

Neutral Citation Number: [2011] EWHC 1831 (Pat)

Case No: HC10 CO3103

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 15 July 2011

Before:

THE HON MR JUSTICE KITCHIN

Between:

Ranbaxy (UK) Limited

Claimant

- and -

AstraZeneca AB

Defendant

John Baldwin QC and Mark Chacksfield (instructed by Messrs S J Berwin LLP)

for the Claimant

Henry Carr QC and Miles Copeland (instructed by Messrs Bristows)

for the Defendant

Hearing dates: 9-10 June 2011

Judgment

MR. JUSTICE KITCHIN:

1. Introduction

2. In this action Ranbaxy, an importer of generic pharmaceuticals, seeks a declaration of non infringement and revocation of EP 1 020 461 (“the Patent”) which is owned by AstraZeneca. AstraZeneca has counterclaimed for infringement.
3. The Patent covers one of AstraZeneca’s drugs called Nexium which is used to treat gastric acid related disease. The active ingredient of Nexium is magnesium esomeprazole, the magnesium salt of the S enantiomer (the (-) enantiomer) of the racemic mixture known as omeprazole which was itself introduced onto the market under the brand name Losec in 1988.
4. The Patent was granted on 22 July 2009 upon a divisional application which was published on 19 July 2000 and has a filing date of 27 May 1994. As will be seen, it describes the use of magnesium esomeprazole with a high optical purity such that the ratio of the S enantiomer to the R enantiomer (the (+) enantiomer) must be $\geq 99.9/0.1$. This optical purity is expressed in terms of enantiomeric excess (e.e.), that is to say the fraction of the compound present as the major enantiomer less the fraction of the compound present as the minor enantiomer. Hence the Patent explains the magnesium esomeprazole must have an optical purity of $\geq 99.8\%$ e.e. This, it is to be noted, is a bulk characteristic of the compound.
5. The parent application was published on 17 May 1995 and granted as EP 0 652 872 on 8 November 2000. This described and claimed the use of magnesium esomeprazole which was “essentially free” of the magnesium salt of the R enantiomer. On 9 December 2006, the Board of Appeal of the EPO held this patent invalid for lack of inventive step.
6. The matter is of some urgency because at present AstraZeneca is the only supplier of esomeprazole in the United Kingdom. Ranbaxy wishes to import a product which it believes does not infringe the Patent and for which it now expects to secure regulatory approval in the course of July 2011. If it is successful in this claim it will be free to sell that product without competition from other generic suppliers. Accordingly, on 25 October 2010, it issued an application for a speedy trial. That application was heard by Mann J who, on 12 November 2010, directed that the infringement issues in the action should be tried as preliminary issues.
7. I am therefore concerned only with the claim by Ranbaxy for a declaration of non infringement and the counterclaim by AstraZeneca for infringement. The parties are agreed these may be determined by reference to claim 1 of the Patent. This is in “Swiss form” and is directed to the use of magnesium esomeprazole with an optical purity of $\geq 99.8\%$ e.e. for the manufacture of a medicament for the inhibition of gastric acid secretion.
8. The product which Ranbaxy wishes to import is made in India. For the purposes of these proceedings there is no dispute that the process of manufacture begins with magnesium esomeprazole with an optical purity of $\geq 99.8\%$ e.e. There is also no

dispute that the process involves the addition of a quantity of omeprazole racemate such that the finished product no longer contains magnesium esomeprazole of that optical purity.

9. In these circumstances AstraZeneca contends that claim 1 is infringed. It argues that the product which Ranbaxy wishes to import is the direct product of a process in which magnesium esomeprazole with an optical purity of $\geq 99.8\%$ e.e. is used to make a medicament for the inhibition of gastric acid secretion.
10. Ranbaxy, on the other hand, contends that claim 1 is not infringed. It says that the product which it wishes to import was not formulated using, and does not contain, magnesium esomeprazole with an optical purity of $\geq 99.8\%$ e.e.
11. The claim and counterclaim therefore depend upon the proper interpretation of claim 1.
12. I heard evidence from only one witness, Dr Roland Collicott, the expert called on behalf of Ranbaxy. He is an analytical chemist with experience of the pharmaceutical industry extending over forty years. He was a careful witness and, so far as it went, I found his evidence of assistance.

