REGULATION (EC) No 1610/96
of the European Parliament and
of the Council

IN THE MATTER OF Application
No SPC/GB97/008 for a Supplementary
Protection Certificate in the name of
BASF Aktiengesellschaft

DECISION

1. Application No SPC/GB97/008 for a Supplementary Protection Certificate in the name of BASF Aktiengesellschaft was lodged on 3 April 1997 with the United Kingdom Patent Office as the competent industrial property office pursuant to Article 9(1) of Regulation (EC) No 1610/96 ("the Regulation"). The application was filed under the transitional provisions of Article 19 which pertained for a six month period from 8 February 1997 and which allowed an application to be based upon a first marketing authorization in the Community obtained at any date after 1 January 1985.

2. In accordance with rule 3(2) of the Patents (Supplementary Protection Certificates) Rules 1997, the application was made on Form SP1 which identified:

- the product for which protection was sought as "3-isopropyl-2,1,3-benzothiadiazin-4-one-2,2-dioxide (bentazone) and its salts";

- the basic patent protecting the product as GB 1595029 (the '029 patent) entitled " Manufacture of 2,1,3-thiadiazin-4-one-2,2-dioxide derivatives";

- the first authorization in accordance with Article 4 of Directive 91/414/EEC or an equivalent national provision to place the product on the market in the United Kingdom (the "Member State") as a plant protection product as

authorization No 0465/85 dated 16 October 1985 obtained under the Pesticides Safety Precautions Scheme ("PSPS")

3. The Examiner in the case first raised objection under Article 19 in the Official letter of 30 October 1997. He had been alerted, by means of third party observations, to a Danish authorization, dated 12 December 1973, for Bentazone to be placed on the market in the Community and in paragraphs 3 and 4 of the letter reported the following:-

> "3. Provided that you do not dispute the veracity of the Danish authorization and its translation into English, it appears that the **first** authorization to place Bentazone on the market as a plant protection product was obtained **before** 1 January 1985 under the Danish legal provision equivalent to Article 4 of Directive 91/414/EEC which allowed for the legal marketing of the product in Denmark. The Danish authorization has to be taken as relevant to the Community because Denmark joined the EEC in January 1973. Thus Article 19 of Regulation 1610/96 is apparently not complied with.
>
> 4. Whilst it is accepted by the Examiner that Bentazone manufactured by the method claimed in the basic patent GB1595029 may not have been marketed until authorized in the United Kingdom under PSPS 0465/85, for the purposes of the Regulation the term "product" in Articles 3(1)(a) and (d) is simply the active substance having plant-protection activity irrespective of how it has been made or formulated (See Articles 1(3) and (8)). Bentazone made by another method was first authorized in 1973, but that is sufficient to prevent any applicant from obtaining an SPC on a basic patent claiming, for instance, a new method of producing the product (active agent), a new formulation of the agent or even a new use in plant protection. In my view as far as Article 3(1)(a) of Regulation 1610/96 is concerned the "product" of basic patent GB 1595029 is identical to that of the prior art referred to on page 1 lines 8 and 12 therein viz DE 2105687 and DE 2357063."

He went on to say that he had studied the 0465/85 authorization which was for "Basagran", a

commercial preparation of bentazone, and it appeared to refer, in the third paragraph, to previous commercial clearance of this product, several dates prior to January 1985 being quoted.

4. In essence these arguments advanced by the Examiner are those he has maintained during the proceedings and they are the reason why the applicants eventually requested a hearing to resolve the issue.

5. In a response dated 29 December 1997 the applicants sought to amend the definition ofthe product on Form SP1 to read:

(1) "3-isopropyl-2,1,3-benzothiadiazin-4-one-2,2-dioxide (bentazone) and its sodium and ammonium salts containing as impurities bentazone-6-sulphonic acid and bentazone-8-sulphonic acid". ("bentazone 2")

6. In addition the applicants argued that bentazone 2 containing the stated impurities is obtainable only by the process defined in the basic patent GB 1595029 and admitted that clearance for sale of bentazone obtained by a prior art method ("bentazone 1"), not containing the impurities bentazone-6-sulphonic acid or bentazone-8-sulphonic acid, had been sought in several countries of the EEC prior to March 1977, the priority date of the basic patent GB 1595029, and sales had taken place. Simultaneously the applicant drew attention to the definition of "substances" in Article 1(2) of the Regulation which reads:

> "chemical elements and their compounds as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process. (Emphasis added)".

