2005 IEHC 226

THE HIGH COURT

2003 NO. 32 J.R.

HYGEIA CHEMICALS LIMITED

APPLICANT

AND

IRISH MEDICINES BOARD

RESPONDENT

Judgment of Finnegan P. delivered on the 4th day of May 2005

Facts

1. The Applicant is the producer of chemical products. In respect of two sheep dip products Hygeia Winter Dip and Hygeia Summer Dip it holds Veterinary Product Authorisations granted for a period of five years from 1st October 1999 the Schedule to the Authorisations having been varied on the 14th March 2001. The products are liquid organophosphate – based (hereafter OP) sheep dips. The products contain 10% diazinon and are sold in plastic containers. To use the products the container is unscrewed and the product poured into the sheep dip bath.

2. For some time there has been a concern that exposure to OP can result in neurological, psychological and psychiatric health effects in humans. It is fair to say that the reports referred to in the course of this hearing are not fully conclusive as to the effects of OP. However the Report of the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment of November 1999 ("The COT Report") justifies the concern in relation to acute poisoning and to a much lesser extent in relation to prolonged low level exposure.

3. The Respondent (hereafter "IMB") requested the Liaison Committee on Organophosphate Veterinary Concentrates to the Veterinary Advisory Committee of the Irish Medicines Board to review the COT Report and other relevant Reports and scientific articles in relation to OP concentrated solutions intended for veterinary use, to evaluate what changes if any were necessary to OP concentrates intended for veterinary use, their containers, labelling and health and safety literature based on the scientific findings and the control mechanisms for the supply of OP concentrated solutions intended for veterinary use. The Liaison Committee reported on the 21st March 2000 and dealt with containers for OP product as follows –

> *"The Committee noted that current containers meet the current requirements under the Carriage of Dangerous Goods by Road (Regulations) 1999 as drafted for transport of dangerous liquids. The Committee noted that considerable variation existed in the type and size of containers marketed in Ireland. However no uniform standard for design specifications of OP concentrate containers for veterinary use appear to be available. The reported practice among some farmers to transfer concentrate to other smaller receptacles, thereby increasing the risk of exposure, appears to have diminished through the provision of small volume containers. The Committee felt that more specialised expertise was necessary to define any new standard for these containers. These specifications would in any event take time to elaborate and products would have to demonstrate stability in any new container.*
>
> *4. The following attributes would be desirable for such containers –*
>
> > *Durable to survive handling, storage and transport from the manufacturer through to farmer.*
> >
> > *Capable of being opened while wearing the recommended gloves.*
> >
> > *Where a handle is provided it should be offset from the spout, to minimise operator contact. It was suggested that a handle would be necessary for handling products greater than one litre.*
> >
> > *Have a wide spout opening to avoid glugging.*
> >
> > *Have a spout which would extend and not allow the fluid to dribble and to pool on the top surface.*
>
> *A closed system of delivery was considered by the Committee as an alternative, but it was acknowledged that there were many practical problems associated with this option. It was noted that there is no generically available system. Many of the simpler closed systems would lead to exposure to the operator at the point of setting up or dismantling or would not give the necessary control for the performance needed or would have a potential for misuse.*
>
> *Attempts to improve existing containers through the provision of a screw top tap for insertion on to the product containers had proved unsuccessful due to cross threading and tap leakage. Other possibilities for ensuring the integrity of the concentrate such as the use of alginates were rejected on the basis of design failures and the need to have a product capable of use at different concentrations to fulfil the requirements for differing initial and replenishment loads which are needed to meet the so called stripping characteristics of the product".*

4. The Committee among its recommendations made the following –

> *"That the containers in which OP concentrates are supplied for veterinary use be kept under review by the Irish Medicines Board in the light of national and international developments and that all authorised products should comply with any new standards".*

5. The Advisory Committee on Veterinary Medicine of the I.M.B. endorsed the Report of the Liaison Committee on the 15th March 2001. On the 19th November 2001 the I.M.B. wrote to the Applicant and having referred to the recommendation of the Liaison Committee said –

> *"The I.M.B. is aware that new standards in delivery systems have been developed or are currently under development by a number of relevant companies. This issue was discussed at a recent meeting of the Veterinary Advisory Committee who concluded that, for all relevant products on the Irish market, new closed delivery systems or similar, aimed at reducing operator exposure to the concentrate must be in place before 31st October 2002 and any product not in compliance with the new standard at that date should be recalled from the market".*

6. At this time two suppliers to the Irish market had introduced closed delivery –

> Coopers Ectoforce introduced a system consisting of an outer foil bag containing an inner water soluble sachet containing the OP and Osmond Goldfleece a pumped delivery system. Each of these products contain 60% diazinon whereas the Applicant's product contains 10% diazinon. Further in 1995 the Applicant in order to avoid risks where the container was of tin plate introduced its plastic container and which while not a closed system as recommended by the Liaison Committee the Applicant contends that it meets all the criteria for containers set out in the Liaison Committee's Report.

6. The Applicant responded to the I.M.B.'s letter of the 19th November 2001 by letter dated 16th July 2002 with which they enclosed a Report which had been commissioned from Willis Corroon Hinton (Ireland) Limited (hereinafter "Willis Report") The Willis Report contained a hazard identification and risk assessment of all three products on the Irish market – that of the Applicant, Coopers Ectoforce and Osmond Goldfleece. It dealt with the Applicant's container in the following terms –

> *"Hygeia dip is dispensed from a plastic container with an open spout. This presents the risk of splashing and dripping of product from the rim of the spout after pouring and when the cap is replaced. However, this risk is minimised through the use of an offset handle (at the opposite side to the spout) and the wide spout which reduces the likelihood of glugging.*
>
> *An important point to note is that the Hygeia dip has a concentration of only 10% compared to 60% for the other two products. This means that if contact does occur, the risk of adverse health effects will be significantly lower. Indeed it is arguable that the Hygeia product should not be classified as a "concentrate"".*

7. It identified the risk associated with Coopers Ectoforce as a risk of puncture and the risk associated with Osmond Goldfleece that the complex nature of its delivery system could present problems in the field. The Report concluded that it would appear that only the Hygeia product clearly meets the I.M.B. requirements, that is the recommendations of the Liaison Committee.

