COMMISSIONER'S DECISION

ADEQUACY OF DISCLOSURE: SECTION 36 - Diaza-Cycloalkanes

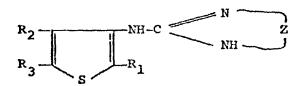
The applicant claimed several methods to make new chemical compounds useful medicinally. The examiner wished to restrict the applicant to one method, holding that the others were not disclosed adequately. It was decided that in the particular circumstances arising here there was sufficient support.

Rejection: Reversed.

The final rejection of patent application 090785, class 260-263, filed August 14, 1970, by Farbwerke Hoechst Aktiengesellschaft as assignee of Robert Rippel et al, has been referred to the Patent Appeal Board to recommend what disposition should be made of the application. The title of the invention is "2-(Thienyl-3'-amino)-1,3-Diaza-Cycloaklenes and Process for Preparing Them." At the request of the applicant a Hearing was held at which Miss M. Morency and Mr. David M. Rogers Q.C. represented the applicant.

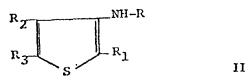
In hi final rejection, the examiner refused claim 1 under Section 36 of the Patent Act on the grounds that the disclosure failed to provide adequate support for all the subject matter covered by the claim. Section 41(1) was also applied for the reason that some of the processes claimed were not "particularly described" in the application. The processes objected to are those covered by parts c, d and e of claim 1, which reads as follows:

A process for preparing 2-(thienyl-3'-amino)-1,3-diazacycloalkenes of the general formula



wherein R_1 , R_2 and R_3 represents hydrogen, low molecular weight, alkyl, halogen, cyano or phenyl, or R_2 and R_3 may represent together a trimethylene or tetramethylene chain, and Z represents a straight or branched alkylene radical having 2-4 C-atoms of which 2-3 C-atoms are members of a ring, in which

(a) a thicnyl-3-isothiuronium salt, -thio-urea, -guanidine, -nitroguanidine, or -cyanamide of the formula II

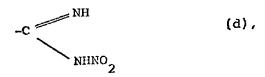


wherein R_1 , R_2 and R_3 have the meanings given above, and R represents the group



$$-c \underset{NH_2}{\longleftarrow} S$$

$$-c \underset{\stackrel{\cdot}{\longrightarrow} NH_2}{NH_2}$$
 (c),

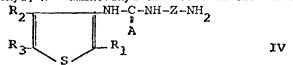


or -CN (e),

wherein R₅ represents low molecular weight alkyl and X represents an acid anion, is reacted with an alkylene-diamine of the formula III

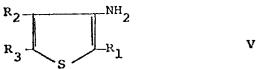
wherein Z has the meaning given above, or a mono salt thereof,

(b) an N-(3'-thienyl)-N' -aminoalkyl-thio urea of the formula IV



wherein R_1 , R_2 , R_3 and Z have the meanings given above, and A represents oxygen or sulfur, is cyclicized,

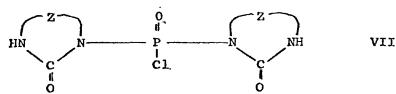
(c) an aminothiophen of the formula V



wherein R_1 , R_2 and R_3 have the meanings given above, is reacted with a 2-alkylmercapto-1, 3-diazacycloalkene of the formula VI

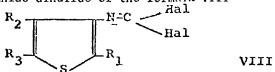
wherein R5 and Z have the meanings given above, or a salt thereof.

(d) an aminothiophen of the formula V is reacted with a bis-(2-oxo-1, 3-diaza-cycloalkyl)-phosphrine chloride of the formula VII



wherein Z has the meaning given above, or

(e) a thiophen-3-isocyanide-dihalide of the formula VIII



wherein R_1 . R_2 and R_3 have the meanings given above, and Halstands for chlorine or bromine, is reacted with an alkylene-diamine of the formula III.

Although the preamble to the claim implies one process is claimed, in fact there are many different processes to make certain diazacycloalkenes.

These alkenes possess hypotensive properties which are useful medicinally, so that Section 41 is applicable to them. In the disclosure some examples are provided of processes (a) and (b), but not for processes (c), (d) and (e).

