

PATENTS ACT 1977

IN THE MATTER OF

Patent Applications GB 9412950.9;

GB 9507929.9; GB 9822734.1 and

GB 9822737.4 in the name of

Kenneth F Prendergast.

STATEMENT OF REASONS

1. These are the reasons for my decision of 17 December 1998 refusing all four applications.
2. The applications in suit comprise (a) parent application GB 9412590.9 of priority date 28 June 1994 and its divisional application GB 9822734.1 and (b) parent application GB 9507929.9 of the same priority date and its divisional application GB 9822737.4.
3. During the course of the pre-grant proceedings the claims of the applications have been considerably amended and in the form rejected by me in my decision all relate to new pharmaceutical uses of either ondansetron or granisetron, both of these compounds being well-known pharmaceutical compounds. Briefly, according to the applications as filed, both ondansetron and granisetron are widely accepted as potent 5HT₂ serotonin, inhibitors. They have a dual site of action in the ileum and, more centrally, in the area postrema. In the treatment of cancer they have the particular use of treating the nausea associated with chemotherapy and radiotherapy.
4. Since both compounds have a known pharmaceutical use the claims available to an applicant who has discovered a new use for them must, according to well established practice in Europe, including the United Kingdom, be in the "Swiss form" format.
5. Thus, the claims in GB 9412950.9 are worded as follows:-

- "1. The use of ondansetron to obtain a medicine for intended therapeutic use in the treatment of battle fatigue.
2. The use of ondansetron to obtain a medicine for intended therapeutic use in the prevention of or treatment of combat stress reaction.
3. The use of ondansetron to obtain a medicine for intended therapeutic use in the prevention of or treatment of post traumatic stress disorder especially associated with combat or body handling or service personnel coping with civilian or military emergencies."

and those of its divisional GB 9822734.1 as follows:-

- "1. The use of ondansetron to obtain a medicine for intended therapeutic use in the prevention or treatment of neurological symptoms provoked by chemical warfare agents, for example nerve gas.
2. The use of ondansetron to obtain a medicine for intended therapeutic use in the prevention of or treatment of nausea, provoked by chemical or biological warfare agents in soldiers or civilians in circumstances where it may be hazardous to vomit."

6. The claims in GB 9507929.9 and its divisional GB 9822737.4 mirror those of GB 9412950.9 and GB 9822734.1 respectively with the difference that they relate to granisetron rather than ondansetron.

7. As I said in my decision there is no argument remaining about the format of the claims but for some time during the pre-grant proceedings there has been a dispute between the Examiner in the case and the Applicant about whether the claims are supported by the description as required by section 14(5)(c) of the Act. It was for this reason that the matter came before me at a Hearing on 8 December 1998 where Dr Prendergast, the Applicant, appeared in person and Mr Jenkins attended as Examiner on behalf of the Office. Following the Hearing, on 17 December, I issued a brief decision, without reasons, finding for the Office that the description did not support the claims in all four applications.

8. Since, according to section 14(5)(c), there is inevitably a focus on the description in deciding what is essentially the appropriate breadth of claim I need briefly to go through the descriptions of all four applications so as to finally show where the problem has been. Fortunately, all four descriptions are very similar so this process only has to be gone through once.

9. The applications start with paragraphs headed "Field of Invention" which merely set the scene for what follows. There then is a large section headed "Theoretical background" which initially points to prior art references where the use of ondansetron or granisetron in the control of cancer-associated nausea is disclosed. The prior art use of both in the treatment of mental illness, especially schizophrenia, is also referred to followed by a statement to the effect that the significant difference between the prior art uses and the disclosed uses is that the latter will all be by people in robust health, at the peak of physical fitness, particularly airforce pilots, and by people generally. There is therefore a stress on the beneficial use of both compounds to assist physically fit people in special circumstances provoked by occasions of exceptional demands.

10. There then follows an analysis of the need to avoid space motion sickness and air sickness, particularly in military situations, of the need to avoid vomiting when exposed to chemical or biological weapons, especially nerve gas, the need to control combat stress, including battle fatigue, and the need to avoid vomiting in situations which may lead to dehydration. This analysis has several references to studies done on, for example, airforce pilots, ground troops and those involved in maritime disasters and points to the obvious desirability of overcoming the problems associated with exceptional demands being made on otherwise fit individuals.

