COMMISSIONER'S DECISION

INSUFFICIENCY OF DISCLOSURL: New Amines

The applicant claimed several ways of making certain new amines useful pharmaceutically. Only some of the processes were described in any detail. It was concluded that the remaining processes were mere conjecture, and on the evidence it could not be said that they had been invented. Other processes refused by the examiner were held to be sufficiently disclosed.

Rejection: Modified.

The Patent Appeal Board has held a Hearing to review the final rejection of patent application 101368, Class 260-239.17. In the application the applicant, Ciba-Geigy AG, assignee of Max Wilhelm, claims certain new chemical components which are useful medically. The applicant was represented at the Hearing by Mr. R. Fuller.

At the time of the rejection, the application contained both process claims and product claims dependent on the process claims (as is required by Section 41 of the Patent Act). The examiner objected to the product claims as being too broad. By amendment subsequent to the Final Action, the product claims were restricted to comply with the examiner's requirement, and they are no longer in issue.

We are left with the refusal of the process claims (now claims 1-16 as amended on August 1, 1975). Claims 1 and 11 illustrate what they cover:

1. A process for the manufacture of new amines of formula I

wherein R_1 represents hydrogen or lower alkyl; R_2 represents lower alkyl; R_3 represents lower alkyl, and Ph represents a meta- or paraphenylene radical, unsubstituted or substituted once by alkyl or alkenyl with 1 to 4 C-atoms or by halogen, and pharmaceutically acceptable salts thereof, which comprises a) reacting a compound of formula V

wherein R_1 , R_2 and Ph have the above significance, N_1 resolvents the hydroxyl group and T represents a reactive extensional hydroxyl group, or N_1 and T together form an epoxy group, with an amine of the formula

wherein R_3 has the above significance; or b) reacting a compound of formula VI

wherein R_{1} , R_{2} and Ph have the above significance, with a compound of the formula

$$Z-R_3$$

wherein Z and R3 have the above significance; or c) reacting a compound of formula VIII

$$\begin{array}{c} R_1 \longrightarrow N - \stackrel{O}{C} - NH - Ph - OH \end{array}$$
 (VIII),

wherein R_1 , R_2 and Ph have the above significance, with a compound of formula X

$$z - CH_2 - CH - CH_2 - NH - R_3$$
 (IX),

wherein Z, X_1 and R_3 have the above meanings; or d) removing from a compound of formula I wherein R_1 , R_2 , R_3 and Ph have the above significance and which possesses a removable radical on the nitrogen atom of the amino group and/or on the hydroxyl group, said radical or radicals; or e) reducing a Schiff base of formulae XII or XIII

$$R_1$$
 OH OT $N - C - NH - Ph - O - CH2 - CH - CH2 - N = R3' (XIII),$

or a ring-tautomer, corresponding to formula XIII, wherein R_1 , R_2 , Ph and R_3 have the above significance and R_3 'H is the same as R_3 ; or f) reducing in a compound of formula XVI

$$R_1$$
 $N - C - NH - Ph - O - CH2 - C - CH2 - NH - R3 (XVI),$

wherein R_1 , R_2 , R_3 and Ph have the above significance, the 2-oxo group to a hydroxyl group; or g) reacting a reactive acid derivative of a carbamic acid of formula XVII

OH

HOOC - NH - Ph - O -
$$CH_2$$
 CH - CH_2 - NH - R_3 (XVII)

wherein Ph and \mathbf{R}_3 have the above significance, with an amine of formula

$$R_1$$
 - NH - R_2

wherein R_1 , and R_2 have the above significance; and, when required, resulting racemates are resolved into the optical antipodes, and/or resulting free bases are converted into their pharmaceutically acceptable salts or resulting salts into the free bases or into other salts which are pharmaceutically acceptable.

11. A process as claimed in claims 1 to 3, wherein compounds of formula III

$$R_{1} \stackrel{\text{OH}}{\longrightarrow} N-C-NH \stackrel{\text{OH}}{\longrightarrow} 0-CH_{2}-CH-CH_{2}-NH-R_{3}"$$

$$R_{4} \stackrel{\text{OH}}{\longrightarrow} 0$$

$$R_{5} \stackrel{\text{OH}}{\longrightarrow} 0-CH_{2}-CH-CH_{2}-NH-R_{3}"$$

$$(111)$$

are prepared in which R_1^{\prime} and R_2^{\prime} each represents lower alkyl, R_3^{\prime} represents lower alkyl, R_4^{\prime} represents hydrogen or chlorine or represents alkenyl with 1 to 4 C-atoms, from corresponding intermediates of the various formulae given in claim 1 in which R_1 , R_2 and R_3 have the same values as given above for R_1^{\prime} , R_2^{\prime} and R_3^{\prime} and Ph is a p-phenylene radical substituted by R_4^{\prime} as defined above.