8. The substantive response from the I.M.B. was by letter dated 19th August 2002 in the following terms-

> *"At a meeting of the Advisory Committee for Veterinary Medicines in October 2001 the issue of new standards in delivery systems for OP sheep dip concentrates was discussed. The Committee decided that "new closed delivery systems, or similar, aimed at reducing operator exposure to the concentrate must be in place before 31st October 2002 and any product not in compliance with the new standard at that date should be recalled from the market." This decision was communicated to you in a letter dated 19th November 2001.*
>
> *As a follow-up to that letter, and notwithstanding the fact that an appeal to the decision detailed above will be considered at the September meeting of the A.C.V.M., I am writing to ascertain the stocks of summer dip and winter dip remaining on the market at this point in time. Further, in the event that your appeal to the A.C.V.M. is not successful, you are requested to confirm that no product in the "open" system will be introduced to the Irish marketplace after the October 31st deadline. As indicated previously, any product and delivery systems not acceptable to the I.M.B. and remaining in the marketplace after October 31st should be recalled".*

9. The I.M.B. sent a second letter to the Applicant dated 19th August 2002 dealing with the appeal and as there is an issue in these proceedings in relation to the appeal and the appeal procedures I propose dealing with that correspondence separately. The Advisory Committee met to consider the appeal against its decision communicated in the letter of the 19th November 2001 on the 18th December 2002 and its decision on the appeal was communicated by letter dated 19th December 2002 and dealt with the outcome of the appeal in the following terms –

> *"Following the discussion the A.C.V.M. is of the unanimous opinion that organophosphate concentrates supplied in open containers that require the user to pour the concentrate into the sheep bath carry an unacceptable risk of user exposure to the concentrate. For this reason the A.C.V.M. decided that Hygeia's winter dip and summer dip as currently presented to the end user carry an unacceptable risk of human exposure to the organophosphate concentrate which arises during their use for dipping sheep.*
>
> *Therefore the A.C.V.M. have moved to suspend the marketing authorisations for both products in accordance with Regulation 19 of the Animal Remedies Regulations 1996 and Article 83 of Directive 2001/82/EC. Consequently, you are directed not to continue to supply winter dip and summer dip to the market and that any product on the market currently should be recalled from retailers before January 31st 2003. A draft recall notice must be provided too and approved by the I.M.B. Inspectorate prior to issue by you. In addition, farmers should be advised by an appropriate notification from your company to return any unopened products to the source of purchase for uplifting by your company. This notification should also be submitted to the I.M.B. for review and approval prior to issue. You are requested to contact Mr. John Lynch or Ms Muireann Lydon, I.M.B. Inspectorate, in respect to the conduct of the recall.*
>
> *I should point out that the suspensions will be lifted should applications for an appropriate delivery system be submitted and authorised by the I.M.B".*

10. The I.M.B. met on the 26th February 2003 to consider the suspension of the product authorisations for the Applicants' products and decided that the product authorisation for the same should be suspended. It was decided that a recall of the products should be commenced so that all products be removed from the market by the 9th April 2003.

The Proceedings

11. On the 22nd January 2003 (that is prior to the decision of the I.M.B.) the Applicants applied for and were granted leave to apply for certain reliefs by way of judicial review. The Applicants also sought interlocutory relief in the nature of a stay on the decision of the Respondent and this was granted on the 21st March 2003. With leave of the Court the Applicants delivered an amended Statement Required to Ground Application for Judicial Review on the 17th April 2003 and an amended Statement of Opposition was delivered to the same.

The Issues

12. At my request the parties agreed the issues for determination by the court in the following terms –

> (1) Whether the internal procedures adopted by the Respondent failed to comply with the principles of natural and constitutional justice and basic fairness of procedures and (sic) any of the grounds identified in paragraph 47 of the

statement of grounds; or were in breach of the principles stated in paragraph 49 (being the principle of proportionality and respect of fundamental rights including rights of property, the principle of legal certainty and protection of legitimate expectation and the principle of equality).

(2) Whether the decision of the Respondent is ultra vires on the grounds set out in paragraphs 37 and 38 of the amended statement of grounds.

(3) Whether the decision of the Respondent was arrived at in breach of the principle of proportionality in circumstances where there were no adverse reactions or adverse human reactions to the Applicants' products.

(4) Whether the Respondent impermissibly took into account the economic implications for companies which are the competitors of the Applicant.

(5) Whether the decisions of the Respondent were vitiated by objective bias by (a) predetermination or (b) the participation of Mr. P.J. O'Connor, Chairman of the Advisory Committee for Veterinary Medicines in the decision of the Board on the 26th February 2003.

(6) Whether the decision of the Respondent is vitiated by subjective bias (paragraph 44 of the amended statement of grounds).

(7) Whether the decision of the Respondent is vitiated by manifest error or misuse of power as identified in paragraph 51 of the amended statement of grounds; and whether the decision of the Respondent is vitiated by a distortion or manifest error of assessment of facts or misuse of power or a clear breach of the bounds of its discretion as a consequence of (i) the non-disclosure of the rapporteur's Report; or (ii) omission to refer to "or similar aimed at reducing operator exposure to the concentrate".

(8) Whether the decision of the Respondent on the 26th February 2003 cures any defect in the procedures to that date or whether they are fatally tainted.

(9) Whether the Applicant is estopped from challenging the procedures of the oral hearing.

(10) Whether the Applicant is estopped from raising the issue of subjective bias of Dr. Beechner in circumstances where the Applicant did not object to Dr. Beechner's presence at the oral hearing before the Advisory Committee for Veterinary Medicine.

(11) In the event that the Applicant is successful on all or some of the above issues whether there is any liability in damages and if so how much.

(It is understood that the above issues relate to the decision of the Advisory Committee for Veterinary Medicines made on the 18th December 2002 and the decision of the Irish Medicines Board made on the 26th February 2003 as appropriate).

The Regulatory Framework

13. The I.M.B. was established by the Irish Medicines Board Act 1995 ("The Act"). The functions of the I.M.B. are set out in section 4 of the Act and include the licensing of the manufacture, preparation, importation, distribution and sale of medicinal products, the exercise of the powers conferred on the competent authority by Council Directive No. 65/65 EEC and any Regulations under the Health Act 1947 giving effect to that Directive, the exercise of the powers conferred on the Supervisory Authority by Council Regulation (EEC) No. 2309/93 and Council Directive No. 81/851/EEC. Council Directive No. 81/851/EEC was repealed and its provisions re-enacted by Council Directive 2001/82/EC which in effect codified the law in relation to veterinary medicinal products. The Act in section 9 provides for the establishment by the Minister of the Advisory Committee on Veterinary Medicines "to assist and advise the Board in relation to any matters pertaining to the safety, quality or efficacy of medicinal products for animal use as are referred to it by the Board and to perform the functions assigned to it by sub-section (8)". The members of the Committee are appointed by the Minister for Health with the consent of the Minister for Agriculture, Food and Forestry and the Chairperson of the Committee is appointed by the Minister. Sub-section (5) provides that the Committee shall regulate "by standing orders or otherwise" the procedure and business of the Committee. Sub-section (8) provides as follows –

> *"The Board shall not refuse to grant a licence in respect of a medicinal product on any ground relating to the safety, quality or efficacy of the medicinal product unless it has requested the advice of the appropriate committee in relation thereto and considered such advice".*

