COMMISSIONER'S DECISION

NON SUPPORT IN DISCLOSURE: The application (claims 15 to 17) describes certain polyhydroxyl-phenyl chromones, known as Silymarin I, II, III, IV.

Claims 15 to 17 were refused because no invention was described commensurate with the scope of claims 15 to 17. The proposed amendment under Rule 52 was also refused because it related to new "subject matter".

Final Action: Affirmed.

This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated March 20, 1975, on application 053,025 (Class 260-373.3). The application was filed on May 29, 1969, in the name of Rolf Madaus, and is entitled "Method For Recovering Polyhydroxyphenyl." The Patent Appeal Board conducted a Hearing on November 17, 1976 at which Mr. K.P. Murphy represented the applicant.

The application described certain polyhydroxy-phenyl chromones, known as Silymarin, which exhibit valuable pharmacological properties relating to stabilizing of cell structure and regulation of the cell metabolism. The claims are directed to:

a) a process for recovering polyhydroxyphenyl chromones (claims 1 to 9);

b) polyhydroxyphenyl chromones whenever produced by the process of claim 1 (claim 10);

c) the process of claims 1 to 7 followed by separating Silymarin II and III from the polyhydroxyphenyl chromones (claims 11 and 12);

d) Silymarin II and III whenever produced by the process of claims 11 and 12 respectively (claims 13 and 14); and

e) a therapeutic composition comprising a mixture of Silymarin I, II, III and IV in association with a pharmaceutically acceptable carrier (claims 15 to 17).

It is to be noted that Silymarin I and IV were known prior to the present application and that Silymarin II and III are novel compounds (see applicant's letter of April 29, 1974, page 2, lines 7 to 10). Claims 1 to 14 were found to be allowable.

Claims 15 to 17 were rejected, and the reason for rejection is that "the therapeutic composition claimed in claims 15 to 17, which allegedly relates to a synergistic mixture of Silymarin I, II, III and IV in association with a pharmaceutically acceptable carrier, is not supported by the disclosure."

In that action the examiner discussed a number of court cases which deal with the requirements of Section 36(1) of the Patent Act. He also stated (in part):

> ...
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> ....The disclosure does not teach that the concentrate comprising Silymarin I, II, III and IV (Silymarin I and Silymarin IV were known prior to the present alleged invention) shows greater activity than would be expected from the summation of the properties of the individual Silymarins alone. There is no indication in the disclosure of any unexpected synergism, or any details about the operation, use of effect of the invention. Clearly Section 36(1) is not satisfied.
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> ...
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> As for evidence now presented (a copy of Applicant's accepted German application 1,923,082, which has a different number than the two Convention Priority applications of the present application) that invention is in fact present, we would refer to the statement of the President of the Exchequer Court in Riddell v Patrick Harrison 1956-60 Ex. C.R. 213 at 225:
>
> > ...what has to be considered in a patent case is the invention as described in the specification and defined in the claims rather than that described in the evidence".
>
> Applicant has submitted that "what is an invention in West Germany is equally an invention in Canada". We do appreciate it, but would like to emphasize that the requirements of an inventive step and proper disclosure of the invention in Canada are governed by the Canadian laws.

In his response to the Final Action the applicant argued along the following lines:

a) the compositions defined in claims 15 to 17 are certainly supported by the disclosure. Page 11, at lines 12 to 14, of the disclosure discloses tablets, sugar-coated tablets or capsules for oral therapy containing Silymarin embedded in a carrier;

b) it would seem that the claims have been rejected for lack of support in view of the absence of the specific term "synergism";

c) the synergism is merely the scientific explanation as to how the advantageous pharmacological effect is achieved and is of a scientific character;

d) there is no requirement in Section 36(1) that the applicant provide a scientific explanation as to why his invention works in the way it does;

e) it is believed that the language employed in the disclosure referring to surprising activity and considerably higher activity is essentially equivalent to "synergism";

f) it is requested that the disclosure be amended to insert at page 3, after line 27, a paragraph reading:

> According to a further aspect of the invention, there is provided a therapeutic composition comprising a mixture of Silymarin I, II, III and IV in association with a pharmaceutically acceptable carrier. The composition of the invention may be conveniently formulated in the form of a tablet or capsule for oral administration with each tablet or capsule suitably containing a total of 35 mg of Silymarin I, II, III and IV.
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> And further that the disclosure be amended at page 6b, after line 10, to introduce the following paragraph:
>
> The therapeutic composition of the invention comprising the mixture of Silymarin I, II, III and IV is found to have a greater activity than would be expected from the summation of the properties of the individual Silymarins alone, for example, when the pharmacological properties of the four components of the Silymarin mixture and the mixture were investigated on animals (mice) complete protection was obtained utilizing 150 mg/kg of Silymarin I; 250 mg/kg of Silymarin II; 150 mg/kg of Silymarin III as compared with 30 mg/kg of the mixture of Silymarin I, II, III and IV;

g) the applicant could also introduce the table appearing in columns 5 and 6 of the applicant's corresponding West German patent 1,923,082 from which the present application claims priority under International Convention;

h) it is believed that the introduction of this matter is permissible under the relevant provisions of the Act and Rules as interpreted by the Courts in Canada; and

i) in support of this view the applicant refers to Canadian Patent 779,890 to Sandoz Patents Ltd. (Jules R. Gilbert Ltd. v. Sandoz Patents Ltd. (1970) C.P.R. Vol. 64, page 14).