11. A section headed "Brief Summary" then, in effect, does precisely that without adding much more to what has been previously disclosed apart from a reference to the need to package the compounds in question in a way that takes account of their use in a theatre of war or in an emergency.

12. The final part of the description is headed "Detailed Disclosure" and starts out by defining such terms as "combat stress reaction", "space sickness", "airsickness" and "seasickness". Two paragraphs which follow explain what will be used in the treatment of such conditions:-

"The articles of manufacture for the intended disclosed uses will encompass pharmaceutical compositions of the racemic mixture of 1:1 R(+) and S(-) ondansetron [or granisetron as the case may be - my addition] whose manufacture was disclosed in US Patent No. 4,695,578 [EP 0200444 Example 6 for granisetron - again my addition] and incorporated fully herein by reference.

Whilst the present disclosure envisages special preferred embodiments, the existing preparations of ondansetron [or granisetron - again my addition] may be used as the said articles of manufacture with certain desirable modifications."

Preferred compositions are then described which take account of the intended use of the active components. Examples 1 to 3 follow which describe the active components formulated as a chewing gum and as a complex with β - cyclodextrin. Both the latter formulations have formed the subject matter of further divisional applications which are not in issue and therefore are not being considered in the present statement of reasons.

The description concludes with reference to the packaging of compositions of ondansetron and granisetron and the related instructions for use in the above mentioned environments.

13. So, there is much in the description about the prior uses of ondansetron and granisetron, about studies done on individuals subjected to extreme circumstances and the compositions which may be used to treat the conditions referred to in the claims but apparently no details which show the activity of the two compounds against those conditions.

14. The Examiner's argument concerning lack of support for the claims has essentially been that raised in paragraph 9 of the official letter of 19 November 1997 on application GB

9412950.9 and, allowing for the different active components used, can be said to apply to all four applications in suit.

15. In that paragraph he said:-

"The claimed therapeutic activity of ondansetron is not supported by any pharmacological data, neither is it made clear how the said activity can be concluded. It is considered that the "Swiss" form of wording used in claims 10, 11, 13 and 14 is **only** rendered novel by the new pharmaceutical indication for ondansetron and that it is incumbent on the applicants in such cases to demonstrate that the said compound actually shows the the said activity and such demonstration must be by *in vivo* or *in vitro* test data obtained prior to the filing date of the application. The new activity cannot, of course, be ascertained by an obvious inference from the prior art. On this basis the applicants have not shown that they have actually carried out the method of therapy on which the first invention is based and the new use could be mere speculation. In return for the grant of a monopoly to a second medical use it would appear necessary for the applicants to have made a full and clear disclosure of the facts on which the invention is based, otherwise the system would seem to be open to abuse by mere "paper" inventions e.g. speculatively listing many further uses for known drugs. In this respect your attention is directed to *Hoerrmann's Application* RPC [1996] page 341, especially page 345 lines 23 to 28, page 346 lines 14 to 25 and page 347 lines 38 to 42, *Consultant Suppliers Ltd's Application* RPC [1996] 348, especially page 355 lines 16 to 19 and page 358 lines 30 to 42 and *McManus's Application* FSR [1994] 558, particularly page 562 lines 13 to 32 and page 564 lines 23 to 34."

16. For completeness I shall briefly trace the history of the proceedings on GB 9412950.9 from the objection first raised as above through to the Hearing being appointed. Later I shall need to expand on some of the arguments made, in particular by Dr Prendergast at the Hearing, in order to explain why I agree, by and large, with the above objection and why I

have found against him on the matter of support for the claims.

17. In their response dated 26 May 1998 the Applicants (there were two but Dr Prendergast by virtue of an assignment is now the only Applicant) argued that pharmaceutical inventions of the Swiss type were being treated differently from mechanical inventions, for instance in requiring proof of testing prior to the filing date. It was considered onerous for private individuals working in this art to produce test results since permission for testing would be needed. They agreed that mere speculation was an abuse of the patent system but believed in their invention and had considered that they had provided sufficient information for it to be put into effect.