14. Council Directive 2001/82/EC Article 83 provides as follows –

> *"1. The competent authorities of the member states shall suspend or withdraw marketing authorisation when it is clear that*
>
> > *(a) The veterinary medicinal product proves to be harmful under the conditions of use stated at the time of application for authorisation or subsequently".*

15. Article 94 of the Council Directive provides as follows –

> *Any decision referred to in this Directive, taken by the competent authorities of the member states, may only be taken on the grounds set out in this Directive and shall state in detail the reasons on which it is based.*
>
> *Such a decision shall be notified to the party concerned who shall at the same time be informed of the remedies available to him under current legislation and the time allowed for seeking such remedies.*

16. The relevant domestic Regulations are the Animal Remedies Regulations 1996. The Regulations in Regulation 5 provide that the I.M.B. shall be the Competent Authority in the State for the purpose of the Council Directive: Council Directive is defined by listing the relevant Directives then in existence but also "any future Directive of the Council, or, as the case may be, the Commission, made after the making of these Regulations which amends, extends or replaces the said Council Directive 81/851/EEC".

17. The I.M.B. accordingly is the Competent Authority for the purposes of Council Directive 2001/82/EC.

18. The Regulations in Regulation 19 provide as follows –

> *"19. The Competent Authority shall suspend or revoke a veterinary product authorisation where in the opinion of the Competent Authority –*
>
> > *(i) The animal remedy proves to be harmful under the conditions of use stated at the time of application for authorisation or subsequently".*

19. I propose dealing with the objections of the Respondent on the grounds of estoppel at Issues 9 and 10 first.

9. Whether the Applicant is Estopped from Challenging the Procedures of the Oral Hearing.

20. The Respondent treated a letter to it from the Applicant dated 16th July 2002 as an appeal against the decision of the Advisory Committee for Veterinary Medicines ("A.C.V.M.") communicated by the letter dated 19th November 2001. By letter dated 19th August 2002 the Respondent informed the Applicant that the A.C.V.M. would consider the appeal documentation which had been provided by the Applicant. By letter dated 6th September 2002 the Applicant requested that it be given an opportunity to attend before the A.C.V.M. The Respondent wrote to the Applicant on the 19th September 2002 following a meeting of the A.C.V.M. on the 16th September 2002 in the following terms –

> *"The A.C.V.M. reviewed the totality of the documentation provided, including recent correspondence between Hygeia and the I.M.B. since we received your submission. The A.C.V.M. deferred a decision on the matter pending further deliberation. They requested the Veterinary Secretariat to prepare an assessment report of the Hygeia submission for consideration by it at its next meeting on November 20th 2002. If necessary following their consideration of the matter the A.C.V.M. will issue an updated position paper on the matter. In the interim the A.C.V.M. have deferred a recall of the Hygeia products. The A.C.V.M. does not consider that it would be useful at this juncture to have a hearing with you in person as the Veterinary Secretariat have yet to report. However, if the Committee is minded to confirm its previous position that closed delivery systems for OP concentrates are necessary, you will be given the opportunity to appeal".*

21. There followed an exchange of correspondence in which the Respondent requested further information which was provided by the Applicant. By letter dated 21st November 2002 the Advisory Committee acceded to the request to be allowed attend before it on the appeal and dealt with the form which the appeal would take in the following terms –

> *"As requested in your letter of September 6th you are invited to attend before the A.C.V.M. to appeal this decision. You are requested to present yourself at the I.M.B. at 3.30 p.m. on December 18th 2002 for the appeal which is expected to last for 20/30 minutes. You are also requested to provide copies of any written documents/overheads you wish to present to the I.M.B. in advance for consideration by the I.C.V.M. These documents which should be marked for my attention should be submitted no later than Monday 9th December to allow for copying, dispatch and consideration by the members of the Committee. Please indicate whether you have any requirements for an overhead or computer projector at that time. You are also requested to advise me of the names of members of your delegation which should not exceed four persons. The appeal should involve a technical, scientific presentation/discussion only and will be based on the safety of your products for human health. Following your presentation, it is expected that members of the A.C.V.M. may ask questions of clarification on the information presented".*

22. The Applicant responded to this letter on the 26th November 2002 raising three matters –

> *(i) The inadequacy of the time allowed to prepare for the appeal.*
>
> *(ii) Requesting copies of studies referred to in a Report of the Advisory Committee for Veterinary Medicines of 20th November 2002 sent to the Applicant with the letter of 21st November 2002 (this document is referred to hereafter as the Risk Assessment).*
>
> *(iii) Requesting a copy of a Risk Assessment carried out in relation to all three products on the market.*

23. In its reply of the 27th November 2002 the Respondent refused the request to defer the appeal and declined to furnish studies related to competitor products for reasons of confidentiality and on the grounds that other products are not relevant to the risk evaluation of the Applicant's product. Copies of the studies requested were not furnished with that letter but were subsequently furnished in advance of the hearing of the appeal. The letter of the 27th November 2002 set out in more detail the appeal procedure in the following terms-

> *"(1) Submission of copies of any written documents/overheads you wish to present to the I.M.B. for consideration by the A.C.V.M. These documents, which should be marked for my attention should be submitted no later than Monday December 9th 2002 to allow for copying, dispatch and consideration by the Members of the A.C.V.M. Note that the appeal documentation is intended to clarify issues already identified and not to present the results of any new studies.*
>
> *(2) Notification to the I.M.B. of the names and professional description of members of your delegation attending the appeal (up to a maximum of four persons) in advance of the appeal which will take place at approximately 3.30 p.m. on Wednesday December 18th 2002.*
>
> *(3) The appeal should involve a technical, scientific presentation/discussion only before the A.C.V.M. and will be based on the safety of your products for human health. The appeal is expected to last for 20/30 minutes. The appeal should focus on the risk of the Hygeia products for human health; matters relating to commercial considerations or to products marketed by other companies are outside the scope of the appeal.*
>
> *(4) Following your presentation it is expected that members of the A.C.V.M. may ask questions of clarification on the information presented.*
>
> *(5) Following your appeal to the A.C.V.M. you will be invited to withdraw from the meeting. The meeting will close regarding your input and the A.C.V.M. will consider the matter.*