The Patent

13. The Patent is entitled “Magnesium salt of the (-) enantiomer of omeprazole and its use”. The description begins with an identification of the field of the invention. Paragraph [0001] explains that the invention is directed to new compounds with high optical purity, their use in medicine and their use in the manufacture of pharmaceutical preparations.
14. Paragraphs [0002] to [0005] set out the background of the invention. Paragraph [0002] explains that omeprazole and its alkaline salts were known to be effective gastric acid secretion inhibitors and useful as anti-ulcer agents. Further, the compounds, being sulfoxides, have an asymmetric centre in the sulfur atom and so exist as two optical isomers.
15. The problem addressed by the Patent is then identified. It is said to have been desirable to obtain compounds with improved pharmacokinetic and metabolic properties which would give an improved therapeutic profile such as a lower degree of inter-individual variation. The invention is said to provide such compounds, these being novel salts of single enantiomers of omeprazole.
16. Paragraph [0003] explains that the separation of the enantiomers of omeprazole on an analytical scale has been described in a paper by Erlandsson published in the Journal of Chromatography in 1990 and on a preparative scale in German patent DE 4 035 455. The latter discloses the use of diastereomeric ether which is separated and thereafter hydrolysed in an acidic solution. The specification continues that omeprazole is quite sensitive under acidic conditions and so the acid has to be neutralised quickly with a base to avoid degradation of the compound. This is said to be disadvantageous. Accordingly, paragraph [0004] explains that a further aspect of the invention provides a new method for preparing the novel compounds of the

invention on a large scale. However, the Patent does not contain a claim to any such new method.

17. These paragraphs suggest that the inventors did not consider the single enantiomers of omeprazole to be new in themselves. However, paragraph [0005] continues that there is no description in the prior art of any isolated or characterised salt of any of the single enantiomers of omeprazole, or of any optically pure omeprazole analogue. Dr Collicott said, and I agree, that the Patent therefore appears to draw a distinction between the isolated enantiomers of omeprazole and the isolated salts of those enantiomers.
18. There then follows a detailed description of the invention. Paragraph [0006] says that the invention refers to new optically pure magnesium salts of omeprazole having a particular formula which is depicted, this being the formula for magnesium esomeprazole.
19. Paragraph [0007] describes the first aspect of the invention as being the provision of the magnesium salt of (-) omeprazole with an optical purity of at least 99.8% e.e. It continues that the invention also provides the use of this salt for the manufacture of a medicament for the inhibition of gastric acid secretion.
20. Paragraph [0008] describes the advantages of the invention. It says that single enantiomers of omeprazole had previously only been obtained as syrups and not as crystalline products. It continues that by means of the method of one aspect of the invention the salts of the invention are now easy to obtain. Further, their crystalline form means they can now be obtained in very high optical purity. Moreover, the salts have a high stability towards racemization which makes it possible to use a single enantiomer salt of the invention in therapy. This important aspect of the invention is repeated in paragraph [0036].
21. The various uses of the compounds of the invention are described in paragraph [0010]. They include the inhibition of gastric acid secretion; the treatment of gastric acid related diseases and gastrointestinal inflammatory diseases such as gastric ulcers, duodenal ulcers, reflux esophagitis and gastritis; the treatment of patients on NSAID therapy, patients with gastrinomas, and patients with acute upper gastrointestinal bleeding; the treatment of patients in intensive care or pre- and post-operatively to prevent acid aspiration and stress ulceration; and the treatment of Helicobacter infections.
22. Paragraphs [0012] to [0017] describe a method of manufacturing the single enantiomers and their salts but, as I have mentioned, this is not the subject of any claim.
23. Paragraphs [0018] to [0025] deal with formulation. They are, I think, important because they provide the basis for claim 1. Paragraph [0018] reads:

“For clinical use the single enantiomers, i.e. the optically pure compounds, of the invention are formulated into pharmaceutical formulations for oral, rectal, parenteral or other

modes of administration. The pharmaceutical formulations contain the single enantiomers of the invention normally in combination with a pharmaceutically acceptable carrier. The carrier may be in form of a solid, semisolid or liquid diluent, or capsule. These pharmaceutical preparations are a further object of the invention. Usually the amount of active compound is between 0.1-95% by weight of the preparation, between 0.2-20% by weight in preparations for parenteral use and between 1-50% by weight in preparations for oral administration.”

24. Further details are provided in subsequent paragraphs. Paragraph [0019] describes the various carriers with which the compounds of the invention may be formulated. Paragraphs [0020] and [0021] describe the production of soft and hard gelatine capsules respectively. Paragraph [0022] describes the preparation of dosage units for rectal administration. Paragraph [0023] describes liquid preparations for oral administration and paragraph [0024] describes solutions for parenteral administration. Finally, paragraph [0025] describes the typical daily dose of the active compound, that is to say the optically pure compounds of the invention.
25. The invention is then illustrated in various examples. These describe the method of isolation of optically pure magnesium esomeprazole and, at paragraph [0036], experiments conducted to determine its stability towards racemization.

The claims

26. Claims 1 to 8 relate to one aspect of the invention, namely the use of magnesium esomeprazole of $\geq 99.8\%$ e.e. to make a medicament.
27. Claim 1 reads:

“The use of a magnesium salt of (-)-5-methoxy-2[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole ((-)-omeprazole) with an optical purity of $\geq 99.8\%$ enantiomeric excess (e.e.) for the manufacture of a medicament for the inhibition of gastric acid secretion.”
28. Claim 2 claims the use as claimed in claim 1 in which the salt is crystalline.
29. Claims 3 to 8 claim the use as claimed in claims 1 or 2 in which the medicament is for the treatment of various different or more specific disorders:
 - “3. The use as claimed in Claim 1 or Claim 2 wherein [the] medicament is for the treatment of a gastric acid-related disease and/or a gastrointestinal inflammatory disease.
 4. The use as claimed in Claim 3 wherein the disease is a gastric ulcer, a duodenal ulcer, reflux esophagitis or gastritis.
 5. The use as claimed in Claim 4 wherein the disease is reflux esophagitis.

6. The use as claimed in Claim 1 or Claim 2 wherein the patient is on NSAID therapy, has a gastrinoma and/or has acute upper gastrointestinal bleeding.

7. The use as claimed in Claim 1 or Claim 2 wherein the medicament is for the treatment of a patient in an intensive care situation and/or is to be used pre- or postoperatively to prevent acid aspiration and stress ulceration.

8. The use as claimed in Claim 1 or Claim 2 wherein the medicament is used in the treatment of a *Helicobacter* infection.”

30. Claim 9 is directed to optically pure magnesium esomeprazole:

“A magnesium salt of (-)-5-methoxy-2[[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole ((-)-omeprazole) with an optical purity of $\geq 99.8\%$ enantiomeric excess (e.e.).”

31. Claims 10 and 11 relate to the further aspect of the invention, namely the optically pure magnesium esomeprazole for use in therapy. These read:

“10. A salt as claimed in Claim 9 for use in therapy.

11. A salt as claimed in Claim 10 for use in the treatment or prophylaxis of a condition as defined in any one of Claims 3 to 8.”

32. Finally, claims 12 and 13 claim a crystalline salt in accordance with any of claims 9 to 11 and a pharmaceutical composition containing any such salt:

“12. A salt as claimed in any one of Claims 9 to 11 which is crystalline.

