

Actavis: Pharmaceutical Swiss Claims; EPO vs. National Precedent;
Kos Case at the Enlarged Board

Today in *Actavis UK Ltd. v. Merck & Co. Inc.*, [2008] EWCA Civ 444 (Court of Appeal 2008)(Ward, Jacob, Rimer, JJ.), the Court of Appeal followed European Patent Office precedent in *Genentech/method of administration of IFG-I*, T1020/03 [2006] EPOR 9, approving a pharmaceutical use claim, departing from national precedent in favor of a rule following EPC patent precedent. The court also noted the *possibility* that a future decision by the Enlarged Board of Appeal in *Kos Life Sciences*, EPO Enlarged Board G 2/08, referred May 7, 2008, might impact *Actavis*; postponing the period for appeal to the House of Lords until after a decision in *Kos Life Sciences*.

Pharmaceutical Use Law Following *Genentech*: In a tour de force comparative analysis of pharmaceutical claims, the court concluded that “[i]n the EPO, Germany, and even in New Zealand, Swiss form claims whose novelty depends on a new treatment by a different dosage regime or method of administration are treated as novel and not as claims to a method of administration. The position is settled.” *Actavis*, ¶ 44.

Choosing EPO Precedent over National Court Decisions: Choosing to follow the European Patent Office decisions on patent law instead of precedents from its own courts, Lord Justice Jacob stated:

“In saying our courts would and should normally follow the settled jurisprudence of the EPO it should be understood, of course, that they are not bound do so. In the unlikely event that we are convinced that the commodore is steering the convoy towards the rocks we can steer our ship away. Technically we are not in the same position as we are in the case of decisions of the European Court of Justice.... And of course if there is no clear message from the commodore or he gives mixed messages we must decide our own course anyway.” *Actavis*, ¶ 48.

Carving out an exception for patent law from the general rule that prior national court decisions should be followed, Lord Justice Jacob said that:

“Decisions as to the principles of patent law are in their nature very specialist, are decided by only a few specialist judges at first instance and to some extent in this court and come up only very infrequently in the House of Lords at all. Furthermore the House of Lords itself has held that the EPO Boards of Appeal, if they have a settled approach on a point of law, should be followed. So to say the Court of Appeal should throw its hands up and leave it to the House of Lords (or Supreme Court)

to reverse it (as it would very likely do, in the absence of a margin of appreciation) is more or less simply to delay the inevitable at great expense.” *Actavis*, ¶ 101.

Setting forth a general rule, “this court is free but not bound to depart from the *ratio decidendi* of its own earlier decision if it is satisfied that the EPO Boards of Appeal have formed a settled view of European Patent law which is inconsistent with that earlier decision. Generally this court will follow such a settled view.” *Actavis*, ¶ 107.

Obviousness as of the Priority Date: As a “postscript” on the issue of obviousness, the court emphasized the shifting nature of how one might approach this point based upon the time slice used to measure obviousness. The court pointed out that “superficially one might think th[e] conclusion [of nonobviousness as of the priority date] is a bit odd given that the invention was once obvious – one might assume that when an invention becomes obvious it must remain so thereafter. But such an assumption would be wrong: obviousness must be determined as of a particular date. There is at least one other well-known example showing how an invention which might be held obvious on one date, would not be so held at a later date. That is where there has been commercial success following a long-felt want. Time can indeed change one’s perspective. The perspective the court must bring to bear is that of the skilled man at the priority date and not any earlier time.” *Actavis*, ¶ 119.

Potential Conflict with EPO Enlarged Board Kos Case: At the eleventh hour, counsel identified a case at the Enlarged Board, *Kos Life Sciences*, EPO Enlarged Board G 2/08, referred May 7, 2008, which might impact *Actavis*. The Court modified its judgment to defer the time for appeal to the House of Lords until *after* the decision of the Enlarged Board in *Kos Life Sciences*.

A highlight marked copy of the opinion in *Actavis* is attached; a copy of the Technical Board decision including the questions referred to the Enlarged Board is also attached.

Regards,

Hal

May 21, 2008



Neutral Citation Number: [2008] EWCA Civ 444

Case No: A3/2007/1625 and A3/2007/1650

IN THE SUPREME COURT OF JUDICATURE
COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
CHANCERY DIVISION (PATENTS COURT)
The Hon Mr Justice Warren
HC 06 C02676

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 21/05/2008

Before :

LORD JUSTICE WARD
LORD JUSTICE JACOB
and
LORD JUSTICE RIMER

Between :

Actavis UK Limited

**Claimant/
Respondent**

- and -

Merck & Co Inc

**Defendant/
Appellant**

Approved Judgment

Lord Justice Jacob (giving the judgment of the court):

1. This is an appeal from a decision of Warren J [2007] (EWHC 1311 (Ch)). He held that Merck's Patent (EP (UK) 0 724 444) was invalid.

2. The case turns entirely on the validity of claim 1:

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.

The dosage amount referred to is per day (see the judgment at [10]). Androgenic alopecia ("aa") is a type of baldness occurring in men (male pattern baldness, "MPB") and women.

3. Merck had patented finasteride itself in 1978 so, as a substance, it was known at the priority date of the patent (15th October 1993). By then it was on the market in tablet form for the treatment of benign prostatic hyperplasia "(BPH)". The dose was 5mg daily, that is to say five or more times the dose of claim 1.

4. The Judge summarised the basic science uncontroversially at [4-6]:

[4] Androgens are a class of steroid hormones which are responsible for the development and maintenance of masculine characteristics *eg* male sexual organs, deepened voice, facial hair, baldness and so on. Testosterone is the major circulating androgen in men. In certain tissues, the principal mediator of androgenic activity is not testosterone but one of its metabolites, dihydrotestosterone ("DHT"). Testosterone is converted to DHT by the action of a membrane bound enzyme called 5 α -reductase. This enzyme is present in a number of adult tissues including prostate, liver and skin.

[5] It is now accepted science that there are two forms ("isozymes") of 5 α -reductase, which I shall refer to simply as "type 1" and "type 2". Isozymes are variants of the same enzyme. They differ in amino acid sequence but catalyse the same reaction – in this case the conversion of testosterone to DHT.

[6] Finasteride is one of a class of compounds known as a 4-azasteroids. It is a strong inhibitor of type 2 but not of type 1. It is now known that type 2 is the relevant isozyme in relation to BPH; finasteride is therefore a suitable treatment for BPH, inhibiting reduction of testosterone to DHT in the prostate. ...

5. The Judge held that claim 1 was invalid on the grounds that it was not novel pursuant to the provisions of the European Patent Convention ("EPC") Art 54 (enacted as s.2 of the

Patents Act 1977) and was unpatentable pursuant to EPC Art.54(5) (enacted as s.2(6)). But he would have rejected the obviousness attack. Merck appeals his findings as regards novelty and unpatentability, Actavis cross-appeals his finding of non-obviousness. For Merck Mr Peter Prescott QC argued the novelty and unpatentability points and Mr Antony Watson QC the obviousness point. Mr Simon Thorley QC undertook the burden of all three points for Actavis.

6. I set out the relevant language of the EPC which, it is common ground, governs this case (i.e. that before the amendments introduced by the EPC 2000):

Art 52 Patentable Inventions

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

(4) 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.

Art 54 Novelty

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(5) The provisions of paragraphs 1 to 4 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 Art 52(4), provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

Art 56 Inventive Step

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art ...

Art 57 Industrial application

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

Swiss form claims in general

7. Swiss form claims have been long accepted in the UK, see *Wyeth* [1985] RPC 545 and the “*BMS*” case, *Bristol-Myers Squibb v Baker Norton* [1999] RPC 253 at [44] (Jacob J at first instance) and [2001] RPC 1 Court of Appeal (at [37] *per* Aldous LJ and [80-81] *per* Buxton LJ). For convenience we here adapt Jacob J’s explanation in *BMS* of the rationale of these. Such a claim steers clear of two obstacles to patentability, namely the requirement of novelty and the ban on methods of treatment of the human body by therapy. It follows a statement of practice regarding “use claims” issued by the Swiss Federal Intellectual Property Office, [1984] OJ EPO 581. The generalised form of such a claim is “the use of compound X in the manufacture of a medicament for a specified (and new) therapeutic use”. Such claims are unnecessary when X is new, for then X can be patented in itself by virtue of the last sentence of Art.52(4). But when X is old, a Swiss form of claim confers novelty and yet is not a claim to a method of treatment.
8. The Enlarged Board of the European Patent Office (“EPO”) so held in *Eisai*, G5/83 [1985] OJ EPO 64. It said:

[23] It is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case where the process of manufacture as such does not differ from known processes using the same active ingredient.”
9. So the manufacture of an old substance for use in a new treatment was considered by the Enlarged Board to be novel. The justification for novelty was the new therapeutic use. And since the claim was to the manufacture of the compound, it was not a claim to a method of treatment.
10. In *BMS* Jacob J wondered how such a claim might work so far as infringement is concerned and thought it might create difficulty. And so it might in some cases (e.g. where the product is just sold as a standard product, like aspirin tablets). But in many cases the difficulty may be more theoretical than real. This is because manufacturers, particularly for prescription medicines and probably many others, have to provide detailed instructions and information about the use(s) and dosage(s) of their products. So in practice you can tell whether someone has used X for the manufacture of a medicament for the treatment of Y. He will have to say that his product is for the treatment of Y on his product information leaflet.
11. This case is about the limits of what can be done with Swiss form claims. In outline the argument for invalidity runs as follows:
 - (a) Finasteride as a substance is not novel;
 - (b) Nor is its use as a medicine (for treating BPH);
 - (c) So its use for the manufacture of a medicament for use as a medicine lacks novelty;

(d) Moreover finasteride had been proposed for treating aa, but with a daily dosage of 5mg or more (see below);

(e) So its use for the manufacture of a medicament for treating aa also lacks novelty.