18. The Examiner maintained his objection in a letter dated 12 August 1998 because in the present case he was of the opinion that no evidence of efficacy was present, even a rudimentary test. Referring to the precedent cases he drew the Applicants' attention to the fact that no pharmacological data, however primitive, had been provided and all the applications forming the basis of those precedents had been refused. He also invited the Applicants to explain the work which motivated their application, suggesting that it might be appropriate to file an affidavit in evidence.

19. In a response dated 15 October 1998 the Applicants filed a statutory declaration relating to a theoretical experiment of the effects of nerve gas. In the Examiner's opinion this, at best, only related to the divisional applications in suit and, being only theory, did not establish the viability of the invention.

20. At the hearing Dr Prendergast presented me with a substantial written submission to which he spoke in defence of his position. This submission was extremely useful in that it comprised a comprehensive account of the points already made in the pre-grant proceedings as well as additional material Dr Prendergast wished me to consider. The best way for me to proceed therefore is to group Dr Prendergast's total submission, both written and oral, under distinct headings and deal with them accordingly.

EFFECT OF EARLIER PRECEDENTS

21. In the early 1980's the UK Patent Office and, no doubt, other patent offices around Europe, including the European Patent Office, had been in receipt of several applications where the invention resided in the discovery of a new medical use for compounds or compositions already recognised as having a medical use. There arose the problem of whether any patent protection at all was available to applicants who had made such an invention. This problem was apparent from the wording of section 2(6) of the then fairly new 1977 Patents Act which allowed protection for a compound allied to its medical use when no previous medical use was known but did not appear to allow similar protection if there was a previously known medical use. Two significant Patent Office decisions, namely those in *Sopharma S.A.'s Application* [1983] RPC 195 and *John Wyeth & Brother Ltd's Application and Schering A.G.'s Application* [1985] RPC 545, appeared to confirm this view. However, the latter, on appeal, was reversed by the then Patents Court on the basis that on patentability issues the UK Patent Office should desirably be in step with the European Patent Office which had by then in *re Eisai Co. Ltd's Application* (Decision Gr 05/83 of the Enlarged Board of Appeal) accepted the suitability of what became known as "Swiss form" claims as being appropriate in the situation of the discovery of a further medical use.

22. The present Applicant is, by definition, in a further medical use situation and as I indicated earlier there is no dispute about the acceptability of the "Swiss form" wording he has chosen to adopt. However, in the correspondence, and at the Hearing, Dr Prendergast seemed to be suggesting that the UK Patent Office, evidenced by the decisions cited by the Examiner and these earlier precedents, was reluctant to grant "Swiss form" claims and thus to some extent he was on the receiving end of this prejudice. Nothing could be further from the truth. The uncertainty of the law in the early 1980's has long been clarified and the UK Patent Office has granted very many applications which contain "Swiss form" claims.

23. Dr Prendergast also sought comfort from the silence about the need for pharmacological testing in the earlier precedents as support for his arguments that such testing was not necessary to support a "Swiss form" claim. Whether there is any force in his arguments or

not I do not think the earlier precedents help him since the point in issue was whether there was any protection available **at all** to an applicant in a further medical use situation not what was needed to support claims based on that further use. It is hardly surprising then that the earlier precedents are silent on the matter of support for "Swiss form" claims.

24. There was just one reference in the Office decision on the Schering case which clearly troubled Dr Prendergast and that was in respect of an argument advanced by Mr Blanco White Q.C. who was appearing as Counsel for Schering A.G. That argument involved a reference to the decision in *Du Pont Inc. (Witsiepe's) Application* [1982] F.S.R. 303 and, in particular, the part of that decision which said that the invention was not in fact made until the new use had been tried, tested and confirmed. Dr Prendergast then ran quite an elaborate argument taking in the judgement of Lord Wilberforce in the *Du Pont* decision with the purpose of showing that Mr Blanco White had quoted that same decision out of context. Whether that be the case or not I think it extremely dangerous to use what was said in the *Du Pont* case, a case which was concerned with the question of novelty in selection patents, as any sort of precedent in a case such as this which is to do with support for "Swiss form" claims.