13. A pharmaceutical composition of a salt as claimed in any one of Claims 9 to 12 together with a pharmaceutically acceptable carrier.”

The rival constructions

33. AstraZeneca accepts that Ranbaxy is not proposing to import a product falling within the scope of claim 9 and is not proposing to use a product as claimed in claim 9 in any kind of therapy. Accordingly, the infringement case is limited to the Swiss form claims and specifically, Claims 1, 3 to 6 and 8. It says that Ranbaxy is threatening to infringe each of these claims by importing a product which is obtained directly by means of the claimed process.

34. Ranbaxy says it is not infringing any of these claims because, on their proper interpretation, they are directed to the use of magnesium esomeprazole with an optical

purity of $\geq 99.8\%$ e.e. for the manufacture of a medicament which contains magnesium esomeprazole of that purity. It has no separate point on any of claims 3 to 6 or 8. The whole issue therefore turns on the proper interpretation of claim 1.

35. AstraZeneca's case is that a process claim is not limited to the manufacture of specific products but extends to the use of the claimed process to make any product. Claim 1 is a process claim which is used if a magnesium salt of esomeprazole with an optical purity of $\geq 99.8\%$ e.e. is used for the manufacture of a medicament for the inhibition of gastric acid secretion irrespective of whether or not the medicament contains magnesium esomeprazole at all. Put another way, it says Ranbaxy is seeking to rewrite claim 1 by inserting a limitation which it does not presently contain.
36. Ranbaxy contends that, construed purposively, claim 1 is directed to the process of making a medicament containing magnesium esomeprazole with an optical purity of $\geq 99.8\%$ e.e. and the teaching of the Patent is to this effect. Moreover, the skilled person would recognise that claim 1 is a Swiss form claim and that such claims are in substance directed to the protection of a new therapeutic use of a medicament containing a known active compound and it follows that the medicament must contain that compound.
37. **Interpretation of the specification**

38. The approach to be adopted to the construction of a patent specification was explained by the House of Lords in *Kirin Amgen v Hoechst Marion Roussel* [2004] UKHL 46, [2005] RPC 9. The question is what the skilled person would have understood the patentee to be using the language of the claim to mean. This is sensitive to context. The skilled person reads the specification in light of the common general knowledge and appreciating that its purpose is to describe and demarcate an invention, that is to say a practical idea for a new product or process. Lord Hoffmann put it this way at [34]:

“34. “Purposive construction” does not mean that one is extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims. The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance. The conventions of word meaning and syntax enable us to express our meanings with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document in words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document *inter rusticos* for which broad allowances must be made. On the other hand, it must be recognised that the patentee is trying to describe something which, at any rate in his opinion, is new; which has not existed before and of which there may be no

generally accepted definition. There will be occasions upon which it will be obvious to the skilled man that the patentee must in some respect have departed from conventional use of language or included in his description of the invention some element which he did not mean to be essential. But one would not expect that to happen very often.”

39. A number of points emerge from this passage which are of particular relevance to these proceedings. First, the words of the claim are to be construed having regard to the patentee’s purpose as set out in the rest of the specification.

40. Second, the exercise is one of interpretation of the words of the claim. It follows that it is not permissible simply to ignore an integer of the claim; nor is it permissible to write a new integer into the claim.

41. Third, it is generally reasonable to infer the patentee intended the various claims to have a meaning different from each other, and so to have some effect.

42. Fourth, a patent specification is not a document *inter rusticos*. This aspect of claim interpretation received further consideration by the Court of Appeal in *Virgin Atlantic Airways v Premium Aircraft Interiors* [2009] EWCA Civ 1062, [2010] RPC 8. Jacob LJ, giving the judgment of the court, said at [15]:

“15 We think it would unrealistic – indeed perverse – for the law to say that the notional skilled reader, probably with the benefit of skilled advice, would not know and take into account the explicit drafting conventions by which the patent and its claims were framed. Likewise when there is a reference to the patent being a divisional application, it would be perverse to work on the basis that the skilled man would not know what that means. A real skilled man reading a patent which, as in the case of the Patent, refers to “the parent application” would surely say “what’s a parent application?” – and he would go on to ask a man who knows, probably a patent agent.”