(f) Novelty cannot be saved by specifying a particular dosage regime even if that dosage was not proposed in the prior art.

(g) Even if that is wrong, this court is bound under the English rules as to precedent by its prior decision in *BMS* to hold that the patent lacks novelty and/or is in substance one for a method of treatment of the human and thus, by virtue of Art. 52(4) is not to be regarded as susceptible of industrial application.

12. Merck's counterargument runs thus:

(i) Points (a) to (e) are accepted.

(ii) But (f) is wrong and contrary both to *Eisai* and EPO Board of Appeal authority subsequent to *BMS* and this court should follow that,

(iii) There is no *ratio decidendi* of *BMS*, or at least not one clear enough, which precludes this court from so doing.

(iv) Even if there is such a *ratio*, this court should recognise (and apply) a new exception to the general rules of precedent for this court, rules adopted long ago and summarised in *Young v Bristol Aeroplane Company* [1944] KB 718.

13. We begin by dealing with the arguments without reference to the impact of *BMS*. There are three stages: first a detailed consideration of a Swiss form claim; secondly, why such a claim is treated as novel and not for a method of treatment, a close examination of *Eisai*; and thirdly, subsequent EPO and other cases.

Swiss form claims in more detail

14. One possible view of novelty in patent law (we speak generally rather than by reference to any particular legislation) is this: that a thing is either old or it is not. If it is old, then a claim to the thing itself cannot be made novel by qualifying it with words specifying an intended use however inventive that use may have been. This was the rule in this country prior to the new, European, patent system brought in by the EPC and the implementing Patents Act 1977.

15. The rule was exemplified by *Adhesive Dry Mounting v Trapp* (1910) 27 RPC 341. The claim was "for carrying into practice" a process of mounting photographs on cardboard using a tissue coated with heat activatable gum on both sides. Such a tissue (called "a pellicle") was in itself old. Parker J held that adding an intended purpose did not confer novelty on an old product:

After Jeyes' patent [i.e. the prior art] it was open to all the world to make and sell such a material. The idea of using an old material for an entirely new purpose, not being analogous to purposes for which it has theretofore been used [i.e. "obvious"], may be good subject matter, but such an idea, however ingenious, can hardly justify a claim for the material itself.

So you could patent an inventive new process using the new material, but not the material "for carrying out the process".

16. This rule had the virtue of certainty when it came to infringement – a man who sold an old product could not infringe. The rule had disadvantages from the patentee's point of view. A method claim was not as effective in practice as a "product for" claim. The person he really wanted to sue was the seller of the product which was going to be used for his patented process. There were difficulties about this, however. Such a seller, though not guilty of infringement as such might otherwise be liable pursuant to some doctrine of contributory infringement or inducement to infringe. The law was not clear about this (cf. *Innes v Short* (1895) 15 RPC 449, the criticism of this case in *Adhesive Dry Mounting* and the general discussion of the problem in §3-210 of the 4th edn, (1974) of *Patents for Inventions* by T.A. Blanco White QC).
17. The rule had a more significant disadvantage in the field of medicines. For you could not get a method claim – methods of treatment were then, as they are now, precluded from patent protection. This meant that there was no patent incentive to investigate whether old substances had a medical use – not even a first medical use for an old substance would be worth researching, *a fortiori* a second medical use.
18. Things are different under EPO case law as was first established in *Eisai* in 1984. Before we examine *Eisai* in more detail it is important to note a parallel, closely related, development which occurred a little later but outside the context of medical use. In *MOBIL/friction reducing additive* G2/88 [1990] EPOR the "use of X as a friction reducing additive in a lubricant composition" was held by an Enlarged Board notwithstanding the fact that the use of X in such a composition for the purpose of rust inhibition was known. Novelty of purpose for use can confer novelty even if the substance is old and unpatentable as such. Lord Hoffmann in *Merrell Dow v Norton* [1996] RPC 76 noted the difficulties which this sort of claim may cause in respect of infringement but clearly deliberately refrained from holding that a *Mobil*-type use claim is invalid.
19. We turn back to *Eisai*. At the conclusion of [18] the Enlarged Board held that a claim to the use of a compound for therapeutic treatment is "confined to the step of treatment" and so unpatentable. No one quarrels with that.
20. The Board then went on to say this by way of an introduction to its consideration of Swiss form claims:

19. ... having regard to the statement of practice of the Swiss Federal Intellectual Property Office, the Enlarged Board has also given careful consideration to the possibility of protecting second (and subsequent) medical indications by means of a claim directed to the use of a substance or composition for the manufacture of a medicament for a specified (new) therapeutic application. Such claims do not conflict with Article 52(4) EPC or Article 57 EPC but there may be a problem concerning the novelty of the invention.
21. We pause there. The Board is clearly saying that this form of claim does not fall foul of Art.52(4). Making up the substance for administration is not in itself administration – is not treatment. That would seem to be the case whether the substance is made up in a factory (here 1mg. pills of finasteride) or in a pharmacy (where it may even be patient specific). We emphasise this because sometimes in the discussion there is a tendency to conflate the novelty and therapeutic treatment objections, as though one followed from the other. What worried the Board was only novelty.
22. Next the Board puts on one side cases where it sees no novelty objection:
- [20] Where the medicament itself is novel in the sense of having novel technical features – e.g. a new formulation, dosage or synergistic combination – 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.
23. In the course of argument Rimer LJ noted that the Board considered that a new *dosage* form would be enough to confer novelty. Mr Prescott seized upon that, submitting that the Board clearly contemplated that a new dosage – even for treating a disease previously treated with the same substance in a different dosage was regarded as novel. We agree. A claim to a pill containing a 1mg dose of finasteride would be a claim to a new thing. No-one had made or proposed such a thing, so why should it not be novel? Whether it would obvious is a quite different matter. Since the patent in fact has no claim to a pill with a 1 mg dose is not necessary to pursue this further, though in view of our conclusion on obviousness it may be that such a claim would have stood as valid on its own.
24. [20] concludes with what the Board saw as the crucial point for it to decide:
- 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.
25. In [21] it began its analysis with the “general principle of patentability for inventions” saying:

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.

26. So generally you can protect a novel and inventive new use for a product by a “use” or, to use the language of the law of infringement (see s.60 of the 1977 Act, corresponding to Art. 25 of the Community Patent Convention), “process” claim. But of course in the case of a method of treatment you cannot have a “use” claim; that is forbidden by Art. 54(4). The Board so recognised as it developed its reasoning in [21] saying:

Article 54(5) EPC provides an exception to this general rule, however, so far as the first use of medicaments is concerned, in respect of which the normal type of use claim is prohibited by Article 52(4) EPC. 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 is this passage which is crucial. Art 54(5) is an exception to the general rule about novelty. It is saying that even if a substance is not novel in the absolute sense, it is to be treated as novel as regards a first use as a medicament.

27. The Board then says the same logic applies by analogy to a second medical use:

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

This 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.”

28. 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?
29. We think that the latter should be the answer is fairly clear from policy. The Enlarged Board clearly had policy in mind for it went on to say:

[22] 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. When Mr Thorley was asked what policy reason there should be for on the one hand allowing Swiss form second medical treatment claims for different diseases but not allowing them for the same disease, the only answer he could devise was that the treatment might cost more. Why, he said, should you have to pay more for a 1mg pill than for an out of patent 5mg pill? The reason is obvious – the 1mg pill has only come about because of expensive unpredictable research. Patented things often cost more. And the reason is because the monopoly has been given as result of the research which led to it. Research into new and better dosage regimes is clearly desirable – and there is simply no policy reason why, if a novel non-obvious regime is invented, there should not be an appropriate patent reward. Such a reward cannot extend to covering the actual treatment but a Swiss form claim which specifies the new, inventive, regime is entirely in accordance with policy.

30. The policy reason for allowing such claims is closely akin (without the complication of the ban on therapeutic use claims) to that behind *Mobil/friction reducing additives*. As Jacob J observed in *BMS*:

57. ... It is arguable that there is no logical or reasonable distinction between [*Mobil*] and the decision in *Eisai*. After all it is the novel (second medical use) purpose of the product of manufacture of the Swiss form claim which is said to create novelty. The product and its method of manufacture are old. So to try and to steer a course between accepting *Eisai* and yet holding *Mobil* wrong is at best going to involve more Byzantine logic.