We have studied with care the able and interesting arguments presented at the Hearing by Mr. Murphy.

The question to be considered is whether or not an invention of the scope covered by claims 15 to 17 is supported by the disclosure.. Claim 15 reads as follows:

> A therapeutic composition comprising a mixture of Silymarin I, II, III and IV in association with a pharmaceutically acceptable carrier.

There was considerable discussion about the term "synergism." The applicant indicated that the application was being rejected because he had not said the mixture was synergistic. We think, however, that the question whether the term "synergism" was used is academic. The real issue is whether the applicant demonstrated in his disclosure that there was a synergistic effect in mixing the compounds.

We are satisfied that the applicant has described the utility of the mixture. The applicant, however, argues that "the therapeutic composition of the invention comprising the mixture of Silymarin 1, 11, 111, and 1V is found to have a greater activity than would be expected from the summation of the properties of the individual Silymarins alone...." At first blush we could probably say that, if properly disclosed, the applicant has obtained a new and unexpected result which is unobvious and inventive over the single compounds.

The specific question is whether claims (15 to 17) to this alleged invention are properly supported by the disclosure, and if not are the proposed amendments, noted above, acceptable.

At the Hearing the question was asked by the Board "Is there a clear indication in the disclosure that the mixture of the Silymarins is different and better than the individual Silymarins [mixture] .... [answer by Mr. Murphy] I am not sure if I would go that far - most of the description of the utility is discussing the mixture itself and it says there is surprising activity - it is not saying it is surprising as compared to one of the compounds."

And later on in the Hearing [the Board]...having read the disclosure [of the instant application]we would not assume that there would be any advantage in using the mixture over the individual compound - [answer]. "That is a fair comment .... My disclosure - the Canadian disclosure -- does not say that the mixture of the 4 Silymarins is more useful than any of the individual ones in the same sort of amount." He also stated, "He does not make a distinction in his original disclosure between the surprising results that he gets when he used the mixture - he doesn't suggest that it is better than using one of the compounds alone."

In our view therefore, it is abundantly clear from the above and the responses to the examiner's actions that the alleged invention defined in claims 15 to 17 is not supported by the disclosure. There is no invention described commensurate with the scope of claims 15 to 17 over the results of using one of the compounds. It is trite law that the applicant must fully describe the invention and its operation and use. This is also codified by Section 36 of the Patent Act.

The next consideration is whether the disclosure may be amended, as proposed above, to support claims 15 to 17.

The proposed amendment relates to "a further aspect of the invention ... comprising a mixture of Silymarin 1, 11, 111, and 1V in association with a pharmaceutically acceptable carrier ... the mixture is found to have a greater activity than would be expected from the summation of the properties of the individual Silymarins alone. The applicant maintains that such an amendment is permissible under the relevant provisions of the Act and Rules and refers to Jules R. Gilbert Ltd. v Sandoz Patents Ltd. (1970) C.P.R. Vol. 64, p.14.

In the Sandoz case an amendment was introduced after the filing of the application which related to an amplified utility. On this point Thurlow J. stated "Nor do I think the scope of a rule invoked by the applicants to amend the specification before the grant of the patent so as to insert the sentence

[respecting the extremely low extra-pyromedal effects of thiaridazine] above referred to and other sentences relating to the utility of the substance of the class can be invoked to give to the specification as amended a different interpretation from that which considered as a whole it bears." In our view this is totally different from the instant application where no invention is described commensurate with the scope of claims 15 to 17.

In our view the proposed amendment relates to new and separate subject matter which cannot be entered under Rule 52. It describes an alleged invention separate from the compounds when used alone. We agree with the applicant when he states that "he does not have to know the composition works in the way that it does." He must however, state what and where the invention is. How is one to make use of the invention when there is no disclosure that there is in fact an invention of the scope as covered by claims 15 to 17.

The applicant argues that the proposed amendments should be accepted in view of the fact that some amendments were accepted by the West German patent office. We must remember however, that the requirements of a proper disclosure in Canada are governed by the Canadian Patent laws, which may well differ from the patent laws of West Germany. In our view the amendments should not be accepted.

We think the wording of the Court in Riddell v Patrick Harrison (1956-60) Ex. C.R. 213 at 225 is pertinent to this case. It states, "...what has to be considered in a patent case is the invention as described in the specification and defined in the claims rather than that described in the evidence...."

It appears there might also be some other reasons to object to claim 15. It covers substantially the same ground as claim 10. Whether that raises such objections as redundancy, an improper avoidance of the requirements of Section 41, or a contravention of the date expressed in Gilbert v Sandoz 1974 S.C.R. 13-36 against composition-with-carrier claims, have not been considered, and we see no need to go into those issues here.

We are satisfied that the claims are not supported by the disclosure, and that the proposed amendments cannot be accepted because they relate to an alleged invention not previously described in the disclosure. We recommend that the decision in the Final Action to refuse claims 15 to 17 be affirmed.

J.F. Hughes
Assistant Chairman
Patent Appeal Board

I have studied the prosecution of this application and have reviewed the recommendation of the Patent Appeal Board. In the circumstances I have decided not to accept the amendment to the disclosure and to refuse claims 15 to 17. The applicant has six months within which to remove claims 15 to 17, or to appeal this decision under the provision of Section 44 of the Patent Act.

J.H.A. Gariépy
Commissioner of Patents

Dated at Hull, Quebec
this 31st day of January, 1977

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