43. The skilled person must therefore be taken to know the basic drafting conventions used to frame a patent and its claims. This has a particular relevance to Ranbaxy’s submission that the skilled person would recognise that claim 1 has been drafted in the Swiss form, about which I must now say a little more.

44. **Swiss form claims**

45. Swiss form claims were introduced under the EPC 1973 to address the exclusion from patentability of methods of treatment of humans or animals. Aspects of their history were recently considered by the Court of Appeal in *Actavis UK Ltd v Merck & Co Inc* [2008] EWCA Civ 444, [2008] RPC 26, although the court was there concerned with an issue rather different from that which arises in this case.

46. The relevant provisions of the EPC 1973 read:

Article 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.

Article 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 Article 52(4) , provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

Article 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...

47. Methods of treatment, though inventions, were, by means of the legal fiction embodied in Article 52(4) EPC 1973, regarded as not susceptible of industrial application. The justification for this approach was founded in the ethical and public health consideration that doctors should be free to take all action they consider appropriate to treat patients uninhibited by patents.

48. The same consideration was not, however, perceived to apply to new medicaments. These met the requirements of Article 54(1) to (4) EPC 1973 and there was no difficulty

with claims directed to the medicament *per se* or to the use of a new active ingredient to prepare such a medicament.

49. An exception to the general rules relating to novelty was also made for the first use of a known substance or composition in a method referred to in Article 52(4) EPC 1973. Hence Article 54(5) EPC 1973 provided that the inventor of a first medical indication could obtain purpose limited product protection for a known substance or composition without having to restrict himself to the substance or composition when in a form technically adapted to a therapeutic purpose. Such claims were typically drawn in the form: “X for use in therapy”.

50. A more difficult question was raised by the case of an invention based upon the discovery of a further therapeutic use of a substance or composition already known as a medicine. This was answered definitively by the Enlarged Board of Appeal in *EISA/second medical indication*, G5/83 [1985] OJ EPO 64 in considering a claim in the Swiss form, that is to say a claim directed to the use of a substance or composition for the manufacture of a medicament for a specified (new) therapeutic application.

51. The Board observed that claims in this form had their foundation in a statement of practice of the Swiss Federal Intellectual Property Office (“FIPO”) dated 30 May 1984, [1984] OJ EPO 581. FIPO considered that a claim to the use of a compound for the treatment of a particular condition was inadmissible under Swiss law because it was directed to a therapeutic treatment. But a claim in the Swiss form was not subject to the same exclusion, as it explained at paragraph [2]:

“2. It is, however, uncontested that the aspect of use “susceptible of industrial application” and thus not excluded from patentability under Swiss law, i.e. the formulation of the pharmaceutical preparation, is patentable. For such a patent to be granted, however, the Office requires the claim to be limited specifically to the “use of a compound ... for the production of agents against ...”, provided this is supported by the original disclosure. Such a claim is perfectly admissible and can also be presented for a second (or subsequent) use of a known medicament. The Office does not examine whether, in the case of a second use, the pharmaceutical formulation is the same as that for the known first indication. The *travaux préparatoires* provide no information on this subject as far as we know.”

52. In *EISA* the Board took the same view. A claim in Swiss form did not conflict with Article 52(4) EPC 1973. But the Board considered there might be a problem with novelty, as appears from paragraph [20]:

“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. 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.”

53. In this paragraph, upon which AstraZeneca placed particular reliance, the Board drew a distinction between new medicaments and the use of known medicaments for a new purpose. In the case of new medicaments there was no difficulty in meeting the novelty requirement and claims to the medicament or to the use of the active ingredient to prepare the medicament were perfectly admissible. But the position was not so straightforward where the invention lay in the discovery of a new use for a known medicament.