31. 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.
32. So holding is far from saying that in general just specifying a new dosage regime in a Swiss form claim can give rise to a valid patent. On the contrary nearly always such dosage regimes will be obvious – it is standard practice to investigate appropriate dosage regimes. Only in an unusual case such as the present (where, see below, treatment for the condition with the substance had ceased to be worth investigating with any dosage regime) could specifying a dosage regime as part of the therapeutic use confer validity on an otherwise invalid claim.
33. The EPO takes the same view about the effect of *Eisai* as us. For there is now clear Board of Appeal authority holding, as we do, that it follows from *Eisai* that a novel dosage regime can confer novelty to a Swiss form claim. In *Genentech/method of administration of IFG-I*, T1020/03 [2006] EPOR 9 a Legal Board of Appeal specifically so held in an unusually detailed and carefully crafted reasoned opinion. It said:

[72].... the Board interprets decision G 5/83 [*Eisai*] allowing Swiss form claims directed to the use of a composition for manufacture of a medicament for a specified new and inventive therapeutic

application, where the novelty of the application might lie only in the dose to be used or the manner of application. This Board allowed such a claim, where only the manner of application was new, already eleven years ago in T 0051/93 of 8 June 1994. The discussion in decision G 0005/83 concerning further medical indications did indeed refer to use for treating a new illness. But the Board regards this significant only of the fact that most further medical use claims will refer to a new illness, as in that case novelty and inventive step are more likely to exist than in the case of a minor modification of the treatment known for an existing illness. The logic of decision G 0005/83 allowing claims to further medical uses of known compositions, seems equally applicable to any use of such known composition for a new and inventive treatment which cannot be claimed as such because of Article 54(4) EPC first sentence.

34. *Genentech* was hardly a new departure in some respects, even though it disapproved certain earlier decisions. The quoted passage refers to T0051/93, an important case not cited in *BMS*. It was about a claim to “use of X for the manufacture of a medicament for use in the treatment by subcutaneous administration of [an identified disorder].” The prior art disclosed the use of X for the same disorder but by intramuscular administration. The difference in the method of treatment was enough to confer novelty because the purpose of manufacture was different. There cannot be any sensible difference between different dosage regimes and different methods of administration: either they confer novelty or they do not. The EPO has decided both do.
35. Mr Thorley accepted that *Genentech* decided that a new dosage regime conferred novelty for a Swiss form claim. But he suggested the position was not to be regarded as firmly settled in the EPO. He made two points here: first that the position was not settled at Enlarged Board level and second that there was authority to that effect.
36. The Enlarged Board point has no substance. It must be remembered that the parties themselves cannot take cases to the Enlarged Board. Only the President of the EPO or a Board of Appeal can refer a question. If a Board regards a question as settled it will not refer - as indeed happened in *Genentech* where the question of a reference was considered in detail (see [47]-[54]). So the more firmly a point is established the less likely it is that there will be a reference to an Enlarged Board.
37. As to the second point, Mr Thorley suggested that *SCHERING/Combination therapy for HCV*, T531/04, casts some doubt on *Genentech*. The claim was in Swiss form and included within its purpose a “total time period of 40-50 weeks” and administration to a class of patients identified by having failed to respond to an earlier identified therapy and having more than a specified load of HCV virus in their blood serum.” The patent was rejected as being obvious, but before that the Board said:

[6] ... Some of the respondents have argued that these features should not be taken into account for the assessment of novelty and

inventive step since they relate to medical methods excluded according to Article 52(4) EPC or do not constitute true distinguishing technical features.

[7] The board considers that the above arguments raise serious legal questions to which the case law of the boards of appeal has not yet provided a completely uniform response. It furthermore notes the auxiliary request of the respondents to refer questions of law with respect to the interpretation of Article 52(4) EPC to the Enlarged Board of Appeal. However, for the purposes of the present decision, this issue need not be addressed since even if it were to be decided in favour of the appellant, the appeal still has to be dismissed for lack of inventive activity of the claimed subject-matter (see points 8-43 below). ..

38. We do not regard this short, *obiter* passage as casting any serious doubt on *Genentech*. No reasoning is set out so it is impossible to understand why the Board said this.
39. Of much greater significance is that several Boards have accepted *Genentech* as being right. Thus in T36/04 *UNIVERSITY OF TEXAS/DNA damaging agents* a different therapeutic regime was enough to confer novelty, the Board saying:

[3] ... The decisive question to be answered in accordance with [*Eisai*] is then whether the intended method of treatment for which the medicament was manufactured was novel and inventive and not any further considerations under rt. 52(4) (cf. [*Genentech*]).

And in *EXOEMIS/Haloperoxide*, T292/04 the Board at [4] referred to [36] of *Genentech* (“use of a composition for making a medicament .. for a specified therapy as a further medical indication” patentable subject to novelty and obviousness”) with clear acceptance that it was right. Another case in which *Genentech* was referred to with approval was *PRAECIS/GnRH Antagonists* T0380/05 at [5] although the actual decision was not concerned with a novel dosage regime. *Genentech* was followed by the Boards of Appeal in *ARS/Infertility* T1074/06 (Swiss-form claim whose novelty depended on the dosage regime being specified in the claim – see [17]), and *SCHERING/Combination therapy HCV* T1399/04 – see [21].

40. Of perhaps particular relevance is *SEPRACOR/Descarboethoxyloratadine* T 230/01. The claim which was held novel read:

Use of DCL, or a pharmaceutically acceptable salt thereof, for the manufacture of a medicament for use in treating allergic rhinitis in a human, said medicament to be administered in an amount sufficient to provide daily dose of 0.2 mg to 1 mg of DCL or pharmaceutically acceptable salt thereof to a human, [our emphasis].

Novelty in this claim came from (a) the selection of allergic rhinitis, where the prior art disclosed only general allergies; and (b) the “to be administered in an amount sufficient to provide daily dose of 0.2 mg to 1 mg of DCL” feature. The Board said:

[10]... the claimed use in claim 1 of the second auxiliary request additionally differs from the disclosure of citation (1) by the recommended daily dose of 0.2 mg to 1 mg of DCL or a pharmaceutically acceptable salt thereof. Novelty is therefore beyond any doubt [our emphasis].

41. The UK Intellectual Property Office clearly understands that *Genentech* is treated by the EPO as established law. The June 2007 version of its *Guidelines for Patent Examination* say this:

116. The EPO has generally taken a more liberal view of what constitutes a “new therapeutic use”. Claims have been accepted in which the prescription regime of the treatment was specified (T 570/92 BAYER (unpublished)) and where the distinguishing feature was mode of administration (T 51/93 SERONO (unpublished)). Indeed, in the recent decision T 1020/03 (T 1020/03 GENENTECH/*Method of administration of IGF-OJEPO* 2007, 204 to **any** new and inventive use falling within Article 52(4) (equivalent to Section 4(2)) – the claim in question was distinguished by the precise dosage regime. Following this decision, the EPO have held that claims drafted in the Swiss format are not objectionable under Article 52(4), regardless of what is defined as the new medical use. However, in view of the binding decision of the Court of Appeal in the *Taxol* case, such claims cannot be accepted in a UK patent application.

The more restrictive view taken by the UK Office is a result of its interpretation of the Court of Appeal decision in *BMS* (also known as “the taxol” case).

42. Moreover, the German Supreme Court has, without (perhaps surprisingly) referring to the EPO jurisprudence, held novel and not a claim to a method of treatment a Swiss form claim whose novelty depended on a dosage regime, *Carvedilol II*, (2006) IIC Vol 38 p479. The claim in question read:

Use of carvedilol for the manufacture of a medicament for decreasing mortality resulting from congestive heart failure in human patients in conjunction with an angiotensin-converting enzyme inhibitor, a diuretic and a digitalis glycoside, with said medicament being formulated for administration purposes at an initial dose containing either 3.125mg or 6.25mg carvedilol per day for a period of 7-28 days, followed by dose increases in bi-weekly intervals up to a maximum dose of 2 x 25 mg carvedilol per day.”

In relation to this claim the court said:

51 – 1. However, there are no reservations against the admissibility of the patent claims according to subsidiary motion 2, which provides under both patent claims that the medication containing carvedilol is formulated in certain doses for administration over certain periods. Accordingly, protection is to be accorded to the use of a chemical substance in the therapeutic treatment of the human body, such substance being formulated to suit such use – for instance, by means of suitable packaging, for the tablet sizes, an inscription on the package or package inserts. Pursuant to this Court’s case law, such use of a chemical substance is not excluded from patent protection under Sec. 5(1) German Patent Act (basically, BGHZ 88, 209, 215 – *Hydroxyridine*). For Art. 52(4) EPC, which corresponds verbatim with Sec. 5(2)(1) German Patent Act, the same is true. The patent claims of subsidiary motion 2 are not opposed by the ineligibility for patent protection of procedures for the surgical and therapeutic treatment of humans or animals.

The court went on to hold the claim obvious on the grounds that the dosage regime would have been arrived at by routine investigation. As we have observed already dosage requirements will often be obvious and this case is a typical example of that. Mr Thorley tried to persuade us by reference to other parts of the decision that the position was not clear in Germany, but the passage we have quoted is clear.

43. Finally it is worth mentioning that the New Zealand Patent Office in the shape of a closely reasoned decision of the Office decided to follow the EPO’s *Genentech, Genentech and Washington University’s Appn.* 15th December 2006.
44. We pause to summarise. In the EPO, Germany, and even in New Zealand, Swiss form claims whose novelty depends on a new treatment by a different dosage regime or method of administration are treated as novel and not as claims to a method of administration. The position is settled.
45. Our courts would normally follow such settled jurisprudence. That would be in accordance with what Lord Hoffmann said in *Merrell Dow Pharmaceuticals v Norton* [1996] RPC 76 at 82:

... the United Kingdom Courts ... must have regard to the decisions of the European Patent Office ("EPO") on the construction of the EPC. These decisions are not strictly binding upon courts in the United Kingdom but they are of great persuasive authority; first, because they are decisions of expert courts (the Boards of Appeal and Enlarged Board of Appeal of the EPO) involved daily in the administration of the EPC and secondly, because it would be highly undesirable for the provisions of the

EPC to be construed differently in the EPO from the way they are interpreted in the national courts of a Contracting State.