24. Following this the solicitors for the Applicant became involved and wrote to the Respondent on the 10th December 2002 raising a

number of matters in relation to the procedures on the appeal. They sought a copy of the Rules for appeals, a copy of the Risk Assessment, a copy of a Study on the Solubility of Sachets. Objection was made to the circumstance that the appeal would be to the same Advisory Committee as had made the original decision. Objection was taken to the time limit of 20/30 minutes. Again objection was taken to the scope of the appeal as set out at (3) in the extract from the Respondent's letter of the 27th November 2002 set out above. The letter went on to state that it was under protest that the Applicant will participate in the appeals procedure and that it would do so without prejudice to all other avenues and remedies available to it. In response to that letter the Respondent. by letter dated 13th December 2002 set out in considerably more detail the manner in which the appeal would proceed. It also set out the sources relied upon for the preparation of the Risk Assessment. Access to any study on the solubility of sachets was denied. In relation to the constitution of the A.C.V.M. it pointed out that the members of that Committee are appointed by the Minister and that the Act does not provide for a differently constituted Committee to hear appeals. It pointed out that a member of the Committee had been appointed to act as Rapporteur and not the member of the I.M.B. staff who prepared the Risk Assessment. With regard to the limitations on the appeal it pointed out that the procedure adopted is in accordance with the practice of international regulatory bodies such as the European Medicines Evaluation Agency which restrict oral presentations. The Applicant's solicitors responded by letter dated 17th December 2002 again seeking a copy of formally adopted rules or regulations for appeals, requesting a copy of the *signed* Risk Assessment and the Study of Solubility of Sachets. The objection to the appeal being considered by the same Committee as made the decision was repeated. It objected to the restriction on the introduction of further independent reports and to the limit for an oral presentation of 20/30 minutes. It was indicated that the Applicant intended to rely on a Report of Professor Hynes and this was in fact considered by the Committee. Finally it was indicated that the submission of the Applicant to the appeal process was not to be taken as an acceptance on their part of the lawfulness or otherwise of the matters complained of in the correspondence.

25. In determining whether the objection on the grounds of estoppel is well founded I think it is appropriate to have regard to the time constraints with which the Applicant was faced. It is also appropriate to have regard to the circumstance that the procedures to be adopted by the A.C.V.M. were stated originally in the letter of 21st November 2002 from the Respondent and expanded upon and clarified in the further letters dated 27th November 2002 and 13th December 2002. The Applicant's position in relation to the procedures was expressly reserved in their solicitor's letters of the 10th December 2002 and 17th December 2002. Thus there was no acquiescence on the part of the Applicant in the stipulated procedures. The circumstances here accordingly differ from those in *Corrigan v Irish Land Commission* (1977) I.R. 317 relied upon by the Respondent where the Plaintiff sought to impugn a decision of the Defendant on the ground of bias in circumstances where two of the lay commissioners who heard the case had previously signed a certificate for the compulsory acquisition of the Plaintiff's lands. The Applicant in that case did not object to the participation of the lay commissioners during the course of the hearing. The term "estoppel" is used in various senses in the law but in each case it seems to me to have as an ingredient the adoption by one party of a position upon which the other relies. In the circumstances of this case the Applicant has never adopted the position and did not lead the Respondent to believe it had adopted a position that it was satisfied with the procedures: rather it had made its objections known and indicated that it intended to reserve its position in relation to the same. I am satisfied accordingly that the Applicant is not estopped.

10. Whether the Applicant is Estopped from Raising the Issue of Subjective Bias of Dr. Beechner in circumstances where the Applicant did not object to Dr. Beechner's presence at the oral hearing before the Advisory Committee for Veterinary Medicine.

26. Dr. Beechner acted as Secretary to the Liaison Committee on Organophosphate Veterinary Concentrates whose Report of the 31st March 2000 recommended that the containers in which OP Concentrates are supplied for veterinary use be kept under review by the Respondent. He is also the Veterinary Director of the Respondent and correspondence from the Respondent to the Applicant was under his hand. The Applicant contends that Dr. Beechner sat on the A.C.V.M. when it made its decision of October 2001 although not a member: further he sat on the A.C.V.M. which heard the appeal. He remained with the A.C.V.M. after the hearing of the appeal and participated in its deliberations. He communicated the decision of the A.C.V.M. on the appeal. He prepared a memorandum which was before the Respondent when it made its final decision. He was the author of the Report of the National Drugs Advisory Board 1995 on OP Sheep Dips.

27. I have carefully considered the Affidavit of Dr. Beechner in response to the allegations of his participation in the deliberations of the A.C.V.M. at the time of its original decision and on the appeal hearing and the deliberations of the A.C.V.M. following that hearing. I have carefully considered the evidence of Dr. Beechner on cross examination. On the evidence before me I am satisfied that Dr. Beechner was not involved in the deliberations of the A.C.V.M. either on the making of the original decision or on the appeal hearing in the sense suggested by the Applicant. Insofar as the latter is concerned the Applicant was present and made no objection: in these circumstances on the authority of *Corrigan v Irish Land Commission* (1977) I.R. 317 I am satisfied that the Applicant is in any event estopped from raising the objection at this stage having failed to do so in the course of the appeal. However there was no possibility for the Applicant to object to any involvement if such there had been by Dr. Beechner in the deliberations of the A.C.V.M. following the appeal hearing: however I am satisfied on the Affidavit evidence before me that Dr. Beechner did not participate in the deliberations. In summary the objection on the basis of estoppel succeeds only insofar as it relates to proceedings on the appeal hearing. As I reviewed the evidence in relation to Dr. Beechner's involvement throughout the entire process in connection with this issue I propose to deal next with Issue 6 and in conjunction with the same the issue raised at 5(a) and which also relates to Dr. Beechner's involvement.

Issue (6)

Where the Decision of the Respondent is Vitiated by Subjective Bias (paragraph 44 of the amended Statement of Grounds)

5(a) Whether the Decisions of the Respondent were Vitiated by Objective Bias by predetermination

28. Paragraph 44 of the Amended Statement of Grounds reads as follows –

> "Before the hearing of the appeal Mr. Declan O'Brien, Director of Animal and Plant Health Association (A.P.H.A.) was told by Dr. Beechner on or about the 20th November 2002 in a conversation that it did not matter what Hygeia presented at its appeal as the decision had already been made to withdraw its sheep dips. The Respondent's decision communicated in the letter of the 19th December 2002 is thus vitiated by prejudgment and bias. The Animal Plant Health Association represents the views of the industry in respect of its member plant pharmaceutical companies."

29. Declan O'Brien swore an Affidavit on the 16th January 2003 in which he deposed as follows –

> "On the 20th day of November 2002 I had a conversation with Dr. Gabriel Beechner, Veterinary Director, Irish Medicines Board in relation to various matters. In the course of our conversation we spoke about the current position with Hygeia's sheep dip products and the forthcoming appeal on the 18th December 2002. Dr. Beechner indicated that it did not matter what was said at the forthcoming appeal as the decision had been made to remove the products from the market. I understood this to mean that the outcome of the forthcoming appeal had already been determined."

