COMMISSIONER'S DECISION

Support for broad claim in disclosure - Sec. 36

The broad claims, which relate to pharmacologically active compounds, were refused because no single compound corresponding to the eight radicals under rejection is fully described and characterized in the disclosure. Narrower claims would be supported, and allowable.

Final Action - Affirmed

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This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated Dec ber 1, 1975, on application 177,408 (Class 260-239.14). The application was filed on July 26, 1973, in the name of Graham Durant et al, and is entitled "Cyanoguanidines." The Patent Appeal Board conducted a Hearing on June 24, 1977, at which Mr. W. Mace represented the applicant. Also in attendance was the British Patent Agent, Dr. R.A.A. Hurst.

The application relates to pharmacologically active compounds, in particular to pharmacologically active cyanoguanidines, to pharmaceutical compositions comprising these compounds and to processes for their preparation.

In the Final Action claims 1 and 14 were rejected in their present form. The reason for such rejection is the presence in the definition of "Het" of eight radicals which define eight classes of compounds of which no representative individual is described in the disclosure. In that action the examiner also stated (in part) as follows:

> ...
>
> The radicals are oxazole, isoxazole, pyrazole, triazole, thiadiazole, pyrimidine, pyrazine and pyridazine.
>
> The standards of description of synthesis of organic chemical compounds have been established for more than one hundred years. As a result, organic chemistry is one of fields, where the norms governing the conditions of full disclosure required by the Patent System, are the best known, the clearest and the simplest.

> The text to which applicants refer in order to include the eight rejected classes of compounds in claims 1 and 14 does not describe claimable subject matter, in the light of the relevant Canadian jurisprudence, a sample of which is provided in the Manual of Patent Office Practice, chapter 9.
>
> The compounds covered by the radicals under rejection are not fully characterized and their utility may merely be suggested on the basis of their structural relationship with the compounds actually described. This does not meet, even closely, the stringent tests defined in the pertinent jurisprudence, especially in the unpredictable field of therapeutic activity.
>
> And the Vidal dilemma, adopted in Canada, for instance in the Rhone-Poulenc case, is fully pertinent: if applicants know more about the 8 classes of compounds than they disclose, they have not complied with the statute regarding full description: on the other hand if applicants know no more than the disclosure teaches, they are claiming an invention which was not made.

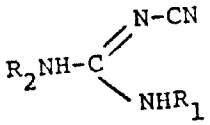
In response to the Final Action the applicant had this to say (in part) as follows:

> ...
>
> Applicant respectfully submits that there is no statutory requirement that all compounds set forth in the specification must include full physical characteristics nor is there any statutory requirement that each and every compound disclosed be fully tested. In applicant's opinion the specification and particularly the radicals objected to by the Examiner meet fully the requirements of Section 36(1) of the Patent Act which provides that the specification shall correctly and fully describe the invention and its operation or use "as contemplated by the inventor" - it is respectfully pointed out that Section 36(1) does not require the inventor to specifically disclose what was actually done by the inventor. It is respectfully submitted that if the inventor "contemplated" the various radicals within the scope of his invention, he then has a positive duty to disclose such radicals in view that he contemplated their use. If for example, the inventor contemplated the radical imidazole but did not specify such in his disclosure would he have complied with the requirements of the Patent Act if later testing showed such radical to be the "best mode"? It is thus a requirement on the part of the applicant to disclose all which is contemplated and based on such disclosure applicant should be entitled to frame claims of a similar nature.

> Applicant respectfully submits that all of the requirements of the Patent Act have been met, both in the present disclosure and with respect to claims 1 and 14 on file rejected by the Examiner. It is submitted that Section 36(1) of the Patent Act has been met in that applicant has, in the specification, described the invention as contemplated by the inventor and with the presence of the various examples in the disclosure including example 16 has set forth clearly the sequential steps of the process for making various compounds. It is further submitted that the requirements of Section 36(2) of the Patent Act have been fully met with respect to claims 1 and 14 in that both claim 1 and claim 14 do state distinctly and in explicit terms the things or combinations which the applicant regards as new. It is further submitted that applicant has complied with the requirements of Section 2 with respect to the definition of "invention" in disclosing new and useful compositions of matter. In addition all of the requirements of Section 28 of the Patent Act have been met as applicant believes that the inventor specified is the first inventor of the subject matter under consideration, the subject matter including the subject of claims 1 and 14. The jurisprudence indicated by the Examiner has been reviewed however such is not deemed to be either pertinent or applicable to the present circumstances. It is applicant's firm belief that if the teachings of the instant application are followed such will result in compounds all of which have the same utility. If by some remote chance unknown to the applicant some compounds are later found not to have the required utility the validity of claims covering such compounds may be in doubt. As previously discussed applicant is willing to accept this consequence and as applicant has previously stated all of the compounds disclosed and defined by claims 1 and 14 are believed to possess the disclosed utility.

