COMMISSIONER'S DECISION

UTILITY - Non support in disclosure.

The application was refused under Section 36 for insufficient disclosure of utility. An amendment to overcome that objection, with an amplified utility, was refused under Rule 52. The amendment was entered as not contravening Rule 52.

Final Action - Reversed

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This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated February 24, 1976, on application 139,256 (Class 260-238.60). The application was filed on April 7, 1972, in the name of Minoru Shindo et al, and is entitled "1,4,5 - Benzotriazocine Derivatives And Process For The Production Thereof." The Patent Appeal Board conducted a Hearing on November 17, 1976, at which Mr. K.P. Murphy represented the applicant.

The present invention is directed to novel 1,4,5 benzotriazocine derivatives and their preparation which compounds possess an action upon the central nervous system and are consequently of use in the medicinal field.

In the Final Action the examiner refused the application because the specification does not meet the requirements of Section 36(1) with respect to the "description of utility." The examiner also refused to enter a proposed amendment under Rule 52 of the Patent Rules because he considered it to be new matter. No objection was made to the claims.

In that action the examiner stated (in part):

> The rejection of this application is maintained as the specification does not meet the requirements of Section 36(1) of the Patent Act with respect to the description of the utility.
>
> In order to meet the criteria of Section 2(d) of the Patent Act the description of the invention and its operation must satisfy the requirements of Section 36(1) of the same Act.

"The description of the invention must also be full; this means that its ambit must be defined, for nothing that has not been described may be validly claimed. The description must give all information that is necessary for successful operation or use of the invention, without leaving such result to the chance of successful experiment". (See: Minerals Separation vs. Noranda Mines, 1947 Ex. C.R. at 316-317).

The disclosure of this application fails to satisfy the requirements of a disclosure as set forth above in regard to the utility of the compounds claimed. It does not give all information that is necessary for successful use of these compounds without leaving such result to the chance of further and successful experiment. There are no measurable and quantitative data about utilizable properties in terms which constitute useful and most needed information for a man skilled in the art in order to avoid such experiments as this applicant carried out.

The applicant's arguments have been considered. However, they cannot be accepted for the following reasons.

At first, for the patentability of organic-chemical compounds both the structure and the utility must be considered as inseparable.

Secondly, there are not two compounds, no matter how closely structurally related they may be, which have the same specific utilizable properties (especially bio-properties).

Therefore, the description of the structure and the processes, without the description of the utility, is not adequate to render the application in conformity with Section 36(1) of the Patent Act. It is even less adequate if the compounds of the same basic structure are already known in the art. Therefore, the applicant's arguments on page 2 of the letter of May 6, 1975 are not acceptable.

The above statements are based on the well accepted fact that the utilizable properties render the compound patentable, and the fact that bio-properties (especially specific properties) are not predictable. Consequently, the utility, as the only unpredictable feature may give the new compound the attributes of "unobvious" and "patentable". The preparation of similar compounds (similar to the already known) does not represent more than imitation. The processes (generally and without the indication to the contrary) are known or are considered as the exercise of a professional skill. Neither imitation nor performance of a professional skill could be considered as patentable invention.

The applicant in his response to the Final Action argued that the original statement of utility is quite adequate to meet the requirements of Section 36(1) of the Patent Act since it quite clearly indicates to those in the art, to whom the specification is directed, the field in which the novel

compounds of the invention are active. Furthermore, it is his position that in any event the disclosure can be amended to amplify the description of the utility to include data in support of the utility which was known to him prior to the filing date of the present application. He further explained his position with respect to the following:

1) The decision of the Exchequer Court of Canada in Jules R. Gilbert Ltd. v Sandoz Patent Ltd. reported in 64 CPR 14; and

2) the provisions of Rule 52 and Section 50(1).