30. Mr. O'Brien was cross examined on his Affidavit. He could not remember the words used by Dr. Beechner but that the effect of the words was that the products would be removed regardless of what was said at the appeal. He had read Dr. Beechner's Affidavit in response to his Affidavit. The conversation was in relation to sheep dip products generally. He was aware of the Applicant's appeal and when it was due to be heard. He was aware of the views of the I.M.B. in relation to closed delivery systems and he was aware in general terms that the A.C.V.M. wanted the product to be marketed with closed delivery systems. He was unable to recall precisely the context in which he alleged Dr. Beechner made the comments in question. He could not recall whether it was in a response to a question posed by him but it may have been. He was unable to recall with any precision anything else that was discussed. He had told Mr. McCartan, the Managing Director of the Applicant, of the conversation on the 4th December 2002. When he told Mr.Cartan of the conversation he could not remember whether he had phoned Mr. McCartan or vice versa but it was more likely that Mr. McCartan had phoned him. In a subsequent telephone conversation with Dr. Beechner he may have said that what he told Mr. McCartan that Dr. Beechner had said was that it was unlikely that the Applicant would be successful on the appeal. In the course of that conversation Dr. Beechner had disagreed with the witness's account of the conversation. He did not agree that Dr. Beechner had merely explained to him his understanding of the concerns of the A.C.V.M. with sheep dip products. He denied that he told Dr. Beechner that at the time he swore his Affidavit he could not recall what he had told Mr. McCartan but had relied on Mr. McCartan's account of what he had told him. He had prepared a statement before the Affidavit was sworn and when presented with this he had corrected it: on further questioning he said the statement may not have been supplied in writing but may have been given in the course of a telephone conversation with the Applicant's Solicitors which was then put in writing and which he had corrected. There was a reference to precise words in the Draft Affidavit which he did not put into the Affidavit as sworn. The initial draft was in effect putting words into his mouth. A contemporaneous note of the witness's conversation with Dr. Beechner made by Dr. Beechner was put to the witness. He disagreed with the note in that it recorded him as saying that he had telephoned Mr. McCartan on the morning following his discussion with Dr. Beechner that is on the 21st November 2002. He disagreed with the note in that it recorded him as having told Mr. McCartan that it was unlikely that the company would be successful in its appeal. The note read as follows –

> "He stated that he was in a difficult position because if he did not sign the Affidavit he would be liable to court action from the company involved".

31. The witness remembered saying words to that effect: he believed if he did not swear the Affidavit he would be subpoenaed. The note contained the following –

> "I told him that at the appeal itself the Chairman at the outset following his welcoming address to the company he had stated that the A.C.V.M. were open minded on the outcome of the appeal and would reach a conclusion on the matter following the appeal. I stated that that statement had been included in the stenographers note of the meeting".

32. The witness accepted that could have been said by Dr. Beechner. He was unable to say that other matters recorded in the note were not dealt with in the conversation. The witness agreed that he had not sworn an Affidavit in response to Dr. Beechner's Affidavit: he had only seen that Affidavit some ten days previously.

33. A letter dated 21st November 2002 was put to the witness which letter notified the Applicant of the date of the appeal: this was the day after the conversation which he had had with Dr. Beechner: it was suggested to him that he could not possibly have known that the appeal date had been fixed for the 18th December at the time of the conversation. The witness was adamant however that he knew that there was an appeal pending although it may have been the case that he did not know the date fixed. As of that date however the decision of the A.C.V.M. had not been communicated to the Applicant the decision having only been made on the day of his meeting with Dr. Beechner. He believed his conversation with Dr. Beechner on the evening in question lasted between fifteen and thirty minutes. The witness could not recollect a discussion on another matter which took place during the conversation and referred to by Dr. Beechner in his Affidavit.

34. Having considered the evidence of the witness on Affidavit and in cross examination and also that of Dr. Beechner on Affidavit and in cross examination my conclusion is as follows. I am satisfied that a discussion took place concerning the Applicant's position. Both Mr. O'Brien and Dr. Beechner were aware of the attitude of the A.C.V.M. Dr. Beechner was aware of the decision of the A.C.V.M. reached on that day. I think it likely that Mr. O'Brien anticipated a decision of the A.C.V.M. unfavourable to the Applicant and anticipated an appeal. I do not accept that Dr. Beechner said that an appeal would be unsuccessful: at most he may have expressed his opinion that the appeal was unlikely to succeed. In these circumstances I am not satisfied that the Applicant has established any element of prejudgment in relation to the appeal process.

Issue (1)

Whether the internal procedures are adopted by the respondent failed to comply with the principles of natural and constitutional justice and basic fairness of procedures and any of the grounds identified in paragraph 47 of the Statement of Grounds; or were in breach of the principles stated in paragraph 49 (being the principle of proportionality and respect of fundamental rights including rights of property, the principle of legal certainty and protection of legitimate expectation and the principle of equality).

35. Paragraph 47 of the Amended Statement of Grounds criticises the Respondent's procedures in the following terms –

> (i) There are no formal written procedures (whether by way of regulations, standing orders or otherwise) describing the manner in which the Respondent's Advisory Committee for Veterinary Medicines conducts appeals.
>
> (ii) The review is considered initially by the Respondent's Advisory Committee for Veterinary Medicines.
>
> (iii) The appeal from the initial decision of the Respondent (through its Advisory Committee for Veterinary Medicines) is to the said Advisory Committee for Veterinary Medicines.
>
> (iv) The appellate procedure constitutes the Respondent (through its Advisory Committee for Veterinary Medicines) a judge in its own cause and fails to respect the nemo iudex in causa sua principle.
>
> (v) The entire procedure is opaque and appears to be conducted on an ad hoc basis according to whatever rules the Respondent's Veterinary Director lays down.
>
> (vi) The absence of published and transparent procedures for applications and appeals before the Advisory Committee for Veterinary Medicines of the Respondent makes the Respondent a judge in its own cause in which it also acts as the presenting or prosecuting authority and participates in the deliberations of the said Advisory Committee for Veterinary Medicines.

(vii) Requiring the Applicant in its written documents and appeal to produce independent evidence and experts in its appeal while allowing the Respondent to rely upon limited written reports or extracts from scientific literature with no opportunity to verify or question assertions made.

(viii) Adopting a procedure for appeals before the Advisory Committee for Veterinary Medicines which encompassed pre judgments on the part of the Respondent.

(ix) Relying on an anonymous unsigned and unpaginated risk assessment.

(x) Acting ultra vires its powers as outlined in paragraphs 37 and 38 above.

36. (i), (ii) (other than in relation to the allegation that the procedures are opaque) and (iii) above are factually correct. Insofar as procedures are concerned the Irish Medicines Board Act 1995 section 8(8) provides as follows –

> "Subject to the provisions of this Act, the Board shall regulate, by standing orders or otherwise, the procedure and business of the Board".