In the final rejection, the examiner stated his objections in the following terms:

The rejection of variations c, d and e in claim 1 is maintained and the reason for such rejection is lack of adequate support from the disclosure; the disclosure fails to meet the requirements of Section 36(1) regarding variations c, d and e and is inadequate to support claims, particularly under Section 41(1) which is designed to limit the monopoly on drugs to their relationship to processes "particularly described".

The disclosure does not contain the description of any particular compound by any of the methods under rejection.

Referring to a paragraph of the last Office Action which was apparently misunderstood: "Contrary to applicant's opinion, the disclosure does not provide "the description necessary to enable one skilled in the art to carry out said variations." The processes are not properly speaking described."

The disclosure fails to indicate the particular way in which the rejected variations must be adapted to produce the desired result and hence does not show their utility in the preparation of the claimed compounds nor even their practicability in such preparation. The wide temperature ranges mentioned as well as the broad list of solvents do not constitute information but rather an absence of definite information, and consequently the public is not put in possession of anything which is not already in public possession.

A patent is not an invitation to experiment, and the disclosure, with respect to the variations under rejection, is insufficient to exempt the interested person from experimenting for the purpose of determining the actual means of adapting the methods, and this without definite guarantee of success.

The concept that a process derives patentability from the patentability of its product is not an exemption from Section 36(1) and the practice of allowing any suggested processes, if adopted, could render Section 41(1) completely inoperative, through the simple expedient of adjoining an exhaustive list of known methods as alternates to the method employed in the original synthesis: Section 41(1) becomes dead letter if a compound claim covers all methods,

In his response of November 28, 1974, one argument made by the applicant was that:

All of the processes are conventional chemical reactions and derive their patentability from the new and unobvious utility of the products of the formula given above. This is in accordance with the decision of the Supreme Court of Canada in Ciba v. The Commissioner of Patents (1959) SCR 378.

As stated above, these reactions were considered to be conventional chemical reactions prior to filing of the subject application. Obviously, the same reactants had never previously been reacted with one another since this would deny the novelty of the processes but similar reactants had been so reacted.

Variation c is concerned with the reaction of a compound of the formula V with a compound of the formula VI. This reaction is discussed in the disclosure on page 6, second line from the bottom to page 7, line 15. In this portion of the disclosure, instructions are given concerning the various parameters of the process. In addition, the preparation of the starting material of the formula VI is also described on page 7.

He then referred to several publications which showed that reactions analogous to processes c and d had been used earlier to make different compounds than those claimed here. In discussing Section 36(1) he stated:

Applicant respectfully submits that the requirements of Section 36(1) have been met in the subject application. The invention resides in the novel compounds and their unexpected utility in pharmaceutical preparations. This invention and its use as contemplated by the inventors is correctly and fully described in the application. According to Section 36, when a process is involved, it is necessary to set forth clearly the various steps in the process and this has been done for each variation which may be used in the preparation of the novel compounds of the invention. This has been done in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which the invention appertains to use the invention. In support of this statement, an affidavit of Dr. Leopold Horner, a Professor of Chemistry at the University of Mainz in Germany, is included.

From this affidavit you will note that Dr. Horner read the disclosure of this application and, using process variations c, d and e, prepared the compound of Example Ib, namely 2-(4'-methylthienyl-3'-amino)-1,3-diazacyclopentene-(2). Dr. Horner's note book records form part of his affidavit. You will also note that it is Dr. Horner's belief that the disclosure is sufficient to enable a skilled chemist to use variations c, d and e to produce the novel compounds.

Applicant is unaware of any statutory requirement that examples be included in support of a process claim. In <u>Gilbert v. Sandoz</u> 64 CPR 14, The Exchequer Court found a claim invalid since there was no particular example in the disclosure directed to the particular process claimed. However, the Supreme Court in reversing this stated that:

"In my view, this cannot be of very great consequence seeing that the "condensation" process is not claimed as new and it is not denied that a competent chemist, using only general knowledge available, could have successfully carried it out without more information than is supplied in the general description." (Sandoz v. Gilcross 8 CPR (2d) 216).

It should be noted that Mr. Justice Pigcon, who delivered the judgement of the Supreme Court, considered the process to be "described" even though it was not "exemplified".

