented on at the 14th meeting of the EPO's Committee on Patent Law in July 2000:

> The *epi* representative tabled the proposal [...] Unlike the first medical use, further medical uses of a known substance were only inadequately protected. Although Enlarged Board of Appeal decision G 6/83 [a decision with the same date and text as G-5/83 *Eisai*] confirmed that such inventions are eligible for protection, the present situation was unsatisfactory because national courts did not consistently recognise European patents in this field. The [Swiss] delegation therefore proposed that a new paragraph (6) be added to Article 54 to guarantee the patentability of a substance for further therapeutic applications. The important thing was to maintain the existing protection for the first indication while putting protection for the second and further indications on a sound legal footing. Unlike the [European Patent] Office's proposal, the *epi* proposal envisaged dealing with the first and second indications separately.
>
> The Swiss delegation supported the *epi* proposal. It referred to decision G 1/83 [also , a decision with the same date and text as G-5/83 *Eisai*] which had provided for effective legal protection of the second medical indication. Legal certainty could be enhanced by enshrinement in law. It stressed the difference in terms of the content of the inventions between the first and any subsequent indications. These should not be merged in a single paragraph, as the practical implication of that might be more restrictive treatment of the first

> medical indication or more liberal treatment of the second and any further medical indication. […]
>
> The Austrian delegation thought *it was not yet clear whether use-bound substance protection* [i.e. 'purpose-limited product protection'] *extended the legal position of the right holder in comparison with therapeutic practice*. ... Without detailed information on this issue, the Austrian delegation could not approve the proposal. (emphasis added)[25]

The EPO put forward a suggested revision which was then commented upon by the British, German and Austrian delegations. The EPO replied that:

> [P]rotection of the first medical indication was clearly an enshrined principle. Case law in practice allowed claims for which support could not necessarily be inferred from the present [i.e. 1973] version of Article 54(5) EPC. Maintenance of broad claims for a first medical indication extending beyond a single specific application was also conceivable under the new formulation, but could not be guaranteed any more than it could under Article 54(5) EPC in its present form. Instead of a process claim for the second medical indication the proposal envisaged a use-bound substance claim, ie a use claim in the form of a substance claim. *This claim formulation probably offered no greater extent of protection than the Swiss-type claim*. […]
>
> It was agreed that the Basic Proposal should retain the Office's last proposal [...] it would be left to the Administrative Council to decide whether that proposal should be retained. (emphasis added)[25]

In September 2000, the Administrative Council duly reported[26] on the initial discussions and commended the change proposed by the Swiss delegation to the "Basic Proposal", the document to be considered by the diplomatic conference of the EPC member states in November 2000. The Basic Proposal[27] then introduced the new paragraph with no discussion or explanation.

The Swiss delegation elaborated on their proposal as follows:

> The new **Article 54(5) EPC** eliminates any legal uncertainty on the patentability of further medical uses. It unambiguously permits purpose-related product protection for each new medical use of a substance or composition already known as a medicine. This protection is equivalent, as far as the further uses are concerned, to that offered by the "Swiss type claim". In contrast to previous Article 54(5) EPC, now Article 54(4) EPC, providing broad (generic) protection for use in a medical method for the inventor of such use for the first time, new Article 54(5) EPC is expressly limited to a **specific** use. This limitation is intended to match as closely as possible the scope of protection to the scope provided by a "Swiss type claim".[11]

Finally, the Minutes of the diplomatic conference reported on the adoption of the Swiss proposal as follows:

> The Swiss delegation said it was against any amendment to the wording of Article 54(4) and (5) EPC as contained in the Basic Proposal. The present wording of Article 54(5) EPC should remain unchanged in respect of what was known as the first medical use; as regards the second or further medical uses, the case law evolved by the Enlarged Board of Appeal should be enshrined in the Convention. *For the sake of transparency and legal certainty the aim of the Basic Proposal was to keep the legal status quo for medical uses.*[…] *The proposed reform satisfied the demand users had long been making for the existing loophole in respect of the patenting of the second and further medical uses to be closed. The Basic Proposal met this demand without extending protection beyond the legal status quo*.
>
> On a suggestion from the Swiss delegation the Conference President first gave the floor to the non-governmental organisations' representatives, who said they were in favour of the solution in the Basic Proposal and largely endorsed the Swiss delegation's statements (*epi*, UNICE, EFPIA, AIPPI, FICPI, UNION, FEMIPI, CNIPA and ICC)[j]. The proposal represented a