54. The Board continued that in all fields of industrial activity other than those of making products for use in therapy, a new use for a known product could be fully protected as such by claims directed to that use. Further, this was the appropriate form of protection as the new and non-obvious use constituted the invention. Article 54(5) EPC 1973, however, provided an exception to this rule in the case of the first use of medicaments. Here the required novelty for the medicament which formed the subject matter of the claim was derived from the new pharmaceutical use.

55. The Board considered this reasoning was also applicable to cases of further new and non-obvious uses, as it explained at paragraph [21]:

“21. It seems justifiable by analogy to derive the novelty for the process which forms the subject-matter of the type of use claim now being considered from the new therapeutic use of the medicament and this irrespective of the fact whether any pharmaceutical use of the medicament was already known or not. It is to be clearly understood that the application of this special approach to the derivation of novelty can only be applied to claims to the use of substances or compositions intended for use in a method referred to in Article 52 (4) EPC.”

56. To prevent the exclusion contained in Article 52(4) EPC 1973 from going beyond its proper limits the Board explained it was appropriate to take a special view of the concept of the state of the art. Further, no intention to exclude second and subsequent medical indications generally from patent protection could be deduced from the legislative history. Thus the Board concluded:

“23. For these reasons, the Enlarged Board considers that 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 in which the process of manufacture as such does not differ from known processes using the same active ingredient.”

57. It is, I think, inherent in all this reasoning that the skilled person would generally understand a Swiss form claim to mean that the medicament must contain the active

ingredient for which the new and inventive use has been found. But for the exclusion contained in Article 52(4) EPC 1973, the claim would have been directed to the new and non obvious use of that ingredient.

58.I do not go so far as to suggest that a claim cast in Swiss form must always be construed as being directed to the use of an active ingredient for the manufacture of a medicament which contains that ingredient. The proper meaning of the claim must be determined having regard to the words of the claim when construed purposively in the light of the specification and the common general knowledge, as the Court of Appeal emphasised in *Monsanto & Company v Merck & Co Inc* [2000] RPC 77. However, it seems to me that is how it would normally be understood. Moreover, the skilled person would appreciate that to construe it otherwise would render the claim vulnerable to an attack of insufficiency.

59.An illustration of how serious such an attack of insufficiency could be is provided by *American Home Products Corporation v Novartis Pharmaceuticals* [2001] RPC 8. American Home Products (“AHP”) was the proprietor of a patent which was based upon the discovery that rapamycin, a known antibiotic, was useful to prevent transplant rejection. The patent therefore contained a claim in Swiss form to the use of rapamycin for the preparation of a medicament for inhibiting transplant rejection. In this action AHP accused Novartis of infringing the patent by selling a medicament which contained a derivative of rapamycin called SDZ RAD. Novartis denied infringement but contended that if the claim was broad enough to cover derivatives of rapamycin then it was invalid for insufficiency. The Court of Appeal construed the claim as excluding derivatives and, on this construction, rejected the allegation of insufficiency. Aldous LJ, with whom Sedley and Simon Brown LJ agreed, put it this way at [52]:

“52. The claim has to be construed in context. It is a Swiss-type claim to an invention for the second medical use of rapamycin. As the specification makes clear, the medicament that provides the inhibition is rapamycin. There is no disclosure of any other medicament. It would be unfair to the patentee to construe the word “medicament” as meaning any product whether or not it contained rapamycin as that would render the patent invalid. SDZ RAD is not a medicament within the meaning of that word in claim 1. As I have pointed out the claim is not a claim to a class or principle and therefore it has to be sufficient across its width. It follows that the claim, to be construed as suggested, would be invalid unless there was an enabling disclosure of medicaments which might not have any rapamycin present and their method of manufacture. There are none. I did not understand that Mr Baldwin wished the claim to be construed in a way that would make it invalid. It follows that the word “medicament” must be construed as referring to the product rapamycin which is the product described in the specification as having been discovered by the inventor to have the beneficial immunosuppressant properties. ”

60. The EPC 1973 has now been revised in the form of the EPC 2000. It embodies some important amendments which have a bearing on this case. The relevant provisions now read:

Article 52

Patentable inventions

(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

Article 53

Exceptions to patentability

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to “ordre public” or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

...