On the above points he stated (in part):

> The disclosure [in Sandoz] refers to an invention in a class of new phenothiazine derivatives, although all the claims in the patent are in fact restricted to a single compound which is known as thiorizadine and its salts.
>
> In the specification of the Sandoz patent as originally filed the only support of the utility of the phenothiazine derivatives are the statements which appear in the sentence at page 4, lines 13 to 16, and page 4a, line 10 to page 5, line 12, of the granted patent. The latter description relates to a fungicidal action of the compounds.
>
> In the decision of the Exchequer Court invention in the novel compound thiorizadine was upheld on the basis of its therapeutical utility as a neuroleptic drug accompanied by extremely weak extra-pyramidal effects. Compounds similar to thiorizadine were known to have neuroleptic properties and in particular the compound chloropromazine was in use as a neuroleptic drug. The significant advantage of thiorizadine over chloropromazine was that thiorizadine had much reduced extra-pyramidal effects which effects were a problem in using chloropromazine.
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> In the decision of the Court it was recognized that it was this superior utility of thiorizadine which made it inventive over the known structurally related and neuroleptically active compound chloropromazine. In this respect reference is made to page 39 of the decision wherein Thurlow J. commented ".... that is to say, its extremely low extra-pyramidal effects which is what gives the discovery of the utility of the substance a character of a patentable invention". And further at page 40 of the decision "....and that fact in itself, in the circumstances as described in evidence, not only distinguishes thiorizadine from other members of the class but gives the discovery the character of a separate invention and, secondly, because the invention of thiorizadine having been a valuable contribution to the art and having been in fact disclosed by the specification and claimed, a construction of the specification which will give effect to the patent, should, I think, be preferred to one the result of which would be to destroy it."

...

The portion of the disclosure of Canadian patent 779,890 which more fully describes the medicinal utility of thiorizadine and which identifies the extremely weak extra-pyramidal activity of thiorizadine was in fact introduced into the disclosure of the Sandoz application some ten years after the filing date of the Sandoz application. For convenience the all important description of utility which was introduced into the Sandoz specification ten years after filing has been encircled in red ink.

It is to be emphasized that this statement of utility introduced into the Sandoz specification is vital to the validity of the Sandoz patent since it establishes the particular significance and utility of thiorizadine in comparison with the larger class of compounds and previously known neuroleptic agents.

Furthermore it is to be noted that the Court specifically approved the introduction of the statement of utility into the Sandoz specification and considered that it was not contrary to Rule 52 of the Patent Rules. In this respect reference is made to page 40 of the decision wherein Thurlow J. stated -

> "Nor do I think the scope of a Rule invoked by the Applicant to amend the specification before the grant of the patent so as to insert the sentence above referred to and other sentences relating to the utility of the substances of the class can be invoked to give the specification as amended a different interpretation from that which considered as a whole it bears."

The reference here to "a Rule" is a reference to Rule 52 of the Patent Rules.

Clearly the Court considered that the introduction of the specific statement of utility into the pending application did not contravene Rule 52 of the Patent Rules and the validity of the claims to the thiorizadine based on this utility was upheld.

...

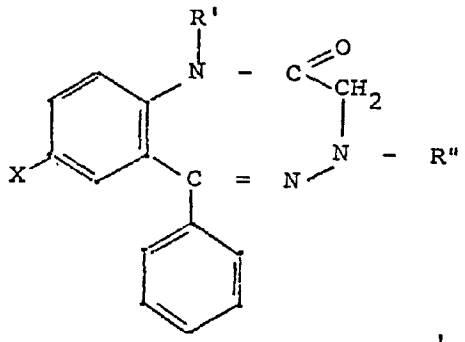
Reference is made to Section 50(1) of the Patent Act which provides for re-issue of any patent which is deemed to be defective or inoperative by reason of insufficient description or specification where the error arose from some inadvertence, accident or mistake without any fraudulent or deceptive intention. Thus, the Statute provides authority for correction of an alleged defect of draftsmanship in an issued patent. It would seem that if the patent on the present application was issued (without the amplified description of the utility) that Applicant would be permitted to re-issue the patent to more fully describe the utility if this was considered necessary in order to render the patent effective. It would seem that an amendment permitted by the Statute to correct a possible defect after issue of a patent should equally be permissible during the pendency of the application and that any other conclusion would be illogical.

The disclosure of the application describes the novel compounds and their preparation in some detail and in particular by reference to thirty-five detailed major examples and some fifty-two subsidiary examples. In all of these examples the novel compounds of the invention are fully characterized by reference to their physical properties.