37. Accordingly it is open to the Board to adopt such procedures as it thinks fit by standing orders or otherwise. There are no standing orders but this does not represent a defect provided the procedures actually adopted are fair and notified. The procedures of the A.C.V.M. in its initial consideration were I am satisfied sufficient and appropriate to the administrative determination involved: in any event it is quite clear that that determination was not final but was subject to what throughout the proceedings was referred to as an appeal procedure. In fact the position was that a preliminary view was formed by the A.C.V.M. and the Applicant was then allowed to make its case before that view was incorporated into a decision in relation to the advice which would be given to the I.M.B. For the appeal procedure I am satisfied that the procedures outlined in correspondence prior to the hearing were appropriate and sufficient. The Applicant however raises a number of specific complaints concerning the preliminary decision and the decision on appeal (as it has been categorised). The Applicant sought but was denied access to the result of tests on the solubility of sachets as a method of delivery utilised by a rival company. I am satisfied that the Applicant was not entitled to this information. The Respondent was concerned with the Applicant's product and not with the rival product. It is complained that the Respondent arrogated to A.C.V.M. competence to make the decision: on the evidence this was not the case. The decision was made by the Irish Medicines Board whose function this is under the Animal Remedies Regulations 1996 Regulation 19. Further the Irish Medicines Board Act 1995 section 9(8) recognises a role for the A.C.V.M. in relation to the grant of a licence. However the role of the A.C.V.M. is wider than this as section 9(2) provides for the establishment of an A.C.V.M. to advise the Board in relation to matters pertaining to the safety, quality and efficiency of medicinal products for animal use as are referred to it by the Board. I am satisfied that it was appropriate for the Board to avail of the expertise of the A.C.V.M in this instance. The A.C.V.M. I am satisfied made no decision either at the preliminary stage or at the appeal stage both of which stages were designed to enable the A.C.V.M. to form an opinion and advise the Board. There is a complaint of "a rush to judgment". The concerns in relation to OP products and their manner of application were long known to the Applicant as they were to other manufacturers and suppliers of products containing OP. This was particularly the case following on from the COT Report, the Report of the Liaison Committee of 21st March 2000 and the endorsement of the same by the A.C.V.M. on the 15th March 2001. I am satisfied that the procedure adopted whereby a preliminary decision was reached subject to the facility afforded to the Applicant to make representations prior to a final view being reached was sufficient and appropriate in the circumstances of this case. Complaint is made of a risk assessment prepared by Dr. Beechner principally that it was not disclosed that he was the author of the same. Had I been persuaded by the Applicant's arguments that Dr. Beechner was biased this would have been relevant but as I have not accepted that submission I do not accept that the omission to name him as the author vitiates the proceedings of the A.C.V.M. or the Respondent.

38. The Applicant makes specific criticism of the role of rapporteur. In his evidence and on cross examination Dr. Beechner described this procedure as having been adopted from procedures at EU level. Mr. Breathnach and expert toxicologist on the A.C.V.M. was appointed to act. His function was to overview the Risk Assessment Report prepared by Dr. Beechner. He was also to assess and filter the documentation put before the A.C.V.M. at the appeal stage. He prepared a Report for the A.C.V.M. The Report in this case was critical of some of the expert reports relied upon in the Risk Assessment and this was not disclosed to the Applicant. The procedure adopted by the A.C.V.M. is that any matters in the rapporteur's report favourable to the company whose product is being considered are not put to the company but it is given an opportunity to deal with those matters in the report unfavourable to it. In the circumstances of this case I am satisfied that the rapporteur is acting as a member of the A.C.V.M. for the benefit of the committee in the manner outlined by Dr. Beechner but that as a member of the A.C.V.M. may express views on the matters before it. Proceedings before the A.C.V.M. are not inter partes. He is not fulfilling the role of a legitimus contradictor to an applicant company. As a member of the committee it is appropriate that he should raise questions of a company seeking to obtain or maintain an authorisation. I would not think it appropriate that he should, as is suggested by the Applicant, ask questions of the A.C.V.M. The position here is not as that in *Frenchchurch Properties Limited v Wexford County Council* 1991 ILRM 769 where there was a matter exercising the mind of the Respondent's official which the Applicant was not given the opportunity to deal. Here I am satisfied that the Applicant was given an opportunity at the oral hearing to deal with all matters which were of concern to the A.C.V.M.

39. Next criticism is made that in its letter of the 19th November 2001 to the Applicant the Respondent wrote that what was required before 31st October 2002 was a "new closed delivery system or similar" but throughout proceedings before the A.C.V.M. the alternative of a "similar" system was not canvassed. It is clear from the evidence that the Applicant's system is an open system and not a closed system and it is not a system that could in any way be described as coming within the phrase "or similar". I do not see this submission as relevant.

40. Finally there is criticism of reliance by the A.C.V.M. on a test of the Applicant's product carried out by Dr. Beechner which has been described as the "toilet test" this being the manner in which Dr. Beechner tested the Applicant's container. The test to me appeared a sensible, practical examination: the Applicant for its part relied on "a desktop examination of the hazards associated with the Applicant's products" by which I understand that no practical tests whatsoever were carried out for the purposes of the same. Where the Applicant itself did not consider it appropriate to carry out any practical tests and I see little merit in its complaint concerning the test carried out by Dr. Beechner.

41. The requirements of natural justice vary with the nature of the enquiry concerned. In the present case I am satisfied that the procedures adopted satisfy the requirements of natural justice. The Applicant was afforded the opportunity to make its case in the procedure adopted. This was an administrative procedure and not in the nature of judicial proceedings inter partes.

42. In paragraph 49 of the Amended Statement of Grounds the Applicant calls in aid the principle of proportionality and respect for fundamental rights, legal certainty, protection of legitimate expectations and the principle of equality. It is common case that there is no instance of adverse human reaction to the Applicant's product. However it is also abundantly clear that there are serious concerns

as to the effect on human health of OP products: see for example the COT Report. In addition to the principles urged by the Applicant it is appropriate to have regard to the precautionary principle. I am satisfied having regard to the documented concerns in relation to OP products the decision reached by the Board to withdraw the authorisation was proportionate. The Applicant had a legitimate expectation of fair procedures but these I am satisfied were accorded to it. Other than to raise in the pleadings the principle of equality this was not elaborated upon.

43. The Applicant complains that the A.C.V.M. by letter dated 19th December 2002 required withdrawal of the Applicant's product by the 31st January 2003 while the next meeting of the Respondent, being the earliest at which a decision could be made, was scheduled for the 29th January 2003: however the Applicant's product was not in fact withdrawn injunctive relief having been obtained. The course of conduct may reflect confidence that the advice of the A.C.V.M. would be followed by the Respondent but it does not convince me that there was prejudgment as the decision made was on the evidence not that of the A.C.V.M. but of the Respondent. The A.C.V.M. being the expert body to advise the Respondent clearly expected its advice to be heeded and its action in causing the letter of the 19th December 2002 being written evidences the seriousness with which it regarded the dangers of OP products and fortifies my view that the advice of the Committee which was followed by the Respondent was proportionate.