The examiner refused such claims on the ground that there was inadequate support for them in the disclosure. He has stated that there is no specific description of processes b to g referred to in claim 1, that they are not particularly described, and (to quote):

- a) none is described at all, therefore insufficiency under Section 36(1).
- b) they are not true equivalents of the method described.
- they require millions of starting materials the majority of which may not exist.
- d) their value is pure conjecture at best.
- e) their presence in the claims deprives the public of the corresponding basic right afforded by Section 41(1).

On the other hand, it is the applicant's position that it is not necessary for him to provide working examples for all the processes claimed because they are directed to methods known generally, and that it would be apparent to those skilled in the art that they could be used to make the compounds desired. He has pointed to the "extensive" description given on pages 11 to 18 of the disclosure. To quote from his response of August 1, 1975:

Applicants believe that it is not necessary for them to exemplify every process specified by means of a worked example but that they should provide sufficient information in their specification to enable the man skilled in the art to understand the invention and to be able to put it into practice on the basis of the disclosure. Applicants believe that this requirement has been completely fulfilled in the present case. Thus, for the Examiner to allege that "one method of preparation does not provide support for all or any other methods" is to ignore two things:

- this invention resides in the useful properties of the products described and
- 2. a detailed description of the various aspects of the process is set out on pages 11 to 18 of the specification.

It is his view that where Section 41 applies, applicants are entitled to claim all known methods "set out" in their specifications, and cites for that proposition Sandoz v. Gilbert 1974 S.C.R. 1336 (8 C.P.R. (2d)210) where the Supreme Court of Canada concluded that where a detailed description of a process for making a phenothiazine using a chloroethane amide had been described in detail, it was not necessary to give the same detail in describing the process when bromoethane amide was used.

He has further submitted that:

The court decisions to which the Examiner has drawn applicants' attention largely primarily attack the claims of the patents concerned on the basis of their undue breadth in respect of the compounds claimed. As previously noted these objections are believed to largely fall away because of the restrictions now made to the scope of the products which are claimed. None of these decisions are considered to be as pertinent in respect of the process claims as the <u>Sandoz v. Gilcross</u> decision which has been discussed in some detail above.

Finally, to deal with the Examiner's remaining objections of the process variants b) and g) which are set out on the last page of the Final Action, applicants have the following comments to make.

- a) The detailed description of these process variants is provided by the detailed description on pages 11 to 18 of the disclosure. It is therefore completely untrue to say that applicants have not satisfied the requirements under Section 36(1) of the Patent Act see the other comments on this point above.
- b) The allegation that "they are not true equivalents of the method described" is not understood. First it is pointed out above that all the methods a) and g) are described in the disclosure. Second, the methods are known and applicants have described them as all applicable to the preparation of the required compounds. Clearly therefore applicants regard them as equivalent and presumably such a view can only be successfully contested [by] the Examiner if he provides clear evidence to the contrary or establishes that one or more of the methods claimed is inoperable. In the absence of such evidence, the Examiner has no right under the Statute to contest the applicants' statements in the disclosure which are made under oath.
- c) In view of the drastic restriction to the scope now made to the claims this objection is believed to have been completely overcome.
- d) Surely the value of these processes is for the applicants to decide not the Examiner. To suggest that they are merely conjecture is clearly untrue in view of the clear proof that applicants have provided in the response filed on this application on October 23, 1972 showing that these processes are not mere speculation but processes which can be used to produce the required compounds.
- e) This objection is not understood. Applicants are clearly entitled under the Patent Act and particularly by Section 41(1) to claim all the known processes for preparing all the useful products that they have described in their disclosure. How the present claims could deprive the public of the corresponding basic right afforded by Section 41(1) is not understood as any further process which is not described by applicants is available to the public to use without restriction provided further patents have not been obtained because they are inventive.

At the Hearing the examiner distinguished the present situation from that in Sandoz on the basis that in Sandoz the method used when bromoethane is employed is the same as that utilized when chloroethane is used, whereas in this application distinctly different methods are claims. In Sandoz the

method was one of condensing 3-methylmercapto-Phenothazine with an ω -halogen-alkyl-amide. In the words of the Supreme Court (p.1338):
"Claims 2 and 3 cover the <u>same process</u> using the chloro-ethane and bromo-ethane amide respectively."