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Article 54

Novelty

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

....

(4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.

(5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in

Article 53(c), provided that such use is not comprised in the state of the art.

61. The exclusion contained in Article 52(4) EPC 1973 has now been moved to Article 53(c) EPC 2000 reflecting an appreciation that such methods are excluded from patentability for ethical and public health reasons rather than lack of industrial applicability.

62. Article 54(4) EPC 2000 corresponds to Article 54(5) EPC 1973. But Article 54(5) EPC 2000 is a new provision. It was considered by the Enlarged Board of Appeal in *ABBOTT RESPIRATORY/dosage regime*, G2/08, a decision of 19 February 2010. A number of questions fell to be answered, the third of which was whether claims could still be granted in Swiss form. The Board noted that, in contrast to the position under the EPC 1973, Article 54(5) EPC 2000 now expressly allows further patent protection of substances or compositions already known as medicines provided their use in a method under Article 53(c) EPC 2000 is specific and not comprised in the state of the art. The Board also explained that it was evident the legislator wished to maintain the status quo as regards the availability of patent protection for further therapeutic uses and, in that respect, intended no change to result from the introduction of Article 54(5) EPC 2000. Therefore the gap in the provisions of the EPC 1973 filled by the decision of the Board in *EISAI* no longer existed and it was not now appropriate to grant claims in Swiss form. However the Board declared its decision did not have retroactive effect.

63. The EPC 2000 came into force on 13 December 2007. A decision of the Administrative Council dated 28 June 2001 on the transitional provisions under Article 7 of the Revision Act states that Articles 52, 53 and 54(4) of EPC 2000 shall apply to European patent applications pending at the time of their entry into force, and that Article 54(5) shall apply to European patent applications pending at the time of its entry into force, in so far as a decision on the grant of the patent has not yet been taken.

64. The application for the Patent was still pending on 13 December 2007. Notification of intention to grant was given on 29 May 2009 and, as I have mentioned, the Patent was granted on 22 July 2009. Accordingly all of the provisions of the EPC 2000 to which I have referred do apply to it but, granted as it was before the decision of the Board in *ABBOTT* took effect, it may also contain claims in Swiss form.

65. **The meaning of claim 1**

66. That brings me to the crucial question, namely what the skilled person would have understood the patentee to be using the words of claim 1 to mean. Those words must be construed purposively in the context of the specification.

67. I have summarised the contents of the specification earlier in this judgment. It recognises that omeprazole and its alkaline salts were known as effective gastric acid secretion inhibitors. It acknowledges too that the enantiomers of omeprazole had been separated. But it says there was nevertheless a need for compounds with improved pharmacokinetic and metabolic properties which would give an improved therapeutic

profile such as a lower degree of inter-individual variation. This, then, is the problem that the Patent seeks to address.

68.The solution to the problem is the provision of magnesium esomeprazole with an optical purity of $\geq 99.8\%$ e.e.; the surprising discovery that this salt is stable towards racemization which means that it is possible to use it in therapy; and the use of the salt to make a medicament for the treatment of the various conditions detailed in paragraph [0010] of the specification and the subject of claims 1 to 8.

69.The specification also explains in paragraph [0018] how optically pure magnesium esomeprazole may be put to clinical use. I have set out this paragraph of the specification at paragraph [22] above. It describes the process of formulation which involves combining the active ingredient with a pharmaceutically acceptable carrier and presenting it in solid, semisolid, liquid or capsule form. Details of each of these forms of presentation are provided in the paragraphs of the specification which follow.