This latter point is of considerable importance since the Examiner has stated that the disclosure in this application is inadequate to support the claims, particularly under Section 41(1) which is designed to limit the monopoly on drugs to their relationship to processes

"particularly described". Applicant respectfully submits that each of process variations c, d and e has been particularly described and considers that the Supreme Court decision in Sandoz v. Gilcross supports the submission.

In rebutting other objections of the examiner the applicant states:

It is applicant's contention that the disclosure does indicate the particular way in which variations c, d and e must be adapted to produce the desired result. This position is substantiated by the affidavit of Dr. Horner, the "person skilled in the art" to whom a patent specification is addressed. It is submitted that an example is unnecessary to show the utility of these processes or their practicability and that there is no statutory requirement or judicial decision which make exemplification necessary.

The Examiner has also stated that the wide temperature ranges mentioned as well as the broad list of solvents do not constitute information but rather an absence of definite information, and consequently the public is not put in possession of anything which is not already in public possession. Applicant has not at any time alleged that the processes of variations c, d and e were new chemical processes but merely processes which were conventional at the time of filing of the subject application. These processes, however, had never before been used to react the various reactants to produce the novel compounds of the invention which have unexpected utility as pharmaceuticals. With reference to the disclosure taken as a whole, the public is put in possession of something which was not in public possession, namely the knowledge of these compounds and their use.

and

The Examiner has stated that a patent is not an invitation to experiment and the disclosure with respect to the variations under rejection is in sufficient to exempt the interested person from experimenting for the purpose of determining the actual means of adopting the method and this without the definite guaranty of success. Applicant submits that the disclosure is sufficient to allow a person skilled in the art to practise the invention and this is all that is required.

Mr. Justice Maclean in the <u>BVD v. Canadian Celanese</u> decision 1936 Ex CR 140 held that:

"Where a specification described an invention sufficiently clearly to enable a reasonably skilled workman to make use of it, even though some experiments are necessary, the patent will be good so long as those experiments do not require any exercise of the inventive faculty".

and

The Examiner has stated that the practice of allowing any suggested processes, if adopted, could render Section 41(1) completely inoperative through the simple expedient of joining an exhaustive list of known methods as alternates to the method employed in the original synthesis. Applicant has not merely suggested processes but has, in fact, described processes. The claims of the subject application do not, in fact, describe all methods but five methods which have been described in the disclosure in such a manner to enable a person skilled in the art to practice the invention.

It is evident that a principal issue is whether the disclosure is adequate to permit certain of the processes to be claimed. In this case the core of the invention is the product, and it is from it that the process claims must acquire their necessary element of inventive ingenuity. As the applicant has put it: "All of the processes are conventional chemical reactions and derive their patentability from the new and unobvious utility of the products.... He relies upon Ciba v. Commissioner of Patents (1959) S.C.R. 378 for that proposition. While he has implied that there are other methods for making the products (1esponse of November 28, 1974, p.7), claim 1 covers the practical methods which would normally be employed to make them, and it is in effect a claim for all known ways to produce them. It comes close to being a claim for a process for making the new compounds by all known methods by which they might be prepared. It would not block others from making the products if they were to develop inventively new methods to prepare them, but barring that contingency would control all useful routes to the compounds. Whether Section 41 permits applicant to claim so broadly is another issue which must be considered.

In discussing Section 36 (then Section 35) in RCA v Raytheon (1956-1960)

Ex. C.R. 98 at 109 the Exchequer Court indicated that the onus of disclosure that the section places on an inventor is a heavy and exacting one.

It stated at p. 108:

It is a cardinal principal of patent law that an inventor may not validly claim what he has not described. In the patent law jargon it is said that the disclosure of the specification must support the claims. If they do not, the claims are invalid. Moreover, there is a statutory duty of disclosure and description that must be complied with if a claim for an invention is to stand....

It further indicated that:

The purpose underlying this requirement is 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 (p. 109).

It is a principle reiterated in Noranda Mines v Minerals Separation (1947) Ex. C.R. 306 at 316; in French's Complex Ore v Electrolytic Zinc 1930 S.C.R. 462 at 470; in B.V.D. v Canadian Celanese 1936 Ex. C.R. 139 and 1937 S.C.R. 22; in Smith Incubator v Sealing 1937 S.C.R. 251; in Gilbert v Sandoz (1971) 64 C.P.R. 7 at 42-45; and in Rhône-Poulenc & CIBA v Gilbert 1966 Ex. C.R. 59 & 1967 S.C.R. 45.