As to the Examiner's objection that the processes described by the applicant are of a speculative nature, the applicant has this to say:

Another objection of the Examiner made in the Final Action was that the process variants which are not exemplified represent mere conjecture. Applicants strongly contest such a view for several reasons.

- 1. The Examiner has produced no evidence to indicate that the processes would not produce the required products.
- 2. The specification is filed together with a sworn petition and therefore the statements must be taken as true in the absence of any evidence to the contrary.
- 3. The Examiner's objection is clearly untrue in view of the clear proof that applicants have provided in the response filed on this application on October 23, 1972 showing that these processes are not mere speculation but processes which can be used to produce the required compounds.

The first question which must be determined, then, is whether there is an adequate description of the processes claimed, and the second is, whether such disclosure as has been made is speculative rather than factual.

The onus of disclosure that Section 36 places upon an inventor is both heavy and exacting (cf. RCA v. Raytheon 1956-1960 Ex. C.R. 98 at 109). In that decision the court 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).

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

At the same time, 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 the invention may claim it as broadly as it would normally be construed by persons skilled in the art (Riddel v Patrick Harrison (1956-1960) Ex. C.R. 213 at 253). And

Where a specification describes 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. (B.V.D. v. Canadian Celanese, 1936 Ex. C.R. 140).

In <u>Gilbert v Sandoz</u> (<u>supra</u>), at p. 52, whereas 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 (1974 S.C.R. 1336 at 1344) reversed, holding that:

... 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.

In this case the products produced by the processes claimed are medicines. Since the processes involve standard chemical methods, and would be unpatentable were they not to derive patentability from the medicines (cf <u>Ciba v.</u> <u>Commissioner of Patents</u> 1959 S.C.R. 378), we are also concerned with subsection (1) of Section 41 of the Patent Act, and in particular its requirement that the processes be "particularly described." It states 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)

We have already referred to 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 using the bromine derivatives valid, the Supreme Court implicitly determined that the claim dependent on 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 there 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 case 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 and 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, the objection of undue breadth in the product claims has been satisfied by the latest amendment.

It will also be useful to consider what was said in <u>Bochringer 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 required 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-phenyl-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 1 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-phenyl-3-methylmorpholine, 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 falling within s-s. (1) of \$. 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 Commissioner of Patents 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-3-methylmorpholine 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 2-phenyl-3-methylmorpholine by dissolving B-phenyl-a-methyl-B,Bl-dihydroxydiethylamine-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". 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. [underlining added]

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 it was invalid by virtue of that depending upon an invalid process claim. From what it said in the Gilbert v Sandoz 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 Bochringer (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 been met, and 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>Société Rhône-Poulenc v Gilbert</u>, 1967 S.C.R. 45, the Supreme Court did not object to multiple processes being claimed where Section 41 is involved, and the processes were all described. 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 objection cannot be made in this case.

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 claims 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 objection does not now exist in the present case, the scope of the product claim has been circumscribed, and the breadth of what is now claimed is supported by sufficient examples of compounds within the class possessing the desired utility, to surmount the obstacle upon which <u>Boehringer</u> foundered. In this instance, it is probable that "a substantial number of the conceivable substances comprised within the class (as now) defined" (<u>Boehringer</u>, p. 413) have the

utility referred to in the specification.

If the applicant is not allowed to protect his invention when made by all the obvious ways of making it, then, as was said by the Supreme Court in Burton Parsons v Hewlett Packard (17 C.P.R. (2d) 97 at 106), if "... some area is left open between what is the invention as disclosed and what is covered by the claims, the patent may be just as worthless as if it was invalid. Everybody will be free to use the invention in the unfenced area" 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.

The same conditions were present, and conclusions reached, in <u>Bochringer</u>
Sohn v Bell Craig 1962 Ex. C.R. 201 and 1963 S.C.R. 410.

What we distil from these cases relative to the issue now being considered 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 substance made by it do not possess the utility claimed for them. It cannot 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 overclaiming, then it too is bad.

We have come to the conclusion that the methods are standard methods known to the skilled chemist. This is confirmed by the amendment of October 23, 1972, showing that variants c, d, e, f and g can be used to prepare the desired compounds. What concerns us, however, is whether at the beginning of 1970 (the priority date of the application) it can properly be said that the inventor had made the invention

claimed, or whether on the contrary at that time the processes (as distinct from the products) were speculative. What we must next determine is whether on the evidence before us the applicant had completed his invention in 1970 in sufficient detail that it can be fairly said that he invented all of the processes claimed.