(2). Whether the decision of the Respondent is ultra vires on the grounds set out in paragraphs 37 and 38 of the Amended Statement of Grounds.

44. This issue was refined in the course of the hearing. Both the A.C.V.M. and the I.M.B. it is alleged took into account off label use of product. The Directive 2001/82/EC Article 83.1(a) provides as follows –

> "1. The Competent Authorities of the Member States shall suspend or withdraw marketing authorisation when it is clear that
>
> > (a) the veterinary medicinal product proves to be harmful under the conditions of use stated at the time of application for authorisation or subsequently

45. The Animal Remedies Regulations 1996 Regulation 19 provides as follows –

> 19. The Competent Authority shall suspend or revoke a veterinary product authorisation where in the opinion of the Competent Authority –
>
> > (1) The animal remedy proves to be harmful under the conditions of use stated at the time of application for authorisation or subsequently, or where the animal remedy does not have any therapeutic effect or its qualitive or quantitive composition is not as stated.

46. The Applicant contends that the Respondent took into account off label use of product: specifically the product authorisations of the Applicant in the Schedule thereto require persons handling or working with the product to take precautions and to wear suitable protective clothing including gloves and wellington boots. The Report of the Liaison Committee of 21st March 2000 acknowledged that familiarity among sheep farmers with sheep dipping may have led to complacency in the use of recommended personal protective equipment and poor dipping practices and that many farmers chose not to wear personal protective equipment during dipping especially in warm weather as it was uncomfortable. The Applicant's label specifically warns those using the products to wear protective clothing. The Applicant argues that having regard to the provisions of the Directive and the Regulations mentioned above it was inappropriate for the Respondent to take into account the circumstance that the product might be used by persons not wearing protective clothing. "Off label use" is defined in Article 1.6 of the Directive –

> "The use of a veterinary medicinal product that is not in accordance with the summary of the product characteristics including the misuse and serious abuse of the product."

47. The term is used in the Directive in Articles dealing with pharmacovigilance rather than in relation to the withdrawal or suspension of authorisations. The Applicant is correct in its submission that suspension or withdrawal should not be triggered by off label use but this is not the term used in Article 83 or Regulation 19. Recital (2) to the Directive reads as follows –

> "The primary purpose of any rules for the production and distribution of veterinary medicinal products must be the safeguarding of public health."

48. Thus Article 83.1 of the Directive provides that if the product proves to be harmful under the conditions of use, which I understand to be the conditions of use in the Schedule to the Directive as varied by the authorisation the Member State shall suspend or withdraw the marketing authorisation. Included in Part III of the Schedule at 6.4 are details of the container which refer to the container formerly used by the Applicant and which I accept was less safe than the container at present in use. However at the date of the Report of the Liaison Committee there was no generically available closed system and closed systems which were available continued to expose the operator to contact with the OP product at the point of setting up or dismantling or were defective in point of the control for the performance needed by an operator or had the potential for misuse. Further the Report of the Liaison Committee evaluated recent scientific data at paragraph 2 and its evaluation accepts that OP products on the balance of evidence can be harmful to humans in terms of acute poisoning: further the possibility of OP exposure causing psychiatric illness could not be excluded. It also noted the position adopted in the Report of the Veterinary Products Committee (UK) on Op Sheep Dips of November 1999 which advised that marketing authorisations be suspended until the design of containers should be improved to minimise the risk of exposure to OP concentrate. The Liaison Committee inter alia recommended that the containers in which OP concentrates are supplied for veterinary use be kept under review by the I.M.B. in the light of national and international developments and that all authorised products should comply with any new standards. The Willis Report prepared on behalf of the Applicant identified risks associated with the Applicant's delivery system –

> Splashing during pouring - low/medium
>
> Dripping down side of packaging from lid – low/medium
>
> On site damage and leakage – low
>
> On site puncturing and spillage – low
>
> Inhalation – low.

49. It also recognised risks associated with the rival products which use a closed delivery system. However it is clear that risks were identified even by the Applicant. The evaluation of those risks is a matter for the Respondent: this Court on Judicial Review will not act as a forum for an appeal and provided there was evidence which if accepted would justify the decision of the Respondent will not interfere. In the reports which I have mentioned including the Applicant's own report risks to human health are identified. These risks exist notwithstanding use of the product under the conditions of use. Therefore the Respondent could in the exercise of its powers under the 1996 Regulations Article 19 suspend or revoke the Applicant's product.

(3) Whether the Decision of the Respondent was arrived at in breach of the principle of proportionality in circumstances where there were no adverse reactions or adverse human reactions to the Applicant's product.
50. I have dealt with this issue in dealing with Issue 1. There have been no reported adverse human reactions to the Applicant's products. However the concerns which exist in relation to OP products is clear: see the COT Report. I am satisfied that the precautionary principle applies. The response of the Respondent was not disproportionate.

(4) Whether the Respondents impermissibly took into account the economic implications for companies which are the competitors of the Applicant.
51. It is clear from the documents exhibited herein that the Applicant's competitors were aggrieved in that they had taken steps to move to a closed system of delivery presumably at considerable expense while the Applicant had not. The Respondent was aware of this. However correspondence emanating from the Respondent is informative. In the letter dated 21st November 2002 to the Applicant it was made clear that the appeal would be based on the safety of the Applicant's products for human health. This approach was borne out by the refusal in a letter dated 27th November 2002 by the Respondent to make available to the Applicant studies related to competitor products. That letter also emphatically states that matters relating to commercial considerations or to products marketed by other companies are outside the scope of the appeal which was to be based on the safety of the Applicant's products for human health only. Again the letter from the Respondent to the Applicant dated 13th December 2002 repeats that the appeal will focus on the risk of the Applicant's products for human health and that matters relating to commercial considerations or to products marketed by other companies would be outside the scope of the appeal. I have also the Affidavit of Dr. Beechner sworn on the 6th February 2003 where at paragraph 34 he deposes that the A.C.V.M. had no regard to the interests of the Applicant's competitors in reaching its decision.

52. On review of all the evidence before me the Applicant has failed to satisfy me that the Respondent had regard to the commercial considerations of the Applicant's competitors.

(5)(b) Whether the decisions of the Respondent were vitiated by objective bias by the participation of Mr. P.J. O'Connor, Chairman of the Advisory Committee for Veterinary Medicines in the decision of the Board on the 26th February 2003.
53. The Applicant's argument on this issue relies on matters raised in relation to the Second Issue in particular the Applicant again raises the contention that the Respondent erred in concentrating on an open system having regard to the phrase "closed system" and not having regard to the phrase "or similar". However it is abundantly clear that the Applicant's system is not a closed system and further it is not similar to a closed system: it is an open system. I find no fault with the Respondent in this regard.