On an earlier occasion we considered the question of sufficiency of disclosure when application 028123 came before the Board. Our findings there were published in the Patent Office Record for November 11, 1975, beginning at page X1. I' think it would be useful here to reexamine one of the cases referred to at that time.

In the <u>Gilbert v Sandoz</u> decision (<u>supra</u>), at p. 52, the Exchequer Court found a process claim invalid because:

... the requirement of S. 36(1) is that the applicant describe his invention and its operation or use as contemplated by him. The public and the reader are entitled to a description of the invention which the inventor has made and to say that a group of substituted phenothiazines may be made by a known type of chemical reaction is, as I see it, to assert merely what is already known as a general proposition rather than to say that he has carried it out in a particular way using particular materials and found that such is a practical method of producing an unexpectedly useful new substance known as thioridazine.

The Supreme Court of Canada, however, (1974 S.C.R. 1336 at 1344) reversed the lower court on this point, saying:

... In my view this cannot be of very great consequence seeing that the "condensation" process is not claimed as new and it is not denied that a competent chemist, using only general knowledge available could have successfully carried it out without more information than is supplied in the general description. Furthermore it is not denied that the bromo-ethane process can be successfully carried out using the procedures and reagents that are described in Example I which illustrates the carrying out of the process as applied to the chloro-ethane compound. Thus, the only objection to the sufficiency of the description of the means of carrying out the invention by the bromo-ethane process is that the inventor did not say that one could proceed as in Example 1 for the chloro-ethane process, although any skilled chemist would know that this must be expected in the absence of any mention of some anomaly in the behaviour of the bromo-ethane compound in the reaction.

We also refer to the following passage in our earlier decision:

As was held in <u>Riddel v. Patrick Marrison</u> (1956-1960) Ex. C.R. 213 at 253, an inventor need not restrict his claims to what has been "specifically described in the specification and illustrated in the accompanying drawings," but within the breadth of his invention, may claim it as broadly as it would normally be construed by persons skilled in the art. For such reasons, we do not consider that Section 36 prohibits the grant of claims 20-30.

In the case which is now before us the applicant has submitted an affidavit of one Dr. Leopold Homer affirming that the disclosure is sufficient to enab? a skilled chemist to carry out variations (c), (d), ξ (e), and copies of articles predating the filing of this application illustrating that the methods had been used to make other compounds. The issue has certain similarities to that decided in <u>Gilbert v Sandoz</u>. We are consequently persuaded that there is adequate disclosure of methods (c), (d) ξ (e), and that the rejection based on Section 36 should not be maintained. We are satisfied that those skilled in the art would be able to make the desired compounds using any of the three methods without difficulty.

Turning to the second main branch of the examiner's objection, we must look at subsection (1) of Section 41 of the Patent Act. It provides that:

In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents.

(underlining added)

It is the examiners view that this provision would be rendered "completely inoperative, through the simple expedient of adjoining an exhaustive list of
known methods as alternatives to the method employed in the original synthesis."
He considers the provision would become a dead letter if a compound claim
could cover all methods of making the compound.

We have already discussed the <u>Gilbert v Sandoz</u> case, in which, the invention, it may be noted, was also governed by Section 41. In finding the process for making the bromine derivatives valid, the Supreme Court implicitly determined that the claim to it satisfied Section 41.

In <u>Hoechst Pharmaceuticals v Gilbert</u> (1965) 1 Ex. C.R. 710 and 1966 S.C.R. 189 both the Exchequer Court and the Supreme Court considered claims for several processes to make new pharmaceuticals. The lower court made the following observations:

(at p. 720)... There follow several pages of general description of the methods - all of which were already well known to chemists and of various starting materials of which it is stated that many of them "suitable for use in the present process have been described in the literature." Up to the end of this portion of the disclosure 'lere is accordingly nothing whatever to indicate a patentable invention for there is nothing inventive in applying known methods to known materials or kinds of materials even if no one has previously applied the methods to the particular materials and even if the result is a new product. To have a patentable invention the products in such a cas: besides being new must be useful in the patent sense and only if they are both new and useful can they and the process for producing them be the subject of a patent. Vide Jenkins, J. in Re May & Baker et al (65 RPC 255 at 281).

and at p. 726

.... In the case of each patent the method of preparing the ureas referred to in claim 1 was not new and it is stated in the patent that many of the starting materials were already known. It was moreover admitted in the course of the trial that for the purposes of this case it could be taken that all of them were known. In this situation, the principles stated by Jenkins, J. in Re May & Baker (supra) and applied by the Supreme Court of Canada in Commissioner of Patents v. Ciba Ltd. (1959 S.C.R. 378) appear to me to apply.