STATUS OF THE MORE RECENT PRECEDENTS

25. Dr Prendergast's points here were that the precedents cited by the Examiner, namely *Hoerrmann, Consultant Suppliers Ltd and McManus* were of low authority. The following seemed to form the main thrust of his argument, each being followed by my comments:-

a) The first two and, initially, the last were only Patent Office decisions. That may well be so but for certainty and consistency I do not believe I should depart from them unless there are very good reasons. The latter was, in fact, upheld by the Patents Court.

b) The first two were decided on the papers without the personal attendance of the Applicant at a hearing. This is not an uncommon occurrence particularly where the

Applicant feels that all his arguments have been put at length before the Examiner during the pre-grant proceedings. The Hearing Officer responsible for the decision carries out an independent assessment and his decision may be appealed before the Court in the same way as any other decision.

c) The decisions were of low authority because they used reasoning of the Hearing Officer prefaced by such phrases as "in my opinion" and "it seems to me". This is common phraseology used in most, including Court, decisions. Of course, ultimately, a decision will be based on the analysis and judgement of a single, or at most a few, individual(s). Again a decision is open to appeal but otherwise stands to be taken into account by the Hearing Officer.

d) Both Hoerrmann and McManus were unrepresented individuals with limited knowledge of patent law. This had very little effect on the final outcome. If there was any way in which the Office and, in the case of McManus, the Court could have helped them achieve their reasonable rights they would have done so.

e) The decisions incorporated paragraphs from Official letters as if they had some weight in deciding the case. It is not unusual for Hearing Officers to incorporate such paragraphs when appropriate to the reasoning adopted. Their effect on a decision has to be measured by reading the decision as a whole.

f) In *Consultant Suppliers* the claims cover a vast number of compounds, as well as a number of diseases which are not connected, whereas in the applications in suit the claims relate only to the use of a single compound in situations which are connected. This could be a factor if I was inclined to think that the general principles confirmed by the decision in *Consultant Suppliers* had been affected by the specific circumstances of the case.

g) The compounds used in all the cases forming the basis for all three decisions were not established in medical use whereas ondansetron and granisetron were clearly

beneficial drugs before the Applicants discovered their new uses. It is beyond doubt that the compounds referred to in the *Hoerrmann* application had an established medical use as evidenced by the reference thereto in the copy of the 28th Edition of Martindale handed up by the Examiner at the Hearing. Prior medical use for the compositions disclosed in *McManus* can be established from the prior art references in the application. In *Consultant Suppliers* it is less clear cut. However whatever the situation the real question centres on what is required to support "Swiss form" claims and this will depend on a case-by-case analysis of the description in each case and not on the efficacy of known compounds when put to other uses.

h) The GATT/TRIPS agreement under Article 41.2 requires equitable and fair treatment and, particularly, forbids costly procedures of which the testing of new drugs is an example. The testing required by the *McManus* decision when read in the light of *Hoerrmann* is not in the nature of clinical trials as will be seen in the argument which is developed later.

DIRECT RELEVANCE OF THE MORE RECENT PRECEDENTS

26. The history of the *Hoerrmann*, *Consultants Suppliers* and *McManus* decisions is that *Hoerrmann* was the first, being issued on 2 June 1993, *McManus* the second, the Patent Office decision issuing on 5 August 1993 to be followed by the Patents Court decision on 20 December 1993 and *Consultant Suppliers* being issued on 30 March 1995. Thus by the time the Hearing Officer came to issue his decision on *Consultant Suppliers* he had had the benefit of considering both of the other decisions. *Hoerrmann* had not been referred to in the *McManus* case probably because its issue cut across proceedings on the latter at a late stage and the question of support for possible "Swiss form" claims was considered for the first time at the Hearing.