7. It was argued that this definition of "substance" is necessarily carried back into the definitions of "active substance" and "product" and that accordingly bentazone 2 must be regarded legally as a different product from bentazone 1 for the purposes of the Regulation.

8. On 30 March 1998 the applicants filed further arguments and an affidavit in the name of Dr K M Liesner demonstrating the differences between the prior art process and that protected by the present basic patent for making bentazones 1 and 2 respectively.

9. However, in the Official letter of 20 May 1998 , the Examiner reported that:

> "I have considered the arguments in your letter of 30 March and the affidavit of Dr. K M Liesner very carefully but am still of the opinion that the application is not allowable. There is no precedent for granting an SPC application where some of the substances named as part of a mixture constituting the "product" are not proven to be active ingredients.
>
> In my view the stated apparently inactive impurities have nothing whatever to do with the definition of the product in the present case. Article 1(8) of Regulation 1610/96 clearly states that the "product" is the active substance as defined in point 3 or combination of active substances of a plant protection product."

10. In their letter of 20 July 1998 requesting the appointment of a hearing the applicants proposed two further versions of the definition of their product on Form SP1:

(2) "3-isopropyl-2,1,3-benzothiadiazin-4-one-2,2-dioxide (bentazone) and its sodium and ammonium salts as manufactured by the process defined in claim 1 of Patent 1595029"

and (3), as (2) with the addition of "and containing as impurities inevitably resulting from its manufacture bentazone-6-sulphonic acid and bentazone-8-sulphonic acid"

11. The examiner's objections under Article 3(1)(d) to the grant of a certificate not having been resolved the matter came before me at a hearing on 24 November 1998 at which the applicants were represented by Miss Denise McFarland (Counsel) instructed by J Y & G W Johnson. Mr S G Hale of J Y & G W Johnson, Dr F Werner of BASF and the Examiner Mr J F Jenkins were also present.

12. This Regulation, like its predecessor relating to medicinal products, exists to compensate a patent holder in some measure for the time lost whilst the product in question is waiting for authorization to be placed on the market. Recitals 11 and 12 to the Regulation make it clear that to provide adequate, effective protection the holder of a patent and a certificate granted under the Regulation should be able to enjoy an overall maximum of 15 years from the time of first authorization of the product in the Community, subject to the certificate not being granted for a period exceeding five years. In this way the Regulation seeks to recognise the importance of research into plant protection products and their contribution to the production and procurement of plentiful food of good quality at affordable prices.

13. Of utmost importance to the present case is the meaning to be attached to the word "product" in the Regulation and, particularly in relation to the facts in the case, whether the product for which the certificate was sought is purely and simply bentazone however prepared, as contended by Mr Jenkins for the Office, or whether it is bentazone prepared according to the process of the '029 patent as contended by Miss McFarland for BASF. Using the shorthand notation adopted during the Hearing, the question comes down to whether the product is bentazone 1, the old bentazone for which there was an earlier product licence, or bentazone 2, the product of the '029 patent, for which there was a much later product licence?

14. Before launching into the details of the case as argued before me I think it would be helpful if I set out the parts of the Regulation around which the arguments have taken place.

15. I begin with Article 1 which, for the purposes of the Regulation as a whole, applies *inter alia* the following definitions:-

> "1. "plant protection products": active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to.....
>
> 2. "substances": chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing

process;

3. "active substances": substances or micro-organisms including viruses, having general or specific action:

(a) against harmful organisms; or

(b) on plants, parts of plants or plant products;

4. "preparations": mixtures or solutions composed of two or more substances, of which at least one is an active substance, intended for use as plant protection products;

8. "product": the active substance as defined in point 3 or combination of active substances of a plant protection product;

9. "basic patent": a patent which protects a product as defined in point 8 as such, a preparation as defined in point 4, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;"

16. Article 3 is another of the key articles for the purposes of this case and reads:-

"**Conditions for obtaining a certificate**

1. A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted, at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorization to place the product on the market as a plant protection product has been granted in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law;

(c) the product has not already been the subject of a certificate;

(d) the authorization referred to in (b) is the first authorization to place the product on the market as a plant protection product.

2. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders."

17. Article 4 was also referred to during the hearing and reads:-

"**Subject-matter of protection**

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorizations to place the corresponding plant protection product on the market and for any use of the product as a plant protection product that has been authorized before the expiry of the certificate."