46. Nicholls LJ (as he then was) said the same thing perhaps with even greater force in *Gale's Application* [1991] RPC 305 at 322:

The Act had a further purpose. The Act did not merely enact the statutory provisions necessary for the provisions of the Convention regarding European patents to take effect in this country. The Act also had a harmonisation objective. On the signature of the Convention for the European Patent for the Common Market, referred to in the Act as the Community Patent Convention, and not to be confused with the European Patent Convention, the governments of the member states of the European Community resolved to adjust their laws relating to patents so as to bring those laws into conformity with the corresponding provisions in the European Patent Convention and other conventions. Accordingly, when construing and applying section 1(1) and (2) of the Act, the court must have regard to the legislative intention with which those subsections were framed, namely, that they were framed so as to have, as nearly as practicable, the same effect in the United Kingdom as the corresponding provisions in Article 52(1), (2) and (3) of the European Patent Convention have in the territories in which that Convention applies. That is the effect of section 130(7) in the present case.

From this brief reference to the European Patent Convention one point which emerges is that it is of the utmost importance that the interpretation given to section 1 of the Act by the courts in the United Kingdom, and the interpretation given to Article 52 of the European Patent Convention by the European Patent office, should be the same. The intention of Parliament was that there should be uniformity in this regard. What is more, any substantial divergence would be disastrous. It would be absurd if, on an issue of patentability, a patent application should suffer a different fate according to whether it was made in the United Kingdom under the Act or was made in Munich for a European patent (UK) under the Convention. Likewise in respect of opposition proceedings.

47. Mr Prescott put the point so colourfully in his skeleton argument that it is worth repeating:

Now, you cannot have 34 [the current number of EPC members] ships steering in the same convoy unless there is something like a commodore. That is why Mustill LJ in *Genentech Inc's Patent* [1989] RPC 147, 266 referred to the Board of Appeal of the European Patent Office as "the central decision making body of the

European patent system” [which] must be hearkened to with particular attention”.

48. In saying our courts would and should normally follow the settled jurisprudence of the EPO it should be understood, of course, that they are not bound do so. In the unlikely event that we are convinced that the commodore is steering the convoy towards the rocks we can steer our ship away. Technically we are not in the same position as we are in the case of decisions of the European Court of Justice (see further below). And of course if there is no clear message from the commodore or he gives mixed messages we must decide our own course anyway.
49. Here, for the reasons we have given and subject to the binding effect, if any, of *BMS*, we would follow the EPO and hold that a new dosage regime is enough to confer novelty on a Swiss form claim.

The contentions about BMS

50. Actavis contends that we cannot follow the EPO, however, because this court’s decision in *BMS* stands in the way. Many have interpreted *BMS* as deciding (1) that a novel non-obvious dosage regime specified in a Swiss form claim cannot make it novel and (2) that such a claim is to a method of treatment. Included in that number are the Opposition Division in relation to the parallel designations of the *BMS* patent itself (reasons dated 22.5.2002 holding the patent lacked novelty but expressly disagreeing with the CA about method of treatment), the Board of Appeal in *Genentech* itself (it was strongly critical of the CA decision in *BMS*), Jacob J in *Merck’s Patents* [2003] FSR 29 at [74] (he was also unhappy with *BMS*), the UKIPO (see above), and Warren J in this case.
51. Mr Prescott submits that the many were wrong: that if one examines *BMS* closely to try to identify its *ratio* or *rationes decidendi*, there is none clear enough to preclude patentability in the present case. And even if he were wrong, we should depart from the decision by way of a new exception to the rules of precedent.

What did BMS decide?

52. More particularly Mr Prescott submits that if one subjects *BMS* to close scrutiny it cannot be taken a deciding, or deciding clearly enough for the purpose of the rules of precedent, either proposition stated in §50 above. We turn to examine that question first.
53. The facts of *BMS* need summarising. The prior art (Winograd) proposed the treatment of cancer by administration of taxol (plus medication to prevent anaphylactic reactions) over a period of 3 hours at a dosages of 175 and 125 mg/hr. The patentees discovered that if you did that there would be less neutropenia (reduction in white blood cells) than you would expect (and got from the known, 24 hour period of infusion). They tried to patent exactly what Winograd had proposed, the claim, broken up into elements, reading:

(1) Use of taxol and sufficient medications to prevent severe anaphylactic reactions

- (2) For manufacturing a medicament for simultaneous, separate or sequential application
- (3) For the administration of from 135mg/m² up to 175mg/m² taxol over a period of about 3 hours or less
- (4) As a means for treating cancer and
- (5) Simultaneously reducing neutropenia.

All but element (5) were specifically disclosed in Winograd. And if you did what he had proposed you would get the benefit of element (5) as an unexpected bonus.

- 54. In those circumstances it is hardly surprising that Jacob J, this court, the Dutch Court of Appeal (the *Yew Tree* case, see below) and the Opposition Division all held the claim lacked novelty. It covered exactly what was known: the claim covered that for which the prior art gave clear and unambiguous instructions. Winograd had already planted the flag where the patentee was seeking to plant it. So no one disputes the principal reason for the decision in every court where it was decided.
- 55. However, there was also a method of treatment attack. Jacob J rejected that. He said:

[50] Nor do I accept that ... the claim amounts to merely a method of treatment. It is to the manufacture of the medicines to be used in that treatment. I am reinforced in that view by the consideration that the Art. 54(4) provision about methods of treatment is an exception to patentability and as an exception should be construed narrowly. As the Board of Appeal in *Harvard/Oncomouse* (T0015/90 OJ EPO [1990] 476) said, speaking of another exception:

"Art. 53(b) is an exception, for certain kinds of inventions, to the general rule under Art. 52(1) that European patents 'shall be' granted for all inventions which are susceptible of industrial application, which are new and which involve an inventive step. Any such exception must, as repeatedly pointed out by the Boards of Appeal, be narrowly constructed (cf. in particular T320/87, point 6 OJ EPO 1990 76)."

[51] A like approach is indicated in *Plant Genetic Systems/plant cells*. (T0356/93 OJ EPO [1995] 545) There is also the limited purpose of the exception to be considered. It is not so broad as to stop doctors using whatever they feel they need to treat patients. If that were the purpose then one would not allow patents for medicines or medical implements at all. The purpose of the limitation is much narrower, merely to keep patent law from interfering directly with what the doctor actually does to the patient. Patent monopolies are permitted to control what he

administers to, or the implements he uses on, the patient. The thinking behind the exception is not particularly rational: if one accepts that a patent monopoly is a fair price to pay for the extra research incentive, then there is no reason to suppose that that would not apply also to methods of treatment. It is noteworthy that in the US any such exception has gone, and yet no-one, so far as I know, suggests that its removal has caused any trouble.

56. When the case reached the Court of Appeal there were three separate judgments. They all concluded, contrary to Jacob J, that the method of treatment objection was good. And they also possibly considered novelty on an additional basis from the straightforward, prior flag planting, basis we have just described. For present purposes it is necessary to try to find the reasons. For it is only a decided point of law, a *ratio decidendi*, which matters for the purposes of precedent. As will be seen below, it is only if there is a clear *ratio* of a first Court of Appeal that a subsequent Court of Appeal is bound by it.
57. We turn first to the leading judgment of Aldous LJ. He dealt with the case under three headings, novelty, obviousness and method of treatment. As far as novelty is concerned, he focussed on whether there was a “second therapeutic use” within the meaning of *Eisai*. He held there was not. But, we think, what he had in mind here was not that the prior art and the claim were concerned with the same medical condition, i.e. cancer, but the suggestion that the discovery of less neutropenia than expected was a second therapeutic use. This appears most clearly in the following passage:

[46] The second submission [i.e. that there was no disclosure in the prior art of the less neutropenia effect] depends upon the discovery that less neutropenia occurred during the three-hour infusion than during a 24-hour infusion. That was not mentioned in the lecture, but it was, as I have already pointed out, a discovery not a second therapeutic use as considered in *Eisai*. Further it is an inevitable consequence of the three-hour, 135mg/m² infusion, described in the lecture and as such cannot impart novelty to the claim.

So Aldous LJ did not decide that for novelty, a Swiss form claim must specify a second medical use in the sense of a distinct and different medical condition.

58. Turning to the method of treatment objection, Aldous LJ upheld the attack. But he did so on a very narrow basis which turned on the particular claim under consideration. This involved a patient specific dosage. He held the claim essentially covered that which doctors would do in relation to patient treatment and so was unpatentable – it was not “susceptible of industrial application.” He said:

[62] ... Article 52(4) was not intended to exclude pharmaceutical preparations from being patentable. That has the result that restrictions can be imposed by patentees upon treatment. The section has the limited purpose of ensuring that the actual use, by

practitioners, of methods of medical treatment when treating patients should not be subject to restraint or restriction by patent monopolies. The difficulty is to decide whether the restraint concerns a method of treatment as opposed to what is available for treatment.