The court subsequently held the claims invalid for "preposterous" overclaiming because it could not be said that "... all, or substantially all, members of the class of sulphonyl ureas defined in them possess some previously unknown

usefulness." (p. 731) But implicit in its findings is the proposition that absent broad overclaiming and if it would be a sound prediction that substantially all the members of the class possessed the required utility, then the process claims would be valid. The Supreme Court put it this way (p.191):

It is conceded that tolbutamide, standing by itself, could have been the subject matter of a valid patent if claimed as such when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent or by their obvious chemical equivalent. (underlining added).

In the application we are considering, no objection has been made that the breadth of the class of products produced by the processes is too great, and that consideration does not arise.

It will also be useful to consider what was said in <u>Boehringer Sohn v Bell</u>

<u>Craig</u> 1962 Ex. C.R. 201, where the effect of the phrase "particularly described and claimed" in Section 41, subsection (1) was weighed. At p. 235 we find:

When s. 41(1) applies...it requires that the claim to such substance be limited to that substance when prepared or produced by the methods or processes which have been (a) particularly described, and (b) claimed, or (c) by the obvious chemical equivalents of the methods or processes which have been particularly described and claimed.

Here, the only limitation expressed in claim 8 is contained in the words "when produced by the process of claim 1, 2 or 3, or by an obvious chemical equivalent". And when one turns to claim 1 to see what process for preparing or producing 2-phenyl-3-methylmorpholine is therein claimed, one finds that it is not a claim for a process for the preparation of that substance but a claim for a process for the preparation of an enormous class of substances of which this substance is but one. In my view, claim 1 is not a claim for a process for the production of 2-pheny1-3-methylmorpholine even though that substance is one of the class, because it is clear that not all the members of the class of starting materials can be used to make 2-phenyl-3-methylmorpholine and claim 1 does not say that they can be used for that purpose, and at the same time, claim I does not say what starting material or materials may be used to make 2-phenyl-3-methylmorpholine. It thus does not state distinctly or in explicit terms any process for the production of that substance and we are back at the comment made earlier, that claim 1 as expressed does not fit the invention of 2-pheny1-3methylmorpholine, but is a claim related solely to the alleged invention of the process for production of the class of substances. In Winthrop Chemical Co. Inc. v. Commissioner of Patents, the Supreme Court held that "a claim cannot be entertained for a substance failing within s-s. (1) of s. 41 unless a claim is also made in respect of the process by which it is produced", vide Martland J. in Parke, Davis & Co. v. Fine Chemicals of Canada, Ltd.; "A process implies the application of a method to a

material or materials", per Martland J. in <u>Commissioner of Patents</u> v. Ciba Ltd..

and at p. 237:

It was also urged in connection with the same submission that under s. 41(1) the claim for 2-phenyl-3-methylmorpholine must be limited not only to that substance when prepared by methods or processes which have been particularly described, or their obvious chemical equivalents, and that the claim to that substance in claim 8 is not limited to the methods or processes which have been particularly described. This, in my opinion, raises a second fatal objection to the validity of claim 8. The only processes for the preparation of 2-phenyl-3methylmorpholine which, in my opinion, can be said to be particularly described anywhere in the specification are those described in examples 2 and 9. Example 2 describes a process for production of 2phenyl-3-methylmorpholine by dissolving B-phenyl-a-methyl-B,Bldihydroxydiethylamine-hydrochloride in concentrated sulphuric acid, allowing it to stand overnight at room temperature, then making alkaline and extracting. Example 9 describes a process by which the same diethanolamine hydrochloride is warmed with 10 per cent hydrochloric acid for six hours in a water bath and the product then worked up "in the usual manner".