27. In the *McManus* decision, aware that "Swiss form" claims might be available to the Applicant the Hearing Officer, at lines 23 to 32 on page 562, said the following:-

"It follows therefore that the novelty of such an invention so claimed must necessarily reside, not in the composition of the medicament itself but in the particular treatment to which it is directed and in consequence a clear indication that such a treatment has been tried and tested is essential to provide the necessary support for the claim. I do not find the requisite support in the present application from the two brief references quoted above and indeed it is my understanding from the applicant at the hearing that she has in fact yet to put this area of her invention into effect. In consequence I would refuse such a claim under section 14(5)(c)."

28. On appeal Aldous J, as he then was, quoting this passage went on to say at lines 23 to 37 on page 564:-

"Mrs McManus says she is entitled to a Swiss-type claim and that she has tried and tested the alleged inventive medicament. She produced to me a document which had been filed at the Patent Office which shows an amendment to her application.

Unfortunately that document seeks to introduce new matter into the patent specification as filed, in such a way that it could not have been allowed. There is no power for the Comptroller to allow new matter, and in particular new matter which would found the basis for a Swiss-type claim, to be introduced into an application after it has been filed. He has power to allow amendment, but not amendment of this type.

It follows that the application as filed did not contain a basis for a Swiss-type claim. Furthermore, it is not in my power nor in the Comptroller's power to allow the particular material to be introduced. I therefore have come to the conclusion that the principal examiner's decision is correct and cannot be faulted. It is, in my view, a detailed and careful decision in which he has dealt with all the claims."

29. In endorsing the Hearing Officer's decision it seems to me inescapable that Aldous J. was confirming that in order to support a "Swiss form" claim there must be "a clear indication that such a treatment has been tried and tested". I take that to mean that there must be in the description of the application not merely a statement that a treatment had been carried out but

some supporting evidence that provides a justification for the claims. Indeed it appears that Mrs McManus tried to introduce new matter to show she had tried and tested the alleged inventive medicament but was prevented from doing so by Aldous J. because adding new matter to a patent specification is not allowed under the Act. Without that new matter, which in the context of the learned judge's remarks must have been more than a simple statement from Mrs McManus that her invention worked, the conclusion was that the application as filed did not contain a basis for a "Swiss-form" claim.

30. This need for a treatment to be tried and tested in order for a "Swiss form" to be supported is, I believe, very much in line with the decision I reached in the *Hoerrmann* case. In that decision although I did not use the phrase "tried and tested" what I did say was very similar and, indeed, went further in identifying the type of information I expected to see if a "Swiss form" claim was to be supported. It would be helpful if I quoted appropriate passages from that decision. At lines 38 to 47 on page 345 I said:-

"In any case relating to the medical use of a compound or composition it is obviously necessary for there to be adequate disclosure enabling the compound or composition to be identified. It would also be expected that information concerning the dosage to be administered would be disclosed as enabling a full understanding of the invention. This information, in itself, might provide adequate support for a claim that is not purpose limited. However, in my opinion, it cannot provide support for an invention in which the only form of protection is via a "Swiss" type claim. Resort to such a claim is an indication that the compounds or compositions as well as the dosage amounts and forms in which they are administered are well known in the art."

Again at lines 29 to 51 on page 346:-

".....There is a complete absence of any pharmacological data to demonstrate that the invention, which I take to be the treatment of the specified conditions, has in fact been carried out, let alone has proved to be effective. The examiner in paragraph 3 of the official letter of 8 October 1992 raised objection in these terms:-

"In amended claims 1-5 (which now take the form of what are generally known as "Swiss type claims") the claimed therapeutic activities of the isomers of lysine or hydroxylysine are not supported by the description where there is a complete lack of pharmacological data to show that lysine or its hydroxy derivative is active against the ailments specified in claims 1-5. Without such data it is not clear how such new therapeutic indications have been arrived at. Any patent application in which claims are dependent for their novelty on *new therapeutic uses* would be expected to include in its description *in vivo* or *in vitro* pharmacological tests to demonstrate the new activities, otherwise the new uses claimed could be construed as being merely speculative."

I have come to the conclusion that this objection must be right. That is not to say that I do not sympathise with Dr. Hoerrmann's problem of having to conduct long and expensive clinical trials but unless there is some indication in the description of applications of this type of tests, however rudimentary, demonstrating that the invention has been carried out in an effective manner then the application must fail for lack of support for the invention claimed."