The objection that a claim is too broad because it covers unknown and unchartered areas where the applicability of the invention is unpredictable, and further inventive experiments would be needed, arises most frequently in the chemical arts. It has been said that "There is no prevision in chemistry" (Chipman Chemicals v. Fairview Chemical 1932 Ex. C.R. 107 at 115), and while that may be an overstatement, nevertheless it indicates the special caution to be exercised when making assumptions in the chemical arts. Since claims are defective if they are speculative, there are important limitations upon an inventor's right to generalize.

In <u>Hoechst v. Gilbert</u>, (1966) S.C.R. 189, a chemical case where certain drugs were claimed, the Supreme Court of Canada has come out (at p. 194) against speculative claiming in these terms:

In challenging the validity of the patents in question, counsel for the respondents put his case upon the footing that no one could obtain a valid patent for an improved and untested hypothesis in an unchartered field. That is what the appellant has tried to do in claim 1 of each of the patents. It has sought to cover, in the words of Thurlow J., "every mathematically conceivable sulphonyl area of the class" and has consequently overclaimed, and, in so doing, invalidated claim 1 in each patent.

The point was also considered in Rhône-Poulenc v Gilbert (1968) S.C.R. 950 at 953.

In <u>Steel Co. of Canada v. Sivaco Wire and Nail</u>, 11 C.P.R. (2d) 153 at 195, we find the term "mere paper suggestions" applied to patents for inventions which have not been developed.

In <u>B.V.D. v Canadian Celanese</u> (1936) Ex. C.R. 139 at 148 it was stated that before a prior patent may be relied upon to anticipate a later patent "It must be shown that the public have been so presented with the invention that it is out of the power of any subsequent person to claim the invention as his own. And an improvement, claimed to be invention, must not be dismissed

as unpatentable merely because of some vague adumbration of it in the prior art." It seems to us that a corollary of that, which should be equally valid, is that a prior patentee should not be entitled to claim an invention which he may have outlined or foreshadowed without bringing it into being. The Supreme Court (1936 S.C.R. 221 at 237) found the B.V.D. patent invalid because: "The claims in fact go far beyond the invention."

In Boehringer Sohn v Bell Craig, 1962 Ex. C.R. 201 we find:

... a patent purporting to give an exclusive property in more than the inventor has invented is also contrary to what the statute authorizes....(p.239)

and

... a patent which includes in its specification a claim which claims more than the inventor has invented purports to grant an exclusive property in more than the inventor has invented and at least in so far as that claim is concerned the patent, in my opinion, is not granted under the authority of the statute and is therefore not lawfully obtained. ...a claim which is invalid because it claims more than the inventor invented is an outlaw and its existence as defining the grant of a property right is not to be recognized as having any validity or effect (p. 241).

Mr. Justice Thurlow found the claim in suit to be too broad because it covered a large number of substances of which only a limited number had been prepared. The Supreme Court (1963 S.C.R. 410 at 412) supported his findings. The Boehringer Sohn case involved pharmacological substances whose properties may be even less predictable than other chemical substances, and the group of compounds claimed was extremely large. Similar conclusions in comparable circumstances were reached in <u>Hoechst v. Gilbert</u> (1964) vol. 1, Ex. C.R. 710 and 1966 S.C.R. 189, and in <u>Re May and Baker</u> (1948) 65 R.P.C. 255, (1949) 66 RPC 8 and (1950) 67 R.P.C. 23. The Supreme Court, in the Hoechst decision, adopted the view that "no one could obtain a valid patent for an unproved and untested hypothesis in an unchartered field." The dangers of speculative claiming were also explored in <u>Société Rhône-Poulenc v Ciba</u> (1967) 35 F.P.C. 174 at 201-205 and 1968 S.C.R. 950 in which a broad claim was found invalid because the majority of the substances of the class had never been made or tested by anyone.

Objections of this nature are not, however, limited to pharmaceutical inventions, or even to chemical inventions. In the Matter of Abraham Esau et al (1936) 49 R.P.C. 85, it was said of an electrical apparatus that

I think that it is most desirable that patentees in such circumstances should realize that it is not the practice of the Patent Office to allow broad and indeterminate claims of a speculative character, and that if they put such claims into their complete specification, they must expect to find them disallowed unless they are able to give a sufficiently detailed and full description to support them.