18. Article 19 is initially of particular significance since the product in question purports to qualify for a certificate by virtue of sub-section (1) which reads as follows:-

"**1.** Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorization to place it on the market as a plant protection product in the Community was obtained after 1 January 1985 under Article 4 of Directive 91/414/EEC or an equivalent national provision may be granted a certificate."

19. During the course of proceedings in the Office, as previously indicated above, the applicants proposed amendments to section 6 of the Form SP1 to identify the product for which protection was sought in a manner that was more in line with their argument that the product was in fact bentazone 2 and not bentazone 1. At the hearing Miss McFarland asked me to consider in my decision all these possible ways of identifying the product. This I shall do although I understood her not to be relying too much on the definition submitted on filing because this would arguably lead, if the applicants' argument is to be followed, to them overextending the monopoly they were seeking. I have to say that Mr Jenkins, on behalf of the Office, seemed to be singularly unimpressed with any of these definitions as overcoming his objections

20. Perhaps at this point it would be useful if I explained where the references to bentazone-6- sulphonic acid and bentazone-8-sulphonic acid in one of the definitions sought by the applicants actually find their origin. I have already said that the applicants have described these two compounds as impurities which arise in carrying out the process of the '029 patent. When first confronted with a reference to these compounds in the definition of the product to be protected Mr Jenkins asked the applicants to supply him with evidence that these impurities existed as such since the '029 patent makes no reference to them. He needed to do this if only for the fact that he needed to satisfy himself that the product was protected by the '029 patent. The applicants filed two affidavits in the names of Drs Liesner and Werner respectively which, I understand, were I to find in the Applicants' favour, Mr Jenkins would accept as providing a basis for the amended definition sought.

21. In fact, Dr Werner, in a short submission at the Hearing, pointed to the usefulness of the presence of these two impurities in providing a "fingerprint" which indicated that bentazone must have been prepared by the '029 process, something which would be extremely useful in infringement proceedings.

22. In fairness to the applicants I think I also ought to say that it is not just the presence of the fingerprinting impurities which distinguishes bentazone prepared by the '029 patent from bentazone prepared by the prior art processes. Dr Werner's affidavit makes clear that the '029

process starts from easily accessible and inexpensive materials and produces bentazone in very high yields and good purity in a simpler and more economic manner. It may be that it is these features of the '029 process which make that process inventive over the prior art. Whether that is the case or not I do not understand it to be any part of the Office's argument that the '029 patent claims an invention which lacks an inventive step, only that bentazone prepared by this inventive process does not make it, for the purposes of the Regulation, a different bentazone from the prior art processes. Miss McFarland's argument on this latter point is clearly the complete opposite.

23. There has been throughout the course of the proceedings and, to an extent, at the Hearing, a certain degree of interchange between Articles 3 and 19 as to which one formed the primary basis for the issues in this case. I think Article 19 must be the most significant because the application was filed while the transitional provisions were in force. If, therefore, I find that the application fails to satisfy all the requirements of Article 19 it seems to me that it cannot be allowed to proceed to grant. Miss McFarland was more concerned to focus on Article 3 because she was maintaining that the first authorization in the Community was obtained after 1 January 1985. However, in order to file their application the Applicants had had to take advantage of Article 19(2) which allowed for applications to be filed within 6 months of the date on which the Regulation had entered into force. Outside of this transitional provision applications have to be filed within 6 months of the grant of the authorization to place the product on the market. Since the Applicants were relying on an authorization dated 16 October 1985 clearly they needed to fall back on the provisions of Article 19(2).

24. I do, however, accept that the conditions for obtaining a certificate set out in Article 3 do provide an almost equivalent framework against which to judge the issues in this case. I would add that whether one focusses on Article 3 or Article 19 it seems to me that eventually recourse has to be made to Article 1 in order to understand the meaning of certain terms used in both, and particularly the meaning of the term "product".

25. Article 3(1)(a) requires that the product is protected by a patent in force. This said Miss McFarland is the '029 patent which clearly relates to a novel and inventive method for

preparing bentazone.

26. The requirement in Article 3(1)(b) that a valid authorisation has been granted to place the product on the market as a plant protection product is satisfied according to Miss McFarland's argument,by Pesticides Safety Precautions Scheme authorization PSPS 0465/85, which refers to the use of bentazone from the new process. To quote Miss McFarland "If that authorization again has been required it is an indication that the product is a new product with a different or sufficiently different active ingredient".