31. It must be beyond doubt from these two decisions that in order to support "Swiss form" claims there must be a part of the description which demonstrates that the treatment, which is the only novel feature on which the invention is based, has been "tried and tested". From *Hoerrmann* it is plain that to achieve this the expectation will be that some form of *in vivo* or *in vitro* testing will have taken place. I wish, however, to emphasise that to launch a patent application the testing required will not be of the detailed kind necessary for clinical trials, because those trials generally follow the filing of a patent application by a number of years, but will need to be of, what I called in *Hoerrmann* a "rudimentary" nature. Thus the indication that an invention has been made might be by the description of laboratory tests on animals, or tests done in test tubes, to demonstrate that for example, a certain chemical or biological effect is achieved. The context of each application will no doubt determine the type of tests that are necessary. One thing is certain and that is there must be some part of the description

which is dedicated to showing how the applicant arrived at the knowledge that a pharmaceutical compound or composition, known to be effective in the treatment of one type of condition, is also effective in the treatment of another.

32. Before proceeding to consider what Dr Prendergast said at the Hearing about how his application compared with these recent precedents I need to quote just one paragraph of the Hearing Officer's decision in *Consultant Suppliers* to show the consistency between these precedents. At line 46 on page 355 to line 4 on page 356 he said:-

"The hearing officer's view in the *Hoerrmann* case was that, to support "Swiss-type" claims, there should be disclosure of at least rudimentary tests to demonstrate that the invention has been carried out in an effective manner and that the treatment it promises is a reality, and that mere disclosure of the active agent, the dosage and the new medical indication is not adequate in this regard. He was further of the opinion that each distinct medical use claimed should be so supported. I am in agreement with this approach: the consideration for granting claims for a subsequent medical use of a known medicament must lie in clear demonstration of the effectiveness of the medicament for the subsequent use, rather than in mere assertion of its effectiveness which would leave the path open for speculative patenting of ranges of new potential but untried uses for known medicaments."

33. At the Hearing Dr Prendergast appeared to be questioning the whole basis of requiring tests to support a claimed invention when there was no actual law stating such a requirement and, in parallel with other areas of technology, no requirement that a prototype be made before a patent application could be launched. I think that there was some confusion in his mind since his arguments seemed to be largely based on the assumption that the precedent decisions required clinical trials to have been performed. I have tried to show above and did so at the Hearing that the tests needed to be only of a rudimentary nature sufficient to demonstrate that the medical indication was achieved to some degree but, having said that, I think that he was unhappy about the idea of the need to supply the results of tests at all.

34. Again, Dr Prendergast was of the opinion that because ondansetron and granisetron had been extensively tested to demonstrate their safety and efficacy in their treatment of nausea associated with chemotherapy and radiotherapy there was no need to provide new test data.

35. It is true that there is no part of the Patents Act which, in so many words, requires a prototype to be built or tests to be made to verify that an invention works. There is, however, the requirement under section 14(3) that the application should disclose the invention in a manner which is clear enough and complete enough to be performed by a person skilled in the art and the requirement under section 14(5)(c) that the claims shall be supported by the description. It might well be regarded that the effect of these sections on their own, but particularly taken in combination, is to require the applicant to have actually made something or done something to confirm the actual existence of an invention. I am, however, prepared to admit that, in some circumstances, once an idea contributing to an invention has been thought of it is possible to know that the invention will work and can be described in a way such that the requirements of the two sections of the Act referred to above will be complied with. What I am not persuaded of is that, in the context of inventions involving the further medical indication of compounds or compositions having a previous medical indication, it is possible to conceive of the idea of the compound or composition working in the area of the new indication and knowing for a certainty that it will without doing any testing at all. If I am right in thinking in this way then the writing down of a claim having at its heart the new medical indication results in a claim which is unsupported unless there is some substantiating evidence involving tests done using the compounds or compositions in question.