The issue to be considered is whether or not claims 1 and 14 are supported by the disclosure. We have carefully studied the prosecution of this application and the remark made at the Hearing by Mr. Mace and Dr. Hurst. Claim 1 reads as follows:

> A process for the production of a compound of the formula



> wherein R_1 is hydrogen or lower alkyl; and R_2 is a grouping of the structure

$$\text{Het} - (CH_2)_m Z (CH_2)_n -$$

wherein Het is a nitrogen containing 5 or 6 membered heterocyclic ring selected from imidazole, pyridine, thiazole, isothiazole, oxazole, isoxazole, pyrazole, triazole, thiadiazole, pyrimident, pyrazine and pyridazine which ring may optionally be substituted by lower alkyl, trifluoromethyl, hydroxyl, halogen or amino; Z is sulphur, oxygen, N.H. or a methylene group; and m and n are integers from 0 to 4 such that their sum is from 2 to 4; in which an amine of the formula

$$R_2NH_2$$

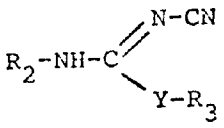
wherein R_2 has the above significance is reacted with a compound of the formula

$$(R_3\text{-}Y)_2C{=}N\text{-}CN$$

wherein R_2 has the above significance is reacted with a compound of the formula

$$(R_3\text{-}Y)_2C{=}N\text{-}CN$$

wherein R_3 is alkyl, aryl or aralkyl and Y is sulphur or oxygen to give an intermediate compound of the formula



wherein R_2, R_3 and Y have the above significance which intermediate compound is then reacted with an amine of the formula

$$R_1NH_2$$

wherein R_1 has the above significance.

We have no quarrel with the jurisprudence (which was discussed at the Hearing) with reference to the requirement of a disclosure as outlined by Thorson P. in Noranda Mines v Mineral Separation C.P.R. 99 - volume 12; nor with the statements, re utility, taken from Boehringer Sohn v Bell Craig (1963) S.C.R. 410.

To the jurisprudence relied upon by the applicant we add the recent findings of the Supreme Court of Canada in Burton Parsons Chemicals v. Hewlett-Packard, which has been reported in 17 C.P.R. (2d) Part 2, April 1975, 97 ff. In considering whether the claims of Burton Parsons were broader than the invention, Mr. Justice Pigeon stressed that:

> While the construction of a patent is for the Court, like that of any other legal document, it is however to be done on the basis that the addressee is a man skilled in the art, and the knowledge such a man is expected to possess is to be taken into consideration (p. 104).

and further

> The evidence makes it clear that this was obvious to any person skilled in the art because the characteristics of suitable emulsions and of suitable salts were well known.

From this it is clear that due consideration must be given to what persons skilled in the art would take from a disclosure.

The objection that a claim is too broad in view of the disclosure because it covers unknown and uncharted areas where the applicability of the invention is unpredictable arises most frequently in the chemical arts. Since claims are defective if they are speculative, there are important limitations upon an inventor's right to claim a generalization from his disclosure. Such claims, if allowed, may create needless litigation with useless expense and impede the true progress of the arts. We are more concerned by what <u>was</u> done by the inventor rather than statements of what may be done with the invention. We now turn to the jurisprudence which examines such issues.

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 overclaiming 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 has also been considered in <u>Rhone-Poulenc v Gilbert</u> (1968) S.C.R. 950 at 953.

In Steel Co. of Canada v. Sivaco Wire and Nail, 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 B.V.D. v Canadian Celanese (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 did involve, of course, 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 Hoechst v. Gilbert (1965) vol. 1, Ex. C.R. 710 and 1966 S.C.R. 189 and in Re May and Baker (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 overclaiming were also explored in Société Rhône-Poulenc v Ciba (1967) 35 F.P.C. 171 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.

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 been considered, for example, in In re Stokal et al, 113 USPQ 283(1957).

We will now consider claim 1. It is clear that each variation or radical of Het represents a class and there are twelve such representations. We find however, that no single compound corresponding to the eight radicals under rejection is fully described and characterized in the disclosure (eight of the twelve radicals in claim 1 were refused). On this point at the Hearing, Mr. Mace

pointed out that the present disclosure "provides a teaching as represented by Example 16 to which one skilled in the art can readily carry out [the invention]." Example 16 lists 13 compounds, introducing 8 different heterocyclics which are then added to the claims as valves for Het. Mr. Mace went on to say that "It is thus submitted that there is sufficient teaching in Example 16 to meet the standards of description of synthesis of organic chemical compounds and that the compounds outlines by Example 16 may be readily prepared." The specific question which must be answered is whether or not the text designated as Example 16 is sufficient to satisfy the requirements of Section 36(1) of the Patent Act.