27. Article 3(1)(c) requires that the product has not already been the the subject of a certificate. This is not an issue under dispute for the reason that the present application was filed under the transitional provisions of what was then a new Regulation and therefore there were no earlier certificates to take into account. Indeed, it is the reason that Article 19 is silent on this requirement.

28. Finally Article 3, at (1)(d), requires that the authorization referred to in (b) is the first authorization to place the product on the market as a plant protection product. In reply at the Hearing Miss McFarland made clear that she accepted that the mere fact that the applicants had applied for a separate authorization was not enough to get over all the hurdles of Article 3. In her opinion what the Examiner had to take into account on this case was the fact that he was confronted with a combination of a new authorization in respect of a novel patented product. I took this to mean that if it was accepted that the product, the subject of the application, was a different product to that known already, the authorization to place it on the market must by definition be the first authorization.

29. I think that once again, even from this brief analysis of this part of Miss McFarland's argument, that what the applicants are asking for is that at every point of Article 3 where the term "product" is mentioned the correct definition to be placed on that term in the present context is the bentazone 2 definition. In brief, it is bentazone prepared according to the process of the '029 patent.

30. Even when turning to Article 1 to consider the meaning of such terms as "product" and "active substances" and "substances" Miss McFarland's arguments came back to the same point that the manufacturing process is very important and these terms must be read against that. So, in relation to the definition of the term "substance" in Article 1(2) Miss McFarland said this:-

"Really, what we say is plain is that in order to walk through the gateway of a substance the subject of a proper application, it is either necessary to identify that substance by its chemical analysis as a substance, i.e. however created by whatsoever method of manufacture, or the substance is tied to a specific method of manufacture. It is a question for the Tribunal to satisfy itself whether if it is the second type, i.e a product linked to a specific manufacturing process, is the Tribunal satisfied that the manufacturing process is sufficiently defined and is independently patentable, valid, subject of inventive endeavour which deserves the "reward" of the certification."

And again:-

"However, we say where the preparation is an active substance, whether or not it has impurities that may or may not impact on the activity, and none of the evidence, it is fair to say, has suggested that the impurities play an active part, but where the impurities act as an indication of differing toxicity or different chemical properties, potentially different chemical properties, and make good the claim that that particular version of the generic bentazone is created by a separately independent inventive process, then we say we are through the gateway of clause (2). In other words, the substance has chemical elements which create active substances that are a result of the manufacturing process used. That manufacturing process is, in the language of Article 3, a result of the basic patent and the subject of valid authorization."

31. The Office, in contrast, as already pointed out in respect of the argument begun in the Official letter of 30 October 1997, has said consistently that the "product" is purely and simply bentazone, no more or no less, and how bentazone happens to have been prepared is of

no consequence. At the hearing Mr Jenkins on behalf of the Office made clear that his argument was based primarily on Article 1 of the Regulation. I quote him when he says

> "How are we to decide what the term "product" means? In fact, in relation to every part of Article 3(1) the word "product" appears there, and Article 19. First of all, the obvious thing is to look to the definition of "product" in Article 1(8): '"Product': the active substance as defined in point 3 or combination of active substances of a plant protection product." You might have one or more than one substance which is going to combine together to make the product but they all have to be active. The plain reading of that article is that the product equals the active substance and nothing else."

32. Clearly I must take into account, as of significant importance, the definitions set out in Article 1. Only in that way can I be sure of the true interpretation to put on the various sub-sections of Article 3 and on Article 19. However, before I do I need to pick up on some of the supporting issues raised by Miss McFarland in the advancement of her case.

33. During the course of the proceedings on this application reference had been made, firstly by the Examiner and then by the Agent for the Applicants, to the Proposal for a Council Regulation, dated 11 April 1990 (the "Proposal") which was presented by the Commission prior to the creation of a supplementary certificate for medicinal products. As far as I understood the situation there was no disagreement between the Applicants and the Office as to the appropriateness of this document when applied also to certificates for plant protection products. Indeed it was agreed that the document might be persuasive when seeking to achieve harmony concerning the policy to be adopted throughout the European Union.

34. Significantly, Miss McFarland referred to paragraph 11 of the Proposal as being "a little helpful on active substance". Although she only quoted part of that paragraph I think to keep the context it would be right for me to quote it all as follows:-

> "The proposal for a Regulation therefore concerns only new medicinal products. It does not involve granting a certificate for all medicinal products that are to be placed on the market. Only one certificate may be granted for any one product, a

product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate."