[63] In my view the form of claim 1 does not disguise its effect. The invention was the discovery that by changing the treatment from a 24-hour infusion to three hours a similar effect was obtained with less neutropenia. That was a discovery that a change in the method of treatment provided the result. The claim is an unsuccessful attempt to monopolise the new method of treatment by drafting it along the lines of the Swiss form claim. When analysed it is directed step-by-step to the treatment. The premedication is chosen by the doctor, and administered prior to the taxol according to the directions of the doctor. The amount of taxol is selected by the doctor as is the time of administration. The actual medicament that is said to be suitable for treatment is produced in the patient under supervision of the medical team. It is not part of a manufacture. In my view Mr Thorley is correct. The invention made and claimed was a method of treatment precluded from patentability by section 4(2) (Article 52(4)). That is emphasised by the way the allegations of infringement were pleaded [i.e. that the carrying out of clinical trials infringed].

59. So Aldous LJ decided the method of treatment point on a very narrow ground indeed. It was that if in essence the claim is merely to a method of treatment it is bad. The claim in the present case is far from that. It is in its essence directed at the manufacturer. The doctor's only involvement will be in prescribing for the treatment of aa the 1mg pill made by an alleged infringer. We do not regard Aldous LJ's *ratio* as binding in its effect so far as the general case of dosage specific Swiss form claims or so far as this case is concerned.
60. We turn to Buxton LJ's judgment. We begin by observing that it is not clear that he thought he was saying anything different from Aldous LJ. He agreed that the appeal should be dismissed and then said "in deference to the arguments addressed to us, I venture to add some words of my own."
61. He began by rejecting the wholesale attack on *Eisai* which had been launched by *Baker Norton*. He rejected that and it is noteworthy that he accepted the principle that UK courts should regard EPO decisions as of great authority, saying:

[81] This may seem to be merely a roundabout way of seeking to patent a medical process, and one that only doubtfully gives proper weight to the first sentence of Article 52(4). It is not, however, in my view open to us to use such doubts as a ground for not applying *Eisai* at all. That is because, although the observations

of the House of Lords in *Merrell Dow* [1996] R.P.C. 76 at p. 82, line 25 as to the undesirability of departing from decisions of the EPO may strictly speaking not have been part of the *ratio* of that case, they are considered and reasoned guidance of a unanimous House, which I do not think we are free to depart from.

This is noteworthy because it follows that, if he did go on to lay down any principle inconsistent with *Eisai*, he surely would not have done so if he had known of the interpretation of that case now followed in the EPO.

62. He then considered the limits of *Eisai*. Here he said:

[83] It is important in this enquiry to remember the emphasis placed by the Board on justification by analogy from cases of first medical use. Recognition of first medical use as a subject of patentability necessarily entails the use of the substance for a new and completely different purposes from that in relation to which it is already known. If the Board's analogy is to hold, therefore, the relationship between the first and the second medical use must be of the same nature: the second medical use must be for an end-purpose distinctively different from the first, albeit also medical, purpose for which the substance was used. That not only follows from the structure of the Board's argument, but also from the need to respect the exclusion of methods for treatment from patentability. If the novelty can lie in the nature of use, rather than in the end-result at which that use aims, then it is indeed the method of treatment on which patentability rests.

And, after further reference to *Eisai*, he went on:

85 .. the very experienced judges of the Patents Court in *Wyeth* expressed the question as involving “the allowability of claims directed to an invention based on the discovery of a second (or subsequent) pharmaceutical use of a known substance or composition, already known for a particular medical use (or particular medical uses), the new use being *unconnected with* the previously known use or uses.” [1985] R.P.C. 545 at p. 556, line 24, emphasis supplied”.

86 That was equally the view of the Court of Appeal of the Hague in *Bristol-Myers Squibb v. Yew Tree* [2000] ENPR 26 , a case concerned with the patent in suit in our case, which, described a second medical indication as—

“an application of a substance for a different therapeutic purpose (for example to fight another illness or for prevention instead of cure)”.

87 The novelty of the second medical use, on which its patentability rests, must therefore be found in applications that are new in the terms used in *Wyeth* and *Yew Tree*. The novelty cannot lie in the method of use, but in the new therapeutic purpose for which the substance is used.

63. Mr Thorley contends that Buxton LJ was here holding that for a second medical use Swiss form claim to be novel, it had to be for a different medical condition. Certainly some sentences suggest this is so. But others do not. Thus his reference to the *Yew Tree* case “for a different therapeutic purpose” incorporates the Dutch court’s exemplification of “fight another illness or for prevention instead of cure.” If these are only examples as the Dutch court considered they were, clearly “different therapeutic purpose” has a very wide meaning indeed and could encompass a different treatment for a known condition.
64. That Buxton LJ is not laying down a “different medical condition” rule also seems apparent from how he reasoned in relation to the case itself. He could simply have said “the prior art method was for the treatment of cancer; so is this. And it follows just from that that it cannot be novel”. That is not what he did. He accepted Jacob J’s finding that there was no second medical use because it was a mere discovery about an old use.
65. Further Holman J agreed with the detailed reasoning of both Lords Justices. After saying at [109] that he agreed with Buxton LJ’s analysis of second medical use claims, he said:
- So there must be a therapeutic application or purpose which is not only inventive but new.
- That is not clearly saying there has to be a treatment of a different disease. It is the application which has to be new and inventive – and a novel dosage regime which is inventive would seem to satisfy Holman J’s test.
66. If one considers Warren J’s judgment on these points it illustrates particularly vividly why it is unlikely that *BMS* actually decided that a Swiss form claim whose difference from the prior art is only in the dosage regime lacks novelty.
67. The Judge held that claim 1 lacked novelty because the only thing that differentiated it from the prior art was the new dosage regime. Spelling that out it means he held that “the use of finasteride for the preparation of a medicament for oral administration useful for the treatment of aa wherein the dosage is amount is about 0.05 to 1.0mg” lacked novelty. But no one had ever used finasteride for that purpose or ever given clear and unmistakable directions so to do. This case is not like *BMS* where Winograd had disclosed the very dosage regime of the claim and had given clear and unmistakable directions for its use and hence to use taxol for the preparation of that dosage regime.
68. The Judge noted that “it may be novel to use it in the small dosage which it is now apparent can result in successful treatment.” He thought it followed from *BMS* that that novelty was not enough to count as novelty for the purposes of validity.

69. What is revealed particularly sharply here is that if that conclusion is right, there are two kinds of novelty attacks possible against Swiss form claims. First there is what may be called the “conventional” novelty attack – the well-known *General Tire* [1972] RPC 457 at 485-6 “clear and unmistakable directions test.” But also available would be a different test – one asks is the novelty of the claim only due to a novel dosage regime? If that is so then it does not matter that no one has ever proposed that regime – the claim lacks novelty.
70. We think that cannot be so – there is only one novelty test and it is the *General Tire* test. We do not think one can conclude that the court in *BMS* was holding that there are two tests and certainly it was not clearly doing so.
71. Accordingly we are not satisfied that *BMS* contains a clear *ratio* that a Swiss form claim lacks novelty if the only difference between it and the prior art is a new dosage regime for a known medical condition.
72. As to method of treatment, Buxton LJ reasoned the same way as Aldous LJ:
- [93] In relation to the patent in suit, however, the manufacture claimed is not the use of the active ingredient, paclitaxel, in the manufacture of taxol; but the mixing in the hospital pharmacy of taxol and other ingredients to produce the medium that is injected into the patient. It is that latter process that is said to be susceptible of industrial application, under Article 52(1) of the EPC. I am afraid that I found that assertion to be, at best, artificial, and one that I do not think would have been made were it not for the need to demonstrate that the invention is not of a method of treatment. We were told that the mixing process could be, and in some cases was, sub-contracted outside the hospital; but that does not prevent it from being a long way away from anything that in normal parlance would be considered an *industrial* application; or, for that matter, as under the old English law, “manufacture”. As my Lord has described, the mixing is of amounts and types of premedication, and of amounts of taxol, all determined by the doctor in relation to the specific patient. It is in reality not a self-standing operation, but subordinate and incidental to the doctor's treatment of the patient. True it is that, in treating the patient, the doctor will, or at least may, administer the drugs according to the guidance contained in the patent. But that merely underlines that what the patent teaches is not how to manufacture a drug for use in the treatment of the patient, which would be in form at least a Swiss form claim, but how to treat the patient: which is the teaching that the Swiss form claim is designed to avoid.
73. There is a *ratio* here – that the claim concerned was essentially to a method of medical treatment. It is the same *ratio* as that of Aldous LJ. Holman J agreed. However it seems clear that the EPO would not accept it as correct. For it accepts that any Swiss form

claim by its nature stops short at claiming a method of medical treatment – it does not monopolise the actual treatment of a patient.

The Judge's conclusions

74. The Judge held the claim lacked novelty and was for a method of treatment. In both cases he considered that *BMS* required him so to do. As to novelty for the reasons we have given we think he was wrong because there is no clear *ratio* of *BMS* on the point.
75. As to the method of treatment point, the Judge dealt with it briefly. He accepted Mr Thorley's submission that the dosing regime was a matter of choice for the doctor and that as far as the prior art was concerned it would make no difference whether the patient was given five 1 mg tablets a day or one 5mg tablets per day. But that is not enough in our view to mean that the claim is in substance to a method of treatment. There is nowhere near the degree of involvement of medical personnel which turned the case in *BMS*. In its essence the claim here is to the use of finasteride for the preparation of a medicament of the specified dosages. It is not aimed at and does not touch the doctor – it is directed at the manufacturer. Putting it another way, even if *BMS* is right on this point, it cannot be extended to cover every case where novelty depends on a specified dosage regime. After all every prescription medicine must be prescribed – that does not mean they are all for methods of treatment.
76. Accordingly we think the Judge was wrong on both aspects. We should record in fairness that he did not have the benefit of the sustained argument we have had before us on these points.