In the Matter of Shell Development, (1947) 64 R.P.C. 151 the application involved a process for separating organic mixtures with sulfolane solvents. The ten detailed examples dealt with separations where the organic mixtures were all hydrocarbons, and while there was no detailed description of processes involving other organic mixture, the specification listed some forty mixtures other than hydrocarbons. In finding the claim too broad, the Patent Tribunal stated:

It is, I think, sufficient to say that from the specification it appears, first, that the prior art consists in the separation of organic mixtures by the use of well known solvents; secondly that the extent to which the field, namely, the separation of organic mixtures by the use of solvents has been explored does not appear on the face of the specification, but, upon a fair reading of the document, I am satisfied that it does not assert, putting the matter at its highest, that anything like the whole of that field has been explored; thirdly, that the Applicants' claim that the employment of their sulfolane solvents, of which they give in the specification a list of over one hundred, give results which compare advantageously with other solvents hitherto used; fourthly, that the Applicants make clear that the methods of employing their solfolane solvents are those which are already well known in relation to the prior art; fifthly, that the Applicants in their specification give particulars of ten experiments, all of which deal with hydrocarbons. It is further, in my view, a fair reading of the specification that the solvent effect of the sulfolanes has been explored by the Applicants primarily in regard to hydrocarbons. It is true that on page 4 of the specification other examples of organic compounds are referred to which, it is stated, "may be separated by the selective solvents of this invention"; but, even so, with the addition of those substances, only the fringe of the field in question is touched.

See also Rohm & Haas v. Commissioner of Patents, (1959) Ex. C.R. 153 where claims were refused for being too broad and going beyond the invention made, Vidal Dyes v. Levenstein (1912) 29 R.P.C. 245, and Eastman Kodak's Application (1970) R.P.C. 548 at 561-563.

The problem before us is not peculiar to Canadian or British jurisprudence. It has also been considered in the United States, for example, in <u>In re Stokal</u> et al, 113 USPQ 283 (1957).

The practical problems which can develop from permitting broad speculative claims are illustrated by the reasons leading to the introduction of both Section 41 into the Canadian Patent Act in 1923, and Section 38A into the British Patent and Designs Act in 1919. Section 38A came into being to remedy an abuse which led to the domination of the British dye industry by foreign interests who obtained broad chemical claims covering substances which they had never made or tested, and who subsequently used such claims to restrict the activities of their competitors (Transactions of the Chartered Institute of Patent Agents, vol. 62, p. 92).

When we turn to the specification now before us, we find that many of the processes are merely proposed processes for making the desired compounds, and such processes are described as "possible" ways to make the products. Indeed the whole disclosure in so far as it relates to the processes is so rife with indications of what might possibly be done, and so replete with various alternatives and suggestions for modifications that it is quite apparent the draftsman could only have been speculating and casting his net far beyond what had really been done. It is only when we turn to the examples themselves that we can perceive any concrete statements about processes really used. They are all limited to process (a). In our view it would be completely inappropriate under such circumstances to allow the applicant to claim as widely as he proposes. To do so would be to condone "arm-chair inventioneering" and "paper chemistry" of the type censured in the decisions discussed above.

Process (a) and (b) both involve amination, with or without alkylation, done in a different sequence, and can, we think, he said to be the "same" process within the meaning of <u>Sandoz</u> (supra p. 5), where both processes found allowable were alkylations using an alkyl halide, in one instance the alkyl chloride, in the other the alkyl bromide. For that reason we would allow processes "a" and "b" to proceed together. The other processes, however,

are quite different. Process "c", for example, involves the preparation of an ether, (f) the synthesis of an alcohol from a ketone, and (g) a urea synthesis.

Recognizing the insufficiency of the disclosure, the applicant, on Oct. 23, 1972, submitted five new examples illustrating five of the six missing processes. We do not believe, however, that the applicant should be permitted to retain claims on the basis of something done after the event, and not part of the original disclosure.

It is on this basis, then, that we consider the examiner's objection was justified with respect to claims 1, 6-11, 14, 18, 19, 20, 21, 22, 23, 26, 27, 33-38, 44-49 as they were on file, and they were properly refused. The remaining process claims and product claims dependent thereon would be allowable where they are restricted to processes (a) & (b), or if not so restricted now when so limited by amendment.

The examiner also had other reasons to reject the claims on file, but we do not need to consider them in view of the amendments proposed on August 1, 1975, which overcame those objections. Of those proposed claims, 1, 6, 8, 9, 10 and 14 should be refused for the reasons stated above. The remaining claims would be allowable if claim 1 was restricted to process (a) or process (b).

Gordon Asher

Chairman

Patent Appeal Board, Canada

Having reviewed the prosecution of this application and the recommendations of the Patent Appeal Board, I have concluded that the claims now proposed by the applicant are unallowable, and I refuse them. However if claim 1 is amended as suggested by the Appeal Board, then claims 1, 2, 3, 4, 5, 7, 11, 12, 13, 15, 16, 17, 18, and 19 would be allowable.

J.H.A. Gariépy

Commissioner of Patents

Dated at Hull, Quebec this 7th day of February, 1977