Taking comfort from this she drew the inference that:-

> ".....where the manufacturing process is so different to create a new substance and a new substance that is identifiable chemically, via toxological data and which is the subject of an independent patent, it must be open to the application of an SPC."

35. Briefly mentioning that paragraphs 12 and 13 of the Proposals were simply making good the parity between the authorization and the patent Miss McFarland then jumped to paragraph 28 which is in the Proposal for the purpose of explaining Article 1.

36. The third and fourth paragraphs of paragraph 28 itself are in these terms:-

> "What is authorized to be placed on the market is referred to as a "proprietary medicinal product", i.e. "any ready-prepared medicinal product placed on the market...."
>
> "However, it may be the medicinal product that is patented, meaning the active ingredient, the process by which the medicinal product is obtained, or an application or use of the medicinal product."

I do not think I am doing Miss McFarland a disservice when I take it that the help she derives from quoting these two paragraphs is that they are further evidence of the active ingredient being tied tightly to the manner in which it is claimed in the patent.

37. For completeness I shall quote two other paragraphs relied on by Miss McFarland in support of the applicants' case. These are the final paragraph under paragraph 28 and all of paragraph 29. Again, I shall quote them in full so as to keep the context.

"Consequently, the term "product" is not understood to mean a proprietary medicinal product or a medicinal product in the wider sense, but in the narrower sense of product used in patent law which, when applied to the chemical and pharmaceutical field, means the active ingredient."

"The purpose of the expression "product protected by a patent" is to specify what types of invention may serve as a basis for a certificate.

The proposal does not provide for any exclusions. In other words, all pharmaceutical research, provided that it leads to a new invention that can be patented, whether it concerns a new product, a new process for obtaining a new or known product, a new application of a new or known product or a new combination of substances containing a new or known product, must be encouraged, without any discrimination, and must be able to be given a supplementary certificate of protection provided that all of the conditions governing the application of the proposal for a Regulation are fulfilled."

I shall return to a consideration of the Proposal later on in my decision to see whether they provide the support claimed for them in respect of the Applicants' arguments.

38. I also need to consider two other documents drawn to my attention by Miss McFarland. One is the decision of the European Court of Justice in Biogen Inc. V Smithkline Beecham Biologicals SA, [1997] RPC 833, and the other is the 1997 revised edition of Supplementary Protection Certificates for Medicinal Products and Plant Protection Products:A Guide for Applicants, published by the Patent Office.

39. I did not understand Miss McFarland to be relying heavily on these documents. Indeed, in the former she relied essentially only on one conclusion reached by the Court and that was at the foot of page 839 where it is said that ".....where a medicinal product is covered by several basic patents, the Regulation does not preclude the grant of a supplementary protection certificate to each holder of a basic patent." As for the latter document I am not sure that it

added anything of substance to her arguments, or for that matter that it could do so being only a guide which, although being extremely helpful to applicants, does not have, of itself, any legal status.

40. It seemed to me at the Hearing, and I have had no reason to change my mind, that in order to determine who is right between the Applicants and the Office it is incumbent upon me to determine, in the context of the case in suit, what is meant by the term "product". Clearly all the conditions of Article 3 and, in this case, Article 19 must be satisfied before the Office can grant an application but those Articles can only be correctly understood if the definitions of certain terms used throughout the Regulation and set out in Article 1 are read thereinto. Quite simply, if I interpret the product in this case as being that as prepared and limited by the process of the '029 patent, bentazone 2 in Miss McFarland's terms, I must find in the Applicants' favour. Alternatively if I interpret the product as simply being the compound bentazone however it may have been prepared, i.e. bentazone 1, then the arguments pursued so far by the Office will be upheld.

41. What I believe I must therefore do is to go through the Article 1 definitions and read them back onto the facts of the case to arrive at a decision. In doing so I need to take into account what Mr Jenkins has said on behalf of the Office since, as I have already indicated above, the Article 1 approach has consistently been the main thrust of his arguments.

42. Looking then at the definitions in Article 1 quite clearly the best place to start is at Article 1(8) because this sub-section actually defines the term "product" which is the real subject of dispute in this application. As Mr Jenkins said at the Hearing the plain reading of Article 1(8) is "that the product equals the active substance and nothing else" and I have no difficulty in agreeing with that statement.