The effect of BMS

77. Mr Prescott went further however. Even if we had concluded otherwise, he submitted we should not be and were not bound to follow *BMS*. He submitted first that the rule of precedent applied in this court was limited to cases where there was a clear *ratio* to be found in a prior decision of this court, And secondly even where there is a clear *ratio*, in the special case of questions of law about patentability, this court should follow clear EPO authority where it is contrary to the *ratio* of one of its own previous decisions – we should recognise a new exception to *Young v Bristol Aeroplane* [1944] KB 718.

What if there is no or only an obscure ratio?

78. The first of these two points is of general application. Self-evidently the rule in *Young v Bristol Aeroplane* can only come into play where there is a *ratio* of an earlier decision to be followed. It is that *ratio* which is then to be treated as settled. As every law student will know it is not always easy to find what the *ratio* of a decision is, and it can be harder the more there are different judgments.
79. Moreover there are cases where there is simply no *ratio*. It is wrong to assume that every decision must have a *ratio* if only it can be found. A clear example of a no-*ratio* decision would be where three judges in the Court of Appeal each reached the same ultimate

conclusion for different reasons, and, *a fortiori*, if they are inconsistent reasons. In such cases there is simply no *ratio* which can be followed.

80. As for an individual judgment, although we suppose every judge who writes his or her own decision tries to articulate a *ratio* it would be an article of faith and contrary to reality to say that every judge has succeeded or that a *ratio* (or *rationes*) can readily be distilled from every judgment.
81. So how should the doctrine of precedent apply if there is no clear *ratio* to be followed? Viscount Dunedin said in *Great Western Railway v Owners of SS Mostyn* [1928] AC 57 at p.73:

Now, when any tribunal is bound by the judgment of another Court, either superior or co-ordinate, it is, of course, bound by the judgment itself. And if from the opinions delivered it is clear - as is the case in most instances - what the ratio decidendi was which led to the judgment, then that ratio decidendi is also binding. But if it is not clear, then I do not think it is part of the tribunal's duty to spell out with great difficulty a ratio decidendi in order to be bound by it.

82. Lord Reid was also of the opinion that there are cases where a *ratio* may be obscure and so not binding. In *Midland Silicones v Scruttons* [1962] AC 446, when he was still living uncomfortably with the rule that the House of Lords was always bound by its previous decisions ("I have on more than one occasion stated that my view that this rule is too rigid and that it does not in fact create certainty", p.475) he said at p.476:

I would certainly not lightly disregard or depart from any ratio decidendi of this House. But there are at least three classes of case where I think we are entitled to question or limit it: first, where it is obscure, secondly, where the decision itself is out of line with other authorities or established principles, and thirdly, where it is much wider than was necessary for the decision so that it becomes a question of how far it is proper to distinguish the earlier decision.

He was speaking of the position of a House of Lords considering an earlier House of Lords decision. By parity of reasoning the same must also apply when the Court of Appeal considers an earlier Court of Appeal decision.

83. These statements of principle are evident common sense. The purpose of the rules about precedent is to produce certainty. If a particular "precedent" is itself obscure, trying to follow it is likely to perpetuate uncertainty rather than achieve it.
84. Since we are satisfied that there is no clear *ratio* of *BMS* governing this case, we are free therefore to hold, and do hold, that we should follow *Genentech* and, subject to the cross-appeal on obviousness, allow the appeal.

Should there be a further exception to the rule in Young v Bristol Aeroplane?

85. We also – and this is a distinct reason for our decision - think the appeal should be allowed if we are wrong about there being no clear *ratio* of *BMS* so that, if the decision were to be followed, the appeal would have to be dismissed. This is because we accept Mr Prescott’s submission that the special circumstances arising from the creation of the European patent system and the central importance given to decisions of the Boards of Appeal require this court to recognise a further exception to the rules laid down *Young v Bristol Aeroplane Company*.

86. We begin by recalling what those rules are, laid down by Lord Greene MR presiding over a six-judge Court of Appeal in 1944 ([1944] KB 718 at 729):

On a careful examination of the whole matter we have come to the clear conclusion that this court is bound to follow previous decisions of its own as well as those of courts of co-ordinate jurisdiction. The only exceptions to this rule (two of them apparent only) are those already mentioned which for convenience we here summarize: (1.) The court is entitled and bound to decide which of two conflicting decisions of its own it will follow. (2.) The court is bound to refuse to follow a decision of its own which, though not expressly overruled, cannot, in its opinion, stand with a decision of the House of Lords (3.) The court is not bound to follow a decision of its own if it is satisfied that the decision was given per incuriam.

87. When *Young* reached the House of Lords, Viscount Simon expressly agreed with this, saying at [1946] AC 163 at 168:

The appeal is from a unanimous decision of the Court of Appeal. That court was specially constituted to hear the appellant's appeal from the judgment given against him by Mr. Commissioner Laski K.C., at Manchester Assizes. Besides Lord Greene M.R., who delivered the considered judgment of the whole court, Scott, MacKinnon, Luxmoore, Goddard and du Parcq L.JJ. were parties to the decision. One of the conclusions reached in the judgment of the Master of the Rolls, with which I agree, is that if the Court of Appeal, when sitting in one of its divisions, has in a previous case pronounced on a point of law which necessarily covers a later case coming before the court, the previous decision must be followed (unless, of course, it was given per incuriam, or unless the House of Lords has in the meantime decided that the law is otherwise), and that this application of the rules governing the use of precedents binds the full Court of Appeal no less than a division of the court as usually constituted.

The rule was re-affirmed in *Davis v Johnson* [1979] AC 264 (see *per* Lord Diplock at p.323, Viscount Dilhorne at p.336, Lord Scarman at p.349) where it had been suggested

that a Court of Appeal of five judges could overrule a previous decision of a three-judge panel.

88. Lord Diplock's reasons for saying that the position for this court was not the same as that for the ultimate court (which by then, following the 1966 Practice Statement, had a limited power to depart from its own previous decisions) were as follows

In an appellate court of last resort a balance must be struck between the need on the one side for the legal certainty resulting from the binding effect of previous decisions, and, on the other side the avoidance of undue restriction on the proper development of the law. In the case of an intermediate appellate court, however, the second desideratum can be taken care of by appeal to a superior appellate court, if reasonable means of access to it are available; while the risk to the first desideratum, legal certainty, if the court is not bound by its own previous decision grows ever greater with increasing membership and the number of three-judge divisions in which it sits – as the arithmetic which I have earlier mentioned shows. So the balance does not lie in the same place as in the case of a court of last resort. (p.326)

The point he makes about numbers has some significance here.

89. Lord Scarman was also concerned about the problem which increasing numbers would bring. He said at p.344

There are now as many as 17 Lords Justices in the Court of Appeal, and I fear that if stare decisis disappears from that court there is a real risk that there might be a plethora of conflicting decisions which would create a state of irremediable confusion and uncertainty in the law. This would do far more harm than the occasional unjust result which stare decisis sometimes produces but which can be remedied by an appeal to your Lordships' House.

90. What was said about the numbers generally applies with even greater force now. *Young* was decided when the Court of Appeal consisted of the Master of the Rolls and six Lords Justices. All members of the court sat, save for Luxmoore LJ, who died shortly thereafter and one infers was unable to sit. By the time of *Davis v Johnson* there were 17 Lords Justices. There are now 38 including Master of the Rolls but not the heads of divisions who are all entitled and not infrequently do sit in the Court of Appeal. It is now all the more important that there are clear rules of precedent.
91. However as Lord Salmon pointed out in *Davis*, the rule in *Young*, however much it is endorsed by the House of Lords, is at heart a rule imposed by the Court of Appeal on itself. He said at 344:

Ever since 1944, this rule [i.e. that laid down in *Young*] has been applied by the Court of Appeal except in the instant case. Your Lordships' House on a number of occasions (once before and three times after 1944) has confirmed the application of the rule to decisions of the Court of Appeal, and has thereby greatly strengthened the rule. In the nature of things however, the point could never come before your Lordships' House for decision or form part of its ratio decidendi. This House decides every case that comes before it according to the law. If, as in the instant case, the Court of Appeal decides an appeal contrary to one of its previous decisions, this House, much as it may deprecate the Court of Appeal's departure from the rule, will nevertheless dismiss the appeal if it comes to the conclusion that the decision appealed against was right in law.