36. If I understood Dr Prendergast rightly at the Hearing he appeared to be saying that the substantiating evidence in the present context need not be in the form of tests but may arise from what is already known about ondansetron and granisetron and that there may then be an intellectual leap which not only suggests that they will have the new indications but provides a certainty to that suggestion. In his written submission he put it this way:-

".....the present applications agents are well established drugs, widely used and

familiar to many in the hospital context. There is abundant physiological and pharmacological data from which a clear indication can be drawn. Indeed the situation as it pertains to established pharmaceuticals is that **all physiological parameters are known and published** the inventive step lies in that spark which sees previously unseen value in a measured parameter listed for regulatory completeness but ignored, until the inventor spots its value and utility."

37. I was prepared for the sake of argument to admit that he could be right but as I saw it that would require that I understood what in the present context was the "spark" which led to his invention in a way that confirming tests would not be necessary and, moreover, would demonstrate an inventive step. In spite of giving him ample opportunity to describe to me how, without testing, he knew ondansetron and granisetron would definitely possess the new indications I do not believe that I was given an adequate answer. Thus I was not able to satisfy myself that there was a "spark" behind the invention which would make it unreasonable for the Examiner to expect details in the application about the testing of the two drugs to confirm the new indications. Moreover, although not directly the subject of the Hearing, without a knowledge of the "spark" I could not be sure that the new indications were any more than the result of a mere extrapolation from what Dr Prendergast described as the "abundant physiological and pharmacological data" available on the two compounds, in which case the application would fail since the invention would not have demonstrated the existence of an inventive step.

38. I think also, just to clarify the matter that it is evident from what I have already said that even though there is a large amount of clinical data available on ondansetron and granisetron this data is not what the examiner is looking for as providing support for a new medical indication. Such data is useful in that it generally confirms the acceptability of the two compounds as drugs which are safe in use, but data over and above that, and directly related to their efficacy in the context of the new indication, is needed to provide the necessary support for the claims sought in the present applications.

39. Dr Prendergast also expressed a difficulty with the interpretation of a "clear indication"

in evaluating what was necessary to provide support for a "Swiss form" claim. For much of the time at the Hearing I was convinced that his interpretation was that he merely had to make the statement that the new medical indications were achieved by use of ondansetron and granisetron and that was the end of the matter. Whether that was the impression he wanted to leave with me I am not entirely sure but in the light of how I have dealt with the recent precedent decisions it ought to be clear that more than a mere statement is necessary. How much more, particularly in relation to test results, will probably vary from case to case. Of course judgement will be needed to come to an appropriate decision but that is not something foreign to those who wish to draft patent specifications which meet the requirements of the Act.

40. It is clear then, from what I have said, that based on the principles set down in the *Hoerrmann*, *McManus* and *Consultant Suppliers* decisions the Examiner was right in rejecting the claims in all four applications as not complying with section 14(5)(c) of the Act. However, before concluding this statement of reasons I need briefly to deal with other just one other strand of argument used by Dr Prendergast in his written submission and at the Hearing.

41. Dr Prendergast carried out an analysis of large sections of the Official letters in the proceedings. Whilst I do not doubt the usefulness of this technique in order to make effective points I think that, in these cases where the issue in question is clear cut, a sentence by sentence analysis of what the Examiner has said can be of limited value in resolving the problem. I have, in any case, dealt with much of what Dr Prendergast said in this analysis in my reasoning above and clearly have relied on the recent precedent decisions which were at the heart of the Examiner's arguments. I do not therefore propose to go through Dr Prendergast's analysis since nothing therein would deflect me from the decision I have reached.

42. In conclusion, therefore I confirm that I am not satisfied that the claims in all the four applications in suit are supported by the respective descriptions as required by section 14(5)(c). I moreover, confirm that I cannot see any way in which the Applicant can remedy

this situation and therefore I decline to allow the applications to proceed to grant.

43. The period for appeal is 6 weeks from 17 December 1998 which is the date on which I issued my decision. If, because of the time it has taken to issue this statement of reasons, the Applicant wishes to obtain an extension to this period he must apply to the Comptroller prior to the expiry of the 6 weeks period. Only one period of extension can be granted by the Office.

Dated this 18th day of January 1999

D L WOOD

Divisional Director, acting for the comptroller

THE PATENT OFFICE