The original disclosure included the following statement (at page 6):

> The compounds represented by general formula (I) are invariably novel compounds which, by virtue of their action upon the central nervous system, are of use as medicines.
>
> It is the object of this invention to provide compounds which, as aforesaid, are new and useful as medicines.

The 1, 4, 5 benzotriazocine derivatives are represented by formula (1) as follows:



> wherein X is hydrogen, halogen or lower alkyl; R' is hydrogen or lower alkyl; R" is hydrogen, $-COCH_2Y$ or $-COCH_2A$, where Y is halogen, and A is a nitrogen atom to which two or three of R_1, R_2 and R_3 are attached and which, when R_1, R_2 and R_3 are attached, carries an anion; R_1, R_2 and R_3 are the same or different and each is selected from hydrogen, lower alkyl, lower alkenyl, phenyl, phenyl-amino and phenyl-lower alkyl; said phenyl and phenyl-lower alkyl being unsubstituted or substituted by one or two substituents selected from lower alkyl, lower alkoxy and halogen, or 2 or 3 of R_1, R_2 and R_3 being taken together, represent a polymethylene group of 4 to 6 carbon atoms which may have one to four hetero-atoms selected from oxygen and nitrogen therebetween.

After the application was refused for failing to meet the requirements of Section 36(1) with respect to the description of utility, the applicant proposed the following amendment to the disclosure:

> The derivatives of formula (I) are novel compounds which possess activities for depression of the central nervous system, more particularly an action for prolonging sleeping time, analgesic activity and sedative activity and are of use in the medicinal field. It is thus an object of this invention to provide derivatives of formula (I) which, as aforesaid, are new and useful in the field of medicine.

The proposed amendment was then refused by the examiner under Rule 52 of the Patent Rules, because it is considered in his view to be "new matter."

We have considered with care the prosecution of this application and the arguments ably presented at the Hearing by Mr. Murphy.

The broad issue to be reviewed is whether the specification meets the requirements of Section 36(1) with respect to the description of utility. The more specific and initial question which we will consider however, is whether the proposed amendment, with an amplified description of utility, would be considered as contravening Rule 52 of the Patent Rules. The reason for looking at the proposed amendment first is we feel that, if accepted, it would give more effective information on how the results of the invention are accomplished which would be beneficial to the public (see Section 36 - operation or use). Further, if the amendment is acceptable the broad issue, referred to above, will not have to be considered.

Rule 52 of the Patent Rules reads as follows:

> No amendment to the disclosure shall be permitted that describes matter not shown in the drawings or reasonably to be inferred from the specification as originally filed, and no amendment to the drawings shall be permitted that adds thereto matter not described in the disclosure.

Rule 52 must necessarily take into consideration the import and content of Rules 53 to 57 as a whole. For example, Rule 53 relates to "subject matter" warranting a new filing date as capable of supporting new claims which are not fairly based on the original disclosure alone. We think the key words in Rule 52 are "reasonably to be inferred." Webster (second edition) gives the meaning of infer: "To derive by reasoning or implication; to conclude from facts or premises...."

Rule 52 does not "countenance" admission of subject matter to complete an invention (except as it qualifies under Rules 52 and 53). This however must be distinguished from the expansion of ancillary description and technical matters relating to "operation or use," which is reasonably to be inferred. Amendments may be made to a disclosure before an application is issued to patent, or in the case of a reissue patent Section 50(1) an applicant may "amend the description and specification" within four years if a "patent is deemed defective or inoperative by reason of insufficient description or specification". It is trite law that the insufficient description referred to can be made accountable to imperfections of draftmanship. We must also keep in mind that in Minerals Separation v Noranda, (1947) Ex. C.R. 306 at 316 a distinction was made between imperfection of draftmanship and non-compliance of statutory requirements.

The specific question then is whether the amplified utility, in the proposed amendment can reasonably be inferred (derived by reasoning or implication) from the specification as filed.

It is of interest to note that the examiner is satisfied that the reference to "the amplified utility in the proposed amendment is in the expected area of such original utility." It is the applicant's position that "the man skilled in the art to whom the specification is directed would appreciate the nature of the utility of the derivatives described in view of the statements in the disclosure indicating that the derivatives were of use as medicines by virtue of their action upon the central nervous system."