70.Importantly, there is no suggestion anywhere in the body of the specification of the provision or use of any analogue or derivative of magnesium esomeprazole or, indeed, of any other active ingredient for the treatment of gastrointestinal disorders or any other condition. Nor is there any suggestion that the specification provides a new way of making a medicament. The whole teaching of the specification is about the production of optically pure magnesium esomeprazole and its use in particular therapies and, for that purpose, its formulation with a conventional carrier.

71.Against this background, I think the skilled person would consider the meaning of claim 1 to be tolerably clear. Recognising the teaching of the specification that magnesium esomeprazole with an optical purity of $\geq 99.8\%$ e.e. is new, he would nevertheless understand claim 1 to be directed to the use of such magnesium esomeprazole to manufacture a medicament which contains that active ingredient.

72.I believe this understanding would, however, be reinforced by the skilled person's appreciation that the claims fall into various sets. Claims 1 to 8 are all drafted in conventional Swiss form with each of claims 3 to 8 directed to the use of magnesium esomeprazole with an optical purity of $\geq 99.8\%$ e.e. for the manufacture of medicaments for the treatment of different or increasingly specific conditions. Claim 9 is directed to optically pure magnesium esomeprazole and is in conventional product claim form. Claim 10 is directed to a product for use in therapy, the characteristic form for a claim for the use of a known product in a method referred to in Article 52(4) EPC 1973. Claim 11 is directed to a product for use in the treatment of a specific condition as defined in claims 3 to 8, as contemplated by Article 54(5) EPC 2000. Finally, claims 12 and 13 are dependent upon claims 9 to 11 and directed to a salt and composition respectively.

73.Claim 1, as a Swiss form claim, and forming as it does the first of a cascade of claims directed to the use of optically pure magnesium esomeprazole to manufacture a medicament for the treatment of different or more specific uses, would, for the reasons I have given, naturally be understood as requiring the medicament to contain the active ingredient for which the claimed use has been found.

74. AstraZeneca nevertheless contends that the skilled person would interpret the word medicament in claim 1 so broadly that it need not contain any magnesium esomeprazole at all. In support of this contention it says that Ranbaxy's construction involves rewriting claims 1 to 8 so that they become "substance for use" claims. I disagree. Ranbaxy's construction does not involve rewriting any claim. To the contrary, it involves interpreting the word medicament in the context of the specification and in the light of the common general knowledge.

75. AstraZeneca also argues that Ranbaxy's construction fails to reflect the fact that, as patentee, it has chosen to claim the invention in different ways; ignores the fact that a part of the technical contribution is the isolation of magnesium esomeprazole of high optical purity; and produces the surprising result that there is no difference between claims 3 to 8 and claim 11.

76. These points are, I think, closely related. As I have explained, the invention is indeed claimed in a variety of different ways. In fact it is claimed in every way it could be claimed, that is to say by product claims, product for use claims, Swiss form claims and, as now permitted under the EPC 2000, product for specific use claims. The skilled person would appreciate this was an entirely sensible approach for a patentee to adopt to the drafting of its claims. It provides a series of positions which reflect what the patent describes by way of a technical contribution, but also gives a measure of protection in case of subsequent challenge. So, for example, if the product claims were to fall for lack of novelty, the product for use in any therapy claims might survive; and if they too were to fall for lack of novelty, the Swiss form claims and the claims to the product for use in specific therapies might survive. As for the overlap between the latter classes (that is to say, claims 1 to 8 on the one hand and the various elements of claim 11 on the other) I believe the skilled person would believe the patentee has simply seized the opportunity afforded under the EPC 1973 and the EPC 2000 to include them both.

77. **Conclusion**

78. Ranbaxy is therefore entitled to its declaration of non infringement and AstraZeneca's counterclaim for infringement fails. I will hear argument as to the form order if it cannot be agreed.