54. Mr. P.J. O'Connor acted as Chairman of the A.C.V.M. but also took part in the meeting of the Board of the Respondent which made the decision in relation to the Applicant's products.

55. In the event of a judicial decision made after a hearing inter partes such circumstances would give rise to a finding of objective bias. The proceedings with which I am concerned however are not inter partes. The true situation is that the Respondent in the first instance through the A.C.V.M. was exercising an administrative function to which requirements of natural justice applied. For this reason having formed a preliminary view it permitted the Applicant to make representations to it before reaching a conclusion. The A.C.V.M. fulfilled its statutory responsibility by furnishing advice to the Respondent. The Respondent considered this advice and made its decision. Mr. O'Connor in addition to being a member of the A.C.V.M. is also an appointee of the Minister to the Board. He also enjoys status as an expert. In partaking in the decision of the Board he was fulfilling the responsibility entrusted to him by the Minister. The position is quite different to that which pertained in the cases relied upon by the Applicant – *Radio Limerick One Limited v Independent Radio and Television Commission* (1997) 2 I.R. 291, *ODonoghue v Veterinary Council* (1975) I.R. 398, *O'Neill and Bova Genetics Limited v Irish Hereford Breeds Society Limited* (1992) 1 I.R. 431, 450.

56. In the first of these cases the decision making body was composed in part of persons engaged in the media and who might have had a pecuniary or proprietary interest in the subject matter of the proceedings: it is not suggested that Mr. O'Connor had such an interest. Then the dicta of Keane J. at page 316 of the Report are relevant –

> "In the present case, the statutory provisions already referred to clearly envisaged that the membership of the Commission may consist, in part at least, of persons engaged in the media who may be assumed to have a special knowledge of the matters with which the Commission has to deal. The fact that its membership is so composed may mean that, in specific instances, when it comes to deal with matters as crucial as the entering into a contract or a suspension or termination, its decisions, although undoubtedly quasi judicial in nature in necessitating the observance of natural justice and fair procedures, may also not have the appearance of impartiality which would be required of a Court of Justice. That, of itself, would not vitiate its conclusions, provided it reached them in good faith and having given the persons affected the protection of natural justice and fair procedures."

57. In the second case a member of the Veterinary Council had been the complainant at an enquiry held before a special Committee of Enquiry and also sat on the Council at its meeting to consider the Report of that Committee: this was held to infringe the nemo judex rule. I do not see that the decision in this case is relevant to the circumstances with which I am dealing: circumstances in the present instance are akin to those in the Radio Limerick One Limited case.

58. Finally in *O'Neill v Irish Hereford Breeds Society Limited* Murphy J. held that not every prior involvement by a member of a board exercising a quasi judicial function with a person or the conduct of a person whose affairs were under consideration by the body would necessarily disbar the member from acting in the matter. Certain forms of involvement would have that result. In that case the Chairman and members of the Editing Committee of the Defendant had recommended the expulsion of the First Named Plaintiff and attended the meeting of the Council of the Defendant which decided to expel the Plaintiff and took a full part in the meeting. The proceedings there were essentially inter partes which I am satisfied is not the case here. There is to my mind a significant difference between a complainant on the one hand and an expert statutorily authorised to advise. I am satisfied that the circumstances in this case are such that involvement in an earlier stage in the administrative process in issue would not disqualify from partaking in the ultimate decision.

(7) Whether the decision of the Respondent is vitiated by manifest error or misuse of power as identified in paragraph 51 of

the Amended Statement of Grounds and whether the decision of the Respondent is vitiated by a distortion or manifest error of assessment of facts or misuse of power or a clear breach of the bounds of its discretion as a consequence of (i) the non disclosure of the Raporteur's Report or paragraph (ii) omission to refer to "or similar aimed at reducing operator exposure to the concentrate.

59. I have already dealt with the argument in relation to the failure to concentrate on the phrase "or similar" after the phrase "closed system". For this argument to carry any weight it would be necessary that the Applicant's system be similar to a closed system and I am satisfied that it is not.

60. Apart from the foregoing the Applicant relies upon the Judgment of the Supreme Court in SIAC Construction Limited v Mayo County Council 2002 3 I.R. 148 as imposing upon the Court a duty to examine the accuracy of the findings of fact and law made by the Respondent and to verify that the decision of the Respondent is not vitiated by a manifest error or a misuse of power and that it did not clearly exceed the bounds of its discretion. In the course of its judgment the Supreme Court referred to the decision of the European Court of Justice in *Upjohn Limited v Licensing Authority* (1999) 1 WLR 927 and again in *Matra S.A. v Commissioner of the European Communities* (1993) ECR 1 – 3203. While I accept this line of authority I do not see that it avails the Applicant anything here. In *R v Licensing Authority Ex Parte Novartis Pharmacuticals U.K. Limited* Queens Bench 30th March 2000 in dealing with both the Upjohn and Matra cases said –

> "Mr. Sales went on to argue, and again I accept, that it followed that it was inappropriate in an application for Judicial Review to invite the Court to engage in a debate between experts on matters of scientific opinion, referring particularly to paragraphs 16 and 35 of the Applicant's skeleton argument on the question of whether the various products had a different pharmaceutical form. The Court should respect the judgment of the decision maker unless it had no rational basis which the skeleton argument did not begin to demonstrate here."

61. Again in *R v Medicines Control Agency Ex Parte Pharma Nord* (UK) 1998 CMLR 109 at 121 Lord Woolf M.R. at page 122 said –

> "Both the determination of the facts and the application of the policy in a case such as this is not ideally suited to the adversarial processes of the Courts. If the case was one where the M.C.A. could not reasonably have come to the decision which it did so that the outcome was one which is conventionally determined on application for Judicial Review, the position would be different. However in this case the M.C.A. is in a better position to evaluate the evidence than a Judge. It has accumulated experience in relation to other products which a Court lacks. It is an expert body. The M.C.A. has to develop a consistent policy between similar products. The issues are to use Simon Brown L.J's approach ones in relation to which the Court should be wary of becoming involved."

62. In the present case even applying the heightened standards suggested by the Applicant I have been unable to find a manifest error or a misuse of power on the part of the Respondent or that the Respondent exceeded the bounds of its discretion. In particular I find no objection to the toilet test as described carried out by Dr. Beechner particularly when it is compared to the desktop study (the Willis Report) relied upon by the Applicant. The evidence has not satisfied me that the risk analysis carried out was unscientific. The consideration of "similar" systems of delivery to closed systems is irrelevant as on any assessment of the facts the Applicant's system is not similar to a closed system identified for me.

63. I refuse the Applicant the relief which it seeks. In these circumstances I propose hearing Counsel as to the Order which I should make and in particular whether I should order the withdrawal of the Applicant's products and if so the timescale for the same.