43. Logically one then goes to Article 1(3) because having ascertained that "product" equals "active substance" one finds that the latter term is also defined. Not surprisingly "active substances" are defined in terms of substances (and micro-organisms which for the purpose of this decision I do not need to take into account) which have an action against something, in

this Regulation as substances which have a general or specific action against harmful organisms or on plants, parts of plants or plant products.

44. I also have to take into account that the term "substances" is also defined. So, in Article 1(2) one finds that "substances" are in fact chemical elements and their compounds which may be naturally occurring or made by a manufacturing process and, if by the latter, may include impurities inevitably produced by the process. This, to my mind, is not a very surprising definition, indeed, it might be regarded as stating the obvious and by its reference to impurities, is simply acknowledging what everybody knows that a manufacturing process may result in the production of an impure substance. Whether one removes the impurities or, as in this case, finds that they have a useful function such that they should be left in association with the substance, is obviously a matter of choice and is dictated by the use to which the substance is to be put.

45. I think then that by looking at Articles 1(2) and (3) together one comes to the inescapable conclusion that in a plant protection product there may be a number of "substances" only some of which, but may be all, are "active substances".

46. This conclusion seems to be confirmed when looking at what the term "plant protection products" itself means in Article 1(1). "Plant protection products" are active substances and preparations containing one or more active substances put up in the form in which they are supplied to the user for the intended end use, a number of end uses being defined. So, a plant protection product as defined in the Regulation could be an active substance on its own but, in practice, as one knows from experience, it is more likely to be supplied to a user in the form of a preparation. Again experience indicates that a preparation will include several substances, only some of which will be active substances, and this is in fact borne out by the definition of "preparations" in Article 1(4) as "mixtures or solutions composed of two or more substances, of which at least one is an active substance, intended for use as plant protection products;".

47. It is worth noting, at this stage, that all the definitions I have quoted above with the exception of the term "product" are carried over directly from the authorization procedure as

laid down in Directive 91/414/EEC and specifically Article 2 thereof. Mr Jenkins brought this to my attention at the Hearing by first indicating that in the prior medicinal Regulation a similar thing had been done by a carry over from Directive 65/65/EEC. Of note, in the context of the Directive relating to plant protection products as opposed to that relating to medicinal products, is the reference to impurities in the definition of the term "substances". This is perhaps not altogether surprising since it is reasonable to suppose that medicinal products need to be substantially more pure than plant protection products because of their intended end use. However, even if impurities may be present in plant protection products those who administer the authorization procedures need to be assured that these impurities are not ultimately extremely harmful. Thus, said Mr Jenkins, impurities are referred to in the Article 2 Directive definition of "substances" because later in Article 4(1)(c) there is reference to the need to address the toxicology thereof. In his view, therefore, as far as I understood it, the reference to impurities has arguably a far greater significance in Directive 91/414/EEC than it has in the present Regulation where it occurs merely as a carry over.

48. The definition of the term "product", as I have previously indicated, is not carried over from the earlier authorization procedure Directives. This is for the obvious reason that it does not occur in those Directives but in the Commission Proposal the situation concerning the term is made clear. Again, I emphasise that the Proposal concerns medicinal products but I do not think there is any dispute about its relevance to plant protection products. Mr Jenkins drew my attention to paragraph 28 which contains these key words:-

"For the purposes of the certificate, which lies at the interface of the two systems [i.e the authorization system and the patent system - my addition] the term "product" has been chosen as a common denominator. The exact meaning given to it is defined in Article 1 which is based on the definition of medicinal product laid down in Directive 65/65/EEC. However, the qualifier "active" is added to the term "substance" in order to include the concept of an "active ingredient" or "active substance" used in patent law.

Consequently, the term "product" is not understood to mean a proprietary medicinal

product or a medicinal product in the wider sense, but in the narrower sense of product used in patent law which, when applied to the chemical and pharmaceutical field, means the active ingredient."

49. Although the submissions in this case have been relatively clear cut, the difficulties in coming to a decision seem to me to lie in the fact that the granting of Supplementary Protection Certificates, as indicated in paragraph 28 of the Proposal referred to above, is at the interface of the authorization system on the one hand and the patent system on the other. This therefore demands that those working under the Regulation must attempt to understand both systems and how they come together to allow sensible decisions to be made about the granting of certificates. So, in approaching the Regulation, whilst due regard must be had to the precise wording of the various Articles, I believe that an understanding of their intended meaning must be informed by practises under the two systems. Moreover, in what is still a fairly new area and, in the absence of precedent decisions, the Commission Proposal concerning the creation of the Supplementary Protection Certificate system must carry some weight towards the same end.