Of pertinence to this decision is the rationale of the court in Gilbert v. Sandoz, supra. In that case, an amendment was introduced after the filing of the application which related to an amplified utility. On this point Thurlow J. (at page 40) stated:

> ... the invention of thioridazine having been a valuable contribution to the art and having been in fact disclosed by the specification and claimed, a construction of the specification which will give effect to the patent should, I think, be preferred to one the result of which would be to destroy it. (Vide: Kellock, J., in Wandscheer et al v. Sicard Ltd., (1948) S.C.R. 1 at p. 17.)
>
> Nor do I think the scope of a rule [Rule 52] 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. [emphasis added]

For convenience we will repeat the utility as presented in the application as filed:

> The compounds represented by general formula (1) are invariably novel compounds which, by virtue of their action upon the central nervous system, are of use as medicines.
>
> It is the object of this invention to provide compounds which, as aforesaid, are new and useful as medicines.

The proposed amendment to amplify the utility reads as follows:

> The derivatives of formula (1) are novel compounds which possess activities for depression of the central nervous system, more particularly an action for prolonging sleeping time, analgesic activity and sedative activity and are of use in the medicinal field. It is thus an object of this invention to provide derivatives of formula (1) which, as aforesaid, are new and useful in the field of medicine.

In the first examiner's action it was indicated that there should have been disclosed (at least) the nature of the CNS action (e.g. anaesthetics, anticonvulsants, analgesics....) and the field of treatment (e.g. psychoses, anxiety...")

This was considered by the examiner as minimum necessary for the disclosure of utility since it was known that structurally similar compounds (benzodiazepines, benzotriazocines) were known to possess CNS activity properties, i.e. the basic structure as a potential carrier of the basic (CNS) properties were known.

The amplified utility more fully describes the medicinal use of the novel compounds. We are satisfied, and the examiner agrees, that the proposed amendment would satisfy the nature of the CNS action and gives a more specific field of treatment as indicated in the first examiner's action.

Of interest it is clear, from the record, that the amplified utility, as stated in the proposed amendment, was clearly known to the applicant prior to the filing dat. of the present application. This was covered by affidavit and the fact that a similar amplified disclosure was present in the United States application which was filed almost of even date with the present application. The point of this of course is to merely indicate that there is no consideration of the proposed amendment relating to matter which was discovered after the filing date of this application.

In considering this case we have been influenced by two factors. First, the examiner is satisfied that the reference to "the amplified utility in the proposed amendment is in the expected area of such original utility;" and secondly, that "it was known that structurally similar compounds (benzodiazepines, benzotriazocines) were known to possess CNS activity properties." Having that in mind we have come to the conclusion that the utility of the novel compounds are, in the present circumstances, reasonable to be inferred from the original disclosure, and that the application could proceed on that disclosure. The disclosure however, would be improved by the amplified utility in the proposed amendment.

In view of the above consideration we are constrained to conclude that the applicant should be permitted to amend the disclosure to introduce the additional data in order to more fully comply with the requirement that, "when the period of monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application." (vide, Mineral Separation v Noranda, supra) It is our opinion that it falls under the heading of imperfection of draftmanship rather than non-compliance of statutory requirements.

In summary, we are satisfied that the scope of the rule used by the applicants in an attempt to amend the disclosure relating to the amplified utility of the substance, as indicated, can not be invoked to give to the specification as amended a different interpretation from that which considered as a whole it bears (see Gilbert v Sandoz, supra).

We recommend that the decision in the Final Action to refuse the application be withdrawn and that the proposed amendment be accepted.

J.F. Hughes
Acting Chairman
Patent Appeal Board, Canada

I have studied the prosecution of this application and have carefully reviewed the recommendations of the Patent Appeal Board. In the circumstances I withdraw the Final Action and will accept the amendment to the disclosure. The application is returned to the examiner for resumption of prosecution.

J.H.A. Gariepy
Commissioner of Patents

Dated at Hull, Quebec

this 20th. day of June, 1977

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