92. So ultimately it is for this court, exercising its powers in favour of legal certainty, to rule on whether there can and should be further exceptions to the rule. That can only be done by considering all the circumstances and practicalities of a proposed exception.
93. In this connection it is important to note that international influences have come to have great significance in our law. At the time of *Young* the English and Welsh system was what the physicists would call "closed." The law was made by the judges as common law and by Parliament as statutory law. Outside sources were negligible. Now things have moved on. This country is now a member of the European Union, is a party to the European Convention on Human Rights, and, of particular relevance to this case, is a party to the European Patent Convention.
94. It would be absurd to say the rule laid down for the closed system in 1944 must necessarily apply in all those changed circumstances. That would be to treat the words of the judgment as those of a statute and a partially obsolete statute to boot.
95. So we hold we are free to consider whether the *Young* rule should apply with its full force in the context of the EPC system. In particular we are free to decide what this court is do if it finds that its earlier interpretation of the "European Law for the grant of patents" is clearly inconsistent with a settled interpretation given by the Boards of Appeal of the EPO.
96. We begin by noting that that the EPC seeks to harmonise patent law for all members of the Union, now numbering 34. Article 1, headed "European Law for the grant of patents" provides:

A system of law, common to the Contracting States, for the grant of patents for invention is established by this Convention.

And the Patents Act 1977 says in its preamble that it is an Act, inter alia, "to give effect to certain international treaties" one of which is the EPC. Section 91 says that "judicial notice shall be taken" of "any decision of, or expression of opinion by, the relevant

convention court on any question arising under or in connection with the relevant convention.” By s.137 the EPO Boards of Appeal are included within that definition. Section 91 uses practically the same language as s.3(2) of the European Communities Act 1972, but unlike that Act (which provides in s.3(1) that a question of law, if not referred, “shall be ... for determination as such in accordance with the principles laid down by and any relevant decision of the European Court or any Court attached thereto”), it does not require our courts to follow EPO decisions.

97. Technically the expression “judicial notice” means no more than the identified material can be received by the court without further proof. But there would be no point in this provision if the court, having admitted an expression of opinion of a Board of Appeal, could not consider it as an aid to reaching its judgment. So there is statutory backing on top of common sense and the high judicial authority we have already quoted all pointing one way: to the conclusion that UK courts should strive to follow the EPO’s interpretation of the treaty.
98. If the UK is out of line, it will either be going too far or not far enough; either recognising as valid patents which the EPO has held should not as a matter of law, be granted (this could happen, for instance, if the application were made to the UK Office) or holding invalid patents which the EPO considers are valid. Either situation would be bad for the European market.
99. Mr Thorley recognised that. He submitted however, that since the decisions of the EPO Boards of Appeal are not declared to be binding, this court, having decided a point one way, should leave matters as they are even if the EPO has firmly decided the other way, and leave it to the House of Lords (or future Supreme Court) to put things right.
100. He reinforced that by reference to what he suggested was an analogous case, one where this court had decided a point under the ECHR and there was a conflicting later decision of the Strasbourg Court. The House of Lords has considered that situation, holding in *Kay v Lambeth BC* [2006] 2 AC 465 that it should be dealt with only by an appeal to the House of Lords and not by this court departing from its previous decision. Lord Bingham explained why in a passage expressly agreed with by a majority of the House and with no dissent expressed. He said:

[43] As Lord Hailsham observed ([1972] AC 1027, 1054), "in legal matters, some degree of certainty is at least as valuable a part of justice as perfection". That degree of certainty is best achieved by adhering, even in the Convention context, to our rules of precedent. It will of course be the duty of judges to review Convention arguments addressed to them, and if they consider a binding precedent to be, or possibly to be, inconsistent with Strasbourg authority, they may express their views and give leave to appeal, as the Court of Appeal did here. Leap-frog appeals may be appropriate. In this way, in my opinion, they discharge their duty under the 1998 Act. But they should follow the binding precedent, as again the Court of Appeal did here.

[44] There is a more fundamental reason for adhering to our domestic rule. The effective implementation of the Convention depends on constructive collaboration between the Strasbourg court and the national courts of member states. The Strasbourg court authoritatively expounds the interpretation of the rights embodied in the Convention and its protocols, as it must if the Convention is to be uniformly understood by all member states. But in its decisions on particular cases the Strasbourg court accords a margin of appreciation, often generous, to the decisions of national authorities and attaches much importance to the peculiar facts of the case. Thus it is for national authorities, including national courts particularly, to decide in the first instance how the principles expounded in Strasbourg should be applied in the special context of national legislation, law, practice and social and other conditions. It is by the decisions of national courts that the domestic standard must be initially set, and to those decisions the ordinary rules of precedent should apply.

101. We do not accept that the analogy holds good for decisions of the EPO. Decisions as to the principles of patent law are in their nature very specialist, are decided by only a few specialist judges at first instance and to some extent in this court and come up only very infrequently in the House of Lords at all. Furthermore the House of Lords itself has held that the EPO Boards of Appeal, if they have a settled approach on a point of law, should be followed. So to say the Court of Appeal should throw its hands up and leave it to the House of Lords (or Supreme Court) to reverse it (as it would very likely do, in the absence of a margin of appreciation) is more or less simply to delay the inevitable at great expense.
102. By way of contrast decisions about the ECHR are likely to be numerous and arise in all sorts of courts. They are apt to be about less precise legal questions than those in patent law with the result that there is much more room for argument as to whether a subsequent Strasbourg decision is actually in conflict with an earlier decision of the Court of Appeal.
103. There are also compelling commercial reasons why the position is different. For if there is an inconsistency between the EPO and this court, the result will adversely affect the market in Europe – potentially for those who need to market their products Europe-wide, disastrously so. A patchwork position across Europe is an uncertainty of a different sort from legal certainty, but possibly of equal importance.
104. And obviously Lord Bingham’s “more fundamental reason” has no application to this situation – there is simply no question of “a margin of appreciation” in European patent law.
105. Mr Thorley also drew our attention to what Jacob LJ said giving the judgment of the court in *Aerotel v Telco* [2006] EWCA Civ 1371, a case where it was contended this court should follow the EPO and there was a prior authority of this court to the contrary:

[29] We are conscious of the need to place great weight on decisions of the Boards of Appeal, but, given the present state of conflict between the old (*Vicom* etc.) and the new (*Hitachi* etc.) approaches, quite apart from the fact that there are three distinct new approaches each to some extent in conflict with the other two, it would be premature to do so. If and when an Enlarged Board rules on the question, this Court may have to re-consider its approach. If such a ruling were to differ from what this court had previously decided a question would arise as to what should be done: should this court (and first instance courts) follow the previous rulings in our courts, leaving it to the House of Lords (or the future Supreme Court) to decide what to do or should the new ruling of the Enlarged Board be followed? It may be that the better course then would be for a decision of the first instance court to be “leapfrogged” to the House of Lords or Supreme Court. For the present we do not have to decide this.

106. The question we face now was foreseen and left unanswered. Although the “better course” referred to was a “leapfrog” appeal, the much deeper analysis which has been called for and given in this case has persuaded us that the problem can be dealt with without recourse to that procedure.

107. So we hold that there ought to be, and is, a specialist and very limited exception to the rule in *Young v The Bristol Aeroplane Company*. Spelling it out it is that this court is free but not bound to depart from the *ratio decidendi* of its own earlier decision if it is satisfied that the EPO Boards of Appeal have formed a settled view of European Patent law which is inconsistent with that earlier decision. Generally this court will follow such a settled view.

108. We have held that to be the case here and for this reason also would reverse the Judge’s finding about novelty and method of treatment. That means the appeal should be allowed unless the obviousness point raised by the respondents’ notice should succeed. To that we now turn.

Obviousness

109. The Judge rejected the obviousness attack. Was he right to do so? It is common ground that the question is simply whether at the priority date, 15th October 1993, it was obvious to the person skilled in the art to have considered that finasteride would or might be suitable for the treatment of aa. If it was then the skilled person would have investigated it for that purpose. Part of that investigation would have involved identifying the appropriate dosage regime – a dose as low as possible consistent with effectiveness is what would have been aimed at.

110. In more detail Actavis’ case ran as follows:

- (1) It had already been proposed to treat aa with finasteride but with a dosage of “5 to 2000 mg preferably from 5 to 200 mg” (Merck patent appn. 0285,382A published on 5th October 1988);
- (2) It was obvious to follow this up – and to investigate suitable doses. One would thereby learn that the lower dose of the patent in suit would do. Hence it was obvious to manufacture finasteride for the manufacture of a medicament for the treatment of aa with such lower doses.
- (3) The Sudduth review paper of August 1993 (“Finasteride: The First 5 α -Reductase Inhibitor”) reinforces this. It says:

DHT appears to be the active androgen in the balding scalp. Thus preventing DHT formation by inhibiting 5 α -reductase may be a viable treatment option

And (after summarising a report of some small scale experiments with balding monkeys in a paper by Diani):

Results from this study suggest a role in reversing established baldness. It also appears that the combination of finasteride and minoxidil may be more effective than either agent alone. Development of a topical finasteride treatment would allow local treatment of baldness without significant systemic alteration of androgens. Clinical trials in humans are planned to establish the drug’s role as either single-agent therapy or in combination with minoxidil in the treatment of MPB.

111. Given just these matters (all of which are accepted as being material which the skilled man would know) Merck accept that the invention would indeed be obvious. Indeed Merck accepts that if Sudduth could fairly be taken alone. But, Merck submits that the skilled man would, at the priority date of the patent, know more. In particular by then he would know that there is no detectable Type 2 in the scalp. Since finasteride was known only to inhibit Type 2 he would think there would be no point in trying it at all for aa. He would never get to investigate suitable dosage forms for he would think there are none.
112. Mr Watson pointed out that Sudduth carefully says that:

“Their (i.e. Types 1 and 2) distribution has not been determined in humans”

Once that state of ignorance went and one knew that there was no detectable Type 2 in the scalp, the basis of Sudduth’s optimism would go with it.