50. I have therefore come to the opinion, after taking into account the submissions of both sides and my understanding of the effects to be achieved by the Regulation that the approach taken by the Office in this case is to be preferred.

51. In coming to this decision I have been very much persuaded by what I believe the Regulation intends to be understood by the definition of the term "product" and how this definition is intended to be read back into the articles of the Regulation which have been under consideration in this case. Without a doubt, because it is what Article 1(8) says, "product" equals "active substance" the latter being defined in Article 1(3) as a substance having a general or specific action against harmful organisms or on plants, parts of plants or plant products. That being said it does not dispose of the argument because one could well argue, as the Applicants have done, that the active substance in this case is bentazone 2 rather than bentazone 1. I think though that this is putting a strain on the Regulation which was not intended by the Commission.

52. My reasons for believing this start with the appreciation that the definition of "active substance" is, in effect, not a new definition created purely for the Regulation but is one which existed for the purposes of Directive 91/414/EEC and has now been adopted without being altered in any form, along with a number of other definitions, for the purpose of the Regulation. Thus, to my mind, this is an area where the authorization system must be taken as informing the system for granting Supplementary Protection Certificates.

53. As I understand the authorization system, both as argued before me and in more detailed study in coming to my decision, I have come to the firm conclusion that it views an active substance primarily as a chemical compound having a discrete structure and definable by a chemical formula and more than likely by an accepted chemical name. Of course the authorization system recognises that the compound must have been made in some way and that once made it may contain impurities and, for plant protection purposes, may be mixed with non-active additives which make it suitable for use. However, these latter, including the method of manufacture, whilst important to the authorization system for the purposes of making sure that the plant protection product has no harmful effect in use, are not in my view defining in any way of the active substance. This, I believe, is consistent with what the Proposal means in paragraph 11 by " a product being understood to mean an active substance **in the strict sense**"[my emphasis].

54. My conclusion about how the authorizing authorities understand the term "active substance" is reinforced by reference to the authorizations provided in this case to support the application. Although it would be beyond dispute if I could find a section of these authorizations headed "Active substance" alongside which was a reference to "Bentazone" I do not think that is absolutely necessary. In context, I believe nevertheless that the wording of the authorizations is to the same effect. Authorization PSPS 0465/85 is headed:-

"COMMERCIAL CLEARANCE OF 'BASAGRAN' (BENTAZONE) FOR USE ON BEANS, LINSEED, ONIONS, CEREALS, PEAS AND LUCERNE - CHANGE IN SPECIFICATION OF BENTAZONE"

Following this heading the second, fourth and fifth paragraphs read:-

"I understand that the product (an aqueous solution containing 480g/l bentazone) would be applied at....."

"Your parent company now intend to manufacture bentazone using a new process which results in a higher level of purity."

"In support of your notification you have submitted a comparison of the product specification from the old and new process. You have also submitted acute toxicity, irritancy and mutagenicity data for bentazone manufactured by the new process."

I can only say that due to the repeated references to bentazone in this authorization I am led to the inescapable conclusion that as far as Pesticides Registration Department of the Ministry of Agriculture, Fisheries and Food (MAFF) were concerned this was the active substance in what was admittedly a new formulation. It was because it was a new formulation that BASF at the time had to submit it for authorization even though other formulations of bentazone had been previously authorized. This is consistent with the fact that MAFF, in its role as an authorizing agency, has to concern itself with the safety and efficacy of the whole formulation and not just the active substance(s) contained therein.

55. All this is I believe consistent with paragraph 35 of the Proposal, the opening two sentences of which read as follows:-

"It occurs very often that one and the same product is successfully granted several authorizations to be placed on the market, namely each time a modification is made affecting the pharmaceutical form, dose, composition, indications, etc. In such a case, only the first authorization for the product to be placed on the market in the Member State in which the application is presented is taken into account for the purposes of the proposal for a Regulation."

Although this paragraph was not referred to at the Hearing it is my view that it is important enough, as a further indicator, that when a modification is made to an active substance, even though in effect it is the same active substance, a fresh authorization has to be sought.