The claim to 2-phenyl-3-methylmorpholine in claim 8 is not stated to be limited to that substance when prepared or produced by these two processes or by their obvious chemical equivalents. It is not even stated to be limited to that substance when produced by the processes which were described generally, earlier in the specification or their obvious chemical equivalents, since the processes so described consist only in (a)introducing a diethanolamine of the class without heating into concentrated (96%) sulphuric acid; or (b) by treating it with diluted acid at a moderate temperature. Thus, even if contrary to my opinion, the general description of these processes could be regarded as sufficiently particular to meet the requirements of the expression "particularly described" in s.41(1), and, if also contrary to my opinion, claim 1 does claim a process for the preparation or production of 2-phenyl-3-methylmorpholine, claim 8 would still not comply with the subsection.

To limit the substance claim of claim 8 only by reference to the substance when prepared by the process of claim 1, or an obvious chemical equivalent, is to ignore the requirement of s. 41(1) that the claim be limited as well to the substance "when prepared or produced by the methods or processes of manufacture particularly described...or by their obvious chemical equivalents". For, as previously pointed out, claim 1 is not limited as is the description to the use of concentrated sulphuric acid at room temperature and to the use of dilute acid at moderate temperatures, nor to the production of the morpholine ring closure by the action of acid on the dicthanolamine. Nor do I think that whatever is embraced in claim 1 is necessarily embraced either within the processes described in the specification, or their obvious chemical equivalents". For, as previously pointed out, claim 1 is not limited as is the description to the use of concentrated sulphuric acid at room temperature and to the use of dilute acid at moderate temperatures, nor to the production of the morpholine ring closure by the action of acid on the diethanolamine. Nor do I think that whatever is embraced in claim 1 is necessarily embraced either within the processes described in the specification, or their obvious chemical equivalents. Claim 8 is thus broader than s.41(1) permits and is accordingly invalid.

The Supreme Court affirmed (1963 S.C.R. 410) one of the reasons of the lower court - without expressing an opinion on the others - by holding that the process claim was too broad and therefore invalid, and that the product claim dependent on 't was invalid by virtue of that depending upon an invalid process claim. From what it said in the <u>Gilbert v Sandoz</u> decision (supra), however, we think it can be taken that every method claimed need not be illustrated in full detail. However the "very process" by which a product is manufactured must be claimed where Section 41 applies before the product may be claimed. As the Supreme Court said in Boehringer (p.414):

... The subsection (41(1)) was intended to place strict limitations upon claims for substances produced by chemical process intended for food or medicine. Such a substance cannot be claimed by itself. It can only be claimed when produced by a particular process of manufacture. Not only that, the claimant must claim, not only the substance, but that very process by which it is manufactured....(underlining added).

In our case each product claim is dependent on a process claim which produces it. The issue of overclaiming has not been raised, and does not seem to be present. And in any event, the claim which has been refused is a process claim, not a product claim to which objections for failures in particularly claiming would be more properly addressed.

In <u>Societé Rhône-Poulenc v. Gilbert</u>, 1967 S.C.R. 45, the Supreme Court did not have any compunction about multiple methods being claimed where Section 41 is involved, and the methods are all known. It said, at p. 48:

This s. 41(1) patent is for a substance produced by three methods or processes. This is permitted by s. 41(1). Section 41(1) does not make it necessary to have three separate applications for the same substance, one by each process....

The patent was subsequently found invalid (1967, 35 F.P.C. 174 and 1968 S.C.R. 950) for overclaiming, because the class of substances claimed was much too broad for the invention made, and in the class of compounds claimed many were not therapeutically useful. That, however, is not the objection made in the rejection of this application. The Exchequer Court also found there was an inadequate disclosure of the therapeutic use of the substances claimed, an

objection which conceivably might have been made, but the examiners implicit acceptance of methods (a) & (b), and of product claims dependent thereon rules out that consideration at this time,

In <u>Bochringer Sohn v. Bell-Craig</u> (1962) Ex. C.R. 201 and (1963) S.C.R. 410, Martland J., in delivering the judgement of the Supreme Court, said of the Section 41 at p. 414:

... The subsection was intended to place strict limitations upon claims for substances produced by chemical process intended for food or medicine. Such a substance cannot be claimed by itself. It can only be claimed when produced by a particular process of manufacture. Not only that, the claimant must claim, not only the substance, but that very process by which it is manufactured. To comply with the subsection he must, therefore, make two claims. In my opinion this means that he must make valid claim to both the process and the substance, if he is to be entitled, successfully, to claim the latter. To interpret the subsection as meaning that all that is necessary is to file a claim for the process, valid or not, would be to defeat its purpose. A person who claims a substance within the subsection, supported only by a process claim which is invalid, is in no better position than was the respondent in the Winthrop case (Commissioner of Patents v. Winthrop Chemical 1948 S.C.R. 46). In the Winthrop case the claimant had claimed too little. In the present case he has claimed too much....