[j] The NGOs mentioned are all organisations representing industry or the patent attorney profession. *epi* is the Institute of Professional Representatives before the EPO; UNICE is the Union of Industrial and Employers' Confederations of Europe; EFPIA is the European Federation of Pharmaceutical Industries and Associations; AIPPI is the International Association for the Protection of Intellectual Property; FICPI is the International Federation of Intellectual Property Attorneys; UNION is the Union of European Practitioners in Industrial Property; FEMIPI is the European Federation of Agents of

> balanced solution for the first and further medical uses and promoted legal certainty and harmonisation of the law for the benefit of users.
>
> […]
>
> In the subsequent debate […] [t]he majority of the delegations[k] were still in favour of the provision in the Basic Proposal [...] *The aim of the reform was to codify current legal practice*, which treated inventions of first and further uses differently in terms of the scope of grantable claims. […]
>
> [Finally], Article 54 [was] adopted by the Conference in the wording of the Basic Proposal with [a minor] editorial amendment (emphasis added)[12]

6.2. Interpreting Article 54(5) EPC 2000 in accordance with Eisai *and the intention of the EPC 2000 legislators*

From the previous section it is clear that the EPC 2000 legislators' intention was only to confirm the patentability of what the Enlarged Board of Appeal had made patentable in *Eisai*. While this could have been done simply by amending the law to confirm the acceptability of Swiss type claims, the legislators chose to introduce Art. 54(5) EPC 2000 *in the clearly expressed expectation* that the effect was the same, i.e. that the freedom of action of the physician and veterinarian was unchanged. As discussed above, however, their freedom of action is *not* unchanged and thus, we would argue, Art. 54(5) EPC 2000 must be interpreted instead in such a manner as to *minimally* restrict that freedom of action and thereby fall as far as possible within the rationale espoused by the *Eisai* Board and the wishes of the EPC 2000 legislators.

Industry in Intellectual Property; CNIPA is the Committee of National Institutes of Intellectual Property Attorneys; and ICC is the International Chamber of Commerce. The full list of NGOs attending the conference may be found in the minutes.[12]

[k] The delegations from France, Switzerland, Italy, Sweden, the United Kingdom, Monaco, Liechtenstein, Ireland, Finland, Turkey and Luxembourg.

Virtually the only way Art. 54(5) EPC 2000 can be interpreted so as to minimise its effect of constraining the freedom of action of the physician, is to interpret the new use in a medical method as being required to be use in a *new indication*, i.e. use in the treatment of a disease *not* previously treated with the known drug. This was the situation faced by the *Eisai* Board in the seven cases referred to it, and faced with which the *Eisai* Board decided that its rulings would not restrict the freedom of action of the physician.

The broader interpretation of Art. 54(5) EPC 2000, which would permit purpose-limited *product* claims where the novelty lies only in the timing or quantity of drug administration in the known treatment of a disease, would, in our view, cause an extension to the scope of patentable subject matter *which was neither intended by the Eisai Board nor by the legislators of the EPC 2000*.

This is not to say, however, that dosage regime inventions cannot be patented. Within the logic of *Eisai* and the *travaux préparatoires* of EPC 2000, and indeed of *Genentech*, such inventions may properly remain the subject matter of *Swiss type* claims, i.e. claims the physician would not need to be concerned about if she chooses the route of generic substitution.

7. Conclusion

Our analysis leads to the following answers to the questions posed to the Enlarged Board:

Question (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?

Answer (1): Yes, where a new formulation of the medicament is essential for the performance of the different, new and inventive treatment, i.e. where earlier known formulations cannot be used, the invention may be claimed with Swiss type and purpose-limited product claims. Yes, also, where earlier known formulations could be used, e.g. in lower or higher dosages, and the invention is claimed using Swiss type claims. No, however, where earlier known formulations could be used and the invention is claimed using purpose-limited product claims.

Question (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?

Answer (2): Yes, where the invention is claimed with Swiss type claims, but no, where it is claimed with purpose-limited product claims.

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

Answer(3): In view of the rationale of *Eisai* that the freedom of action of medical practitioners should not be compromised and given the clear intention of the legislators of EPC 2000 that the rationale of *Eisai* should be followed, in order to minimise the inhibitory effect of patents on medical practitioners carrying out their day-to-day tasks of deciding on the appropriate treatment of their patients, the patent

coverage for a new dosage regime must be via Swiss type **use** claims and **not** via purpose-limited **product** claims.

If this line of reasoning were to be followed, the 2000 revision of the EPC need not imply an attack on generic substitution and the granting of patents in this field can fulfil its double role of both promoting innovation and protecting the public interest.

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