56. Where then does this leave the role of the '029 patent in the application procedure for a certificate? Miss McFarland, I think, was trying to persuade me that because the patent related to a patentable modification of an already known product I ought to accept that it provided the gateway through the requirement of Article 3 (1)(a) that the product is protected by a basic patent in force. In many ways I am prepared to be so persuaded but in view of the fact that I have found that the "product" for the purposes of this application to be bentazone without qualification what I would add, in conformity with the definition of "basic patent" in Article 1(9), is that I regard the '029 patent merely as a candidate patent on which the application for a certificate for bentazone could be launched. It is because I have so found that whilst Article 3(1)(a) may be satisfied by relying on the '029 patent, the application must be refused under Article 3(1)(d) because the PSPS authorization dated 16 October 1985 was not the first authorization to place the product on the market in the United Kingdom as a plant protection product. Nor for that matter, as required by Article 19, is it the first authorization to place the product on the market in the Community.

57. Again, I believe this to be consistent with the Proposal in paragraph 29 which I have quoted above. What this paragraph makes abundantly clear is that all research that is patented whether it relates to a new product, a new process for obtaining a new or known product, a new application of a new or known product or a new combination of substances containing a new or known product, may on the basis of the patent be granted a supplementary protection certificate. The existence of a basic patent does not, in itself, provide sufficient justification for the grant of a certificate because as paragraph 29 concludes there is the further proviso that "all of the conditions governing the application of the proposal for a Regulation are fulfilled." It is all the conditions of Article 3 (1) that have to be fulfilled for the grant of a certificate and my findings are that they are not.

58. I must briefly deal with the point that Miss McFarland made about the Biogen decision.

All I would say is that I do not believe it adds any weight to her submissions if only for the fact that it was a decision made under the Regulation for Medicinal Products which does not contain an equivalent to Article 3(2) of the Regulation for Plant Protection Products. Article 3(2) was something added to the latter Regulation to make clear that the holder of more than one patent for the same product shall not be granted more than one certificate for that product. Moreover, as a further clarification it emphasises that where two or more applications for the same product and emanating from two or more holders of different patents are pending before the national Office, one certificate for this product may be issued to each of the holders. If this Article was to be of any help to the Applicants it would only be in the circumstance that I had found differently on the meaning of "product".

59. In reply, Miss McFarland also presented to me the interesting proposition that the Windsurfer test was appropriate in helping to decide the matter in the Applicants' favour. I would dismiss that proposition particularly as I have come to the conclusion that, by and large, the issue may be decided by reference to the wording of the Regulation informed by the Commission's Proposal and an understanding of the patent and authorization systems which interface the system for granting certificates.

60. I think that the approach I have taken concerning the meaning of the term "product" inevitably leads to me rejecting all of the alternative ways of identifying the product suggested by the Applicant. If, as I have found, the active substance is simply bentazone then reference to its preparation by the process of the '029 patent and/or to the impurities it contains do not alter that basic finding. Indeed reference to it being prepared by the process of the '029 patent might be considered to be redundant in the light of Article 4 of the Regulation which defines the protection conferred by the certificate as being within the limits of the protection conferred by the basic patent.

61. I have therefore come to the following conclusions:-

(a) the application fails to comply with Article 19 of the Regulation in so far as the first authorization to place bentazone on the market as a plant protection product in

the Community, namely the Danish authorization dated 12 December 1973, was obtained before 1 January 1985.

(b) notwithstanding the decision made under Article 19 and allowing for the fact that during the proceedings and at the Hearing much of the argument concentrated on the Article 3 conditions as if the application had not been filed during the transitional phase, the application would fail under Article 3(1)(d) because the PSPS authorization dated 16 October 1985 was not the first authorization to place the product on the market in the United Kingdom as a plant protection product.

(c) it makes no difference as to how the product is defined in section 6 of the from SP1, the application form, since the product to be protected i.e. the active substance is bentazone without qualification.

62. I therefore reject this application for a supplementary protection certificate.

63. Regulation 5 of the Patents (Supplementary Protection Certificate for Plant Protection Products) Regulations 1996 extends the existing provisions of the Patents Acts 1977 and 1949 to certificates. Accordingly, in accordance with Order 104, rule 19(2)(b) of the Rules of the Supreme Court, any appeal against this decision must be lodged within six weeks of the date of the decision.

Dated this 13th Day of January 1999

D L WOOD
Divisional Director, acting for the Comptroller

THE PATENT OFFICE