It is thus clear that there must be present a valid process claim. The Court then proceeded in Boehringer to find the process claim invalid, not, it should be noted, because the process was defined inadequately, but because it was too broad, since it covered the production of a large number of compounds which did not possess the utility ascribed to them. That particular objection has not been made by the examiner in the present case, the scope of the product claim is much more circumscribed, and, more important, the breadth of what is claimed is supported by numerous examples of compounds within the class possessing the desired utility, sufficient in number we believe, to surmount the obstacle upon which Boehringer foundered. In this instance, it is probable that "a substantial number of the conceivable substances comprised within the class defined" (Boehringer, p. 413) have the utility referred to in the specification.

If the applicant is not allowed to protect his invention by claiming such obvious ways of making it as are disclosed "... some area is left open between what is the invention as disclosed and what is covered by the claims, (and) the patent may be just as worthless as if it was invalid. Everybody will be free to use the invention in the unfenced area." (Burton Parsons v'Hewlett Packard, S.C.C., 17 C.P.R. (2d) 97 at 106) Later on the same page the Court refused to approve an objection that the claims covered "every practical embodiment," leaving it to the man skilled in the art to work out the details.

In <u>Boehringer Sohn v Bell Craig</u> 1962 Ex. C.R. 201 at 235 (affd. 1963 S.C.R.410) we also find that S. 41(1) requires that claims to "substances be limited to that substance when prepared or produced by the <u>methods or processes</u> which have been (a) particularly described, and (b) claimed, or (c) by <u>the obvious chemical equivalents</u> of the <u>methods or processes</u> which have been particularly described and claimed." (Emphasis added)

What we distil from these several cases relative to the matter now before us is the following.

- (1) A process claim is bad if it claims so broadly as to encompass the production of inoperative species, or so broadly that it is improbable that a substantial number of the substances made by it do not possess the utility claimed for them. It cannot be speculative, nor encompass large numbers of compounds which have never been prepared.
- (2) Where Section 41 applies the applicant can only claim such methods as are specifically described, or, provided they are specifically referred to, one skilled in the art would readily appreciate how to carry them out.
- (3) A chemical compound governed by Section 41 can only be claimed when made dependent upon a process claim which prepares it. If it is dependent upon a broad process claim which is bad for over-claiming, then it too is bad.

It is also important in our view, that it be clearly indicated in the original disclosure that the process has been carried out and is operative.

A reference, to a "possible" process for preparing the products would we think be speculation, and not meet that test. In this disclosure, however, we find clear indications that the process has been tried and operates. For example in describing process (e) on page 7 of the specification the solvents used, the temperatures employed, and information about the reaction are given in some detail.

Consequently we are satisfied that claim 1 should not be rejected on the grounds applied against it, and recommend that the refusal be withdrawn. This should not be taken as meaning, however, that broad process claims are always allowable, nor that they are allowable where the factual situation is different, nor that there might not be other reasons for refusing them. In many instances broad process claims which derive their patentability from the new and unobvious utility of the products they produce may be objectionable as speculative, for encompassing the production of groups of compounds so large that it is improbable that a substantial number of the substances made by it possess the utility claimed for them, when it is evident that many of the compounds have never been prepared, or where there has been an inadequate disclosure of how the compounds have been used. These, however, were not the objections made against claim 1.

G. Asher Chairman

Patent Appeal Board

I concur with the findings of the Patent Appeal Board, and direct that claim 1 should not be refused for the reasons given in the final rejection. The application is to be returned to the examiner to resume prosecution.

J.H.A. Gariépy

Commissioner of Patents

Dated at Hull, Quebec this 19th day of August, 1976

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