113. Merck say that the state of knowledge of the skilled man was radically changed by two documents which it is accepted the skilled man would have read at the priority date. They are Thigpen et ors. (“Tissue Distribution and Ontogeny of Steroid 5 α -Reductase

Isozyme Expression”), published in August 1993 and Harris et ors. (“Identification and selective inhibition of an isozyme of steroid 5 α -reductase in Human Scalp”), published November 1992. Merck says these documents clearly point to Type 1 as the culprit responsible for baldness, for instance Harris says:

“5 α -reductase 1-type activity appears to be the major reductase activity in the scalp.”

And Thigpen reported that Type 2 could not be detected in any region of the balding scalp – in experiments which were quite sensitive.

114. The Judge accepted Merck’s argument. He was taken through much detail before he reached that conclusion. We, on appeal, should only disturb that conclusion if he made some sort of error of principle, see *Biogen v Medeva* [1997] RPC 1 at 45.
115. Mr Thorley developed his attack on the Judge’s conclusion at some length taking us to much of the evidence and a number of papers. We have read his submission again in transcript form. We confess that as he proceeded it seemed more and more that he was really asking us to re-evaluate the evidence rather than identifying any error of principle. The transcript confirmed that impression.
116. His main point was that but for and prior to Thigpen and Harris, it was obvious to try finasteride for aa. And that there was not enough in these two documents to put the skilled man off. As Mr Thorley put it: “The question is has it [i.e. the expectation of success] fallen so low that you would never start?”
117. We are of the opinion that the Judge had ample material upon which to conclude, as he did, that the expectation had indeed fallen so low. Mr Watson took us to some of that:
 - (1) Professor Russell’s factual evidence (he was also Merck’s expert witness and a consultant to Merck before and at the time of the invention):

50. Thigpen thus suggests that balding might be treated by a type 1 inhibitor while a type 2 inhibitor is unlikely to be effective in scalp skin (since the data suggested the type 2 isozyme is absent in the adult scalp). In discussions as a consultant to Merck, I therefore suggested to Dr Ed Scolnick around the time of publication of Thigpen that Merck should concentrate on developing a type 1 inhibitor for MPB.”

- (2) The fact that Professor Russell gave evidence in chief which was not directly challenged that even if one had a belief that there might be type 2 in the critical area of the follicle, he would have thought it highly unlikely that finasteride would cure baldness. Mr Thorley submitted that the Professor’s answers to other questions undermined that evidence, but we do not see that is so – and given it was the only oral evidence in chief it cried out for direct attack if a real attack could be made. In the end the position is this: the scalp had lots of Type 1 and finasteride would not tackle that.

- (3) The fact that Dr Thornton (Actavis' expert) clearly accepted in several passages in the evidence that you would not use finasteride unless you thought that balding was caused by Type 2 (see transcript p.113₁₀ and p.114₁₀).
118. It is not necessary (indeed would be wrong) to go into the detail any further. No error of principle was demonstrated. Indeed we think the Judge was right to conclude that the invention was not obvious at its priority date.
119. We add a small postscript: superficially one might think this conclusion is a bit odd given that the invention was once obvious – one might assume that when an invention becomes obvious it must remain so thereafter. But such an assumption would be wrong: obviousness must be determined as of a particular date. There is at least one other well-known example showing how an invention which might be held obvious on one date, would not be so held at a later date. That is where there has been commercial success following a long-felt want. Time can indeed change one's perspective. The perspective the court must bring to bear is that of the skilled man at the priority date and not any earlier time.

Conclusion

120. Merck's appeal should be allowed and the order for revocation of the patent should be rescinded.

Postscript

121. The above is our judgment including minor editorial and typographical corrections suggested by the parties' legal advisers after we had supplied the draft a few days before the day fixed for the formal handing down, namely May 9th 2008. Five minutes before the formal handing down was due Mr Thorley made a telephone application asking us not to hand down judgment because he had just learned of a Board of Appeal decision which might affect our views. Mr Hinchcliffe, Merck's junior counsel consented to this. So we agreed, requiring the parties to make written submissions on the point and to supplement, if they saw fit, the submission they had already made relating to costs, an injunction and permission to appeal to the House of Lords.
122. The decision in question is **T1319/04 Kos Life Sciences**. The claim in question (omitting detail unnecessary for present purposes) reads:

1. 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.

The Board held on the facts that the particular method of administration (once per day prior to sleep) was novel and non-obvious. The question was whether this Swiss-form claim was patentable under the amended EPC ("EPC 2000").

123. The Board considered the question was important saying:

5.2 Whether medicaments for use in methods of treatment by therapy where the only novel feature is a dosage regime are patentable under Articles 53(c) and 54(5) EPC 2000 is an important point of law, as the situation arises quite frequently. If patenting is to be excluded in such circumstances, then applicants need to know this for certain, so that in cases where the novel dosage regime can be practiced using a new physically different form of the medicament, information on this is included in the application on filing, so that at least for this patent protection can be obtained.

124. It decided to refer the following 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?”

125. We regard the decision of the Board to refer as very sensible. Important questions of patentability need settling once and for all. That is what the Enlarged Board is for. Plainly the position under EPC 2000 needs settling.

126. Mr Thorley contended that the fact of the reference showed that we were wrong in saying that the position as regards new dosage regimes conferring novelty was settled in the EPO. We were invited to reconsider the draft judgment on that basis. He proposed that we should give a “preliminary judgment” and stay all further proceedings pending the Enlarged Board Decision. He accepted that if we did so it would be appropriate for an interlocutory injunction to be granted provided Merck was willing to give a cross-undertaking in damages should Actavis ultimately prevail.

127. Mr Thorley sought to draw an analogy with what this Court did in the trade mark case of *Boehringer Ingelheim v Swingward* [2008] EWCA Civ 83. There we decided that the defendants’ appeals were allowable, subject to a possible decision of the ECJ on a pending reference from the Austrian Courts and accordingly a final decision was deferred.

128. Mr Prescott contended that *Kos Life Sciences* made no difference and we should deliver a final judgment in Merck’s favour as in the draft. In particular he submitted that:

(a) *Kos Life Sciences* involved a question under EPC 2000, whereas this case (as is common ground) falls to be decided under the unamended EPC. The last word on that was *Genentech* and the cases which followed it.

(b) The Board in *Kos Life Sciences* at no point cast doubt on *Genentech*. Moreover it is fairly clear that the Board considered that the law established in *Genentech* should be carried over into EPC 2000 – hence its consideration in §5.1 of the *travaux préparatoires* to EPC 2000. The real point of the reference was to get an early confirmation that EPC 2000 made no difference to that which had been established in *Genentech*.

129. We conclude that Mr Prescott is almost certainly right, but we cannot say so definitely. It is just possible that the Enlarged Board may rule that *Genentech* was wrong. To do so it would have, as the Board in *Kos Life Sciences* says at §3.4, to give the language in *Eisai* at 23.2 a restricted meaning. And, we think, it would have to qualify in some way the reasoning in *Mobil*. We consider this unlikely.
130. In these circumstances we have concluded that Mr Thorley’s “interim judgment” approach should be rejected. The position is not the same as in *Boehringer Ingelheim* for at least the following reasons: (a) whatever the Enlarged Board does will not be binding (even though highly persuasive) whereas a decision of the ECJ is, (b) one could not know why the ECJ had continued with the Austrian reference following its decision in *Boehringer Ingelheim* so one could not readily make a prediction as to the outcome, even though to us it seemed the point had already been covered, (c) the delay involved here will be greater (at least until early next year according to informal inquiries we have made of the EPO) – the date for the oral hearing in the Austrian case had already been set at the time this Court was hearing *Boehringer Ingelheim* and (d) the points we had decided would not in any event be disturbed by any new ruling, on a further and different point, by the ECJ.
131. Accordingly we have decided:
- (a) That this final judgment should be delivered;
 - (b) To allow for the remote possibility that the decision in *Kos Life Sciences* might affect this case, the time for leave to appeal to the House of Lords should be extended until 28 days after the Enlarged Board gives its decision in that case;
 - (c) That the form of order should be as proposed by Merck with the following variation. The injunction is to be suspended unless Merck gives a cross-undertaking in damages should Actavis ultimately prevail in this litigation
132. In so deciding we have considered the following matters
- a) Merck’s suggestion that a cross-undertaking in damages is unnecessary because Actavis are not threatening immediate infringement. Whether or not that is so would be a matter for any inquiry as to damages under the cross-undertaking. It is irrelevant here.

(b) Actavis' suggestion that the period for an interim payment of costs of £250,000 should be 28 days. It should be the usual 14 days. No reason is given for the longer period and besides, the result has been known for some time.

(c) Actavis' suggestion that the undertaking to repay the whole or part of the interim payment, if it proved to be too much or the liability reversed on appeal, should be a solicitor's undertaking. The sole reason offered is because Merck are foreign. That is not good enough given Merck's size and international standing. The suggestion is petty and should never have been made.

(d) There is no point in reserving the costs of the inquiry as to damages or account of profits as proposed by Actavis. We are not making any ruling about them.

133. We direct the parties to produce a final minute of order in compliance with this decision within 7 days.