Before reaching our conclusions we think it also appropriate to refer to a recent British decision, Olin Matheson v. Biorex (1970) RPC 157, and in particular to two passages, the first of which is taken from the arguments for the patentee, at p. 169:

> Inevitably in a case of this kind broad claims will be open to attack, but the question is whether the inventor ought to be limited to the actual substances which he has tested, and if he be entitled to venture a little further, how much further? If he were restricted to substances actually tested the value of the patent would be nil because the patentee would be making a present to those who would wish to avail themselves of the start made by him and thereby develop improvements upon his tested materials with impunity. Additionally, if the patentee was not entitled to claim more than what he had tested and verified as being useful, there would be no basis for selection patents. The other important point is that there is a world of difference between making a very broad claim in an unexplored field, and making one, as is the case here, where although the claim may cover millions of compounds, the field has been so well explored by others that one may rely upon their work in making a reasonable prediction as to the usefulness of all the compounds within the claim. [It should be noted that the invention involved the insertion of the CF_3 radical into the 2-position of a well known and 'well-worked' group of pre-existing compounds.]

The second is taken from the judgement itself, at page 193:

> Where, then, is the line to be drawn between a claim which goes beyond the consideration and one which equiparates with it? In my judgement this line was drawn properly by Sir Lionel when he

> very helpfully stated in the words quoted above that it depended upon whether it was possible to make a sound prediction. If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so [emphasis added].

This last paragraph puts succinctly what we have been able to distil from the jurisprudence discussed above. An applicant, in our view, should be able to put forward a claim in generic terms to a group of like substances, all of which need not have been prepared or tested, where it would be reasonably able and sound to make a prediction about the area covered.

A recent Canadian case is also very much to the point - Monsanto v Commissioner of Patents in the Federal Court (June 24, 1977) were Heald J. had this to say on a case which was concerned with broad claims where there was lack of support in the disclosure.

> We are all of the opinion that the Commissioner of Patents did not err in affirming the refusal of a patent in respect of Claims 9 and 16 in the appellant's application. The refusal is justified on the ground alone that the disclosure in the appellant's application is not sufficient to support the claim to such a broad range of new compounds. We would refer to the reasoning of Jackett, C.J. in the case of Leithiser v. Pengo Hydra-Pull of Canada Ltd. 17 C.P.R. (2d) 110 to the effect that full and explicit compliance with section 36(1) of the Patent Act requires a specification that tells all the world what the invention is and how to make use of it and also describes how to produce the product for which an invention is claimed. Claim 9 covers a vast number of compounds. Claim 16 claims, as the product of Claim 9, some 126 different specific compounds. The specifications provide details in respect of only three of these specific compounds. A perusal of these details makes it clear that detailed and specific instructions (different in a number of particulars in each case) are necessary in order for a skilled chemist to be able to make use of the invention. Such detailed and specific instructions are not contained in the specifications except for the three specific compounds referred to above.
>
> Further, the Commissioner was entitled to weigh the expert opinion as to whether there could be a sound or reasonable prediction that all the compounds would possess utility and to arrive at a contrary judgment or opinion on the basis of the finding and recommendation of his own advisors acting as the Patent Appeal Board.

In applying the above principle to the application before us it is abundantly clear, as mentioned, that no single compound corresponding to the eight radicals, under rejection in claim 1, is fully described and characterized in the disclosure. Example 16, lists 13 compounds, introducing eight different heterocyclics which are then added to the claims as values for Het. In other words the claim is extremely broad, and covers eight classes of compounds in which no representative individual is described in the disclosure. We think it goes beyond the area of reasonable prediction and have no hesitation in recommending the refusal of claim 1. Claim 14 is a product claim which is of the same scope as claim 1 and should also be refused. The arguments used in refusing claim 1 apply equally to it.

In the Final Action the applicant stated: "If by some remote chance unknown to the applicant some compounds are later found not to have the required utility the validity of claims covering such compounds may be in doubt. As previously discussed applicant is willing to accept this consequence...." We are not overly impressed with this act of coverage, especially while drafting narrow independent claims which are possibly immune to invalidity. This we perceive is further evidence that the claims are speculative. An applicant must not set out to monopolize "an unexplored field in organic chemistry so as to prevent others during the life of the patent from exercising their right to search in the field for new substances which might turn out to be useful or even more useful" (see Farbwerke Hoechst v Commissioner of Patents (1966) Ex. C.R. at page 91).

In summary, we are satisfied that claims 1 and 14 are not properly supported by the disclosure because no single compound corresponding to the eight radicals under rejection is fully described and characterized therein. We recommend that the decision in the Final Action to refuse claims 1 and 14 be affirmed. Claims 1 and 14 would however, in our view, be allowable if all the radicals from "OXAZOLE" to "PYRIDAZINE" inclusive were deleted from the claims.

J. J. Hughes
Assistant Chairman
Patent Appeal Board, Canada

I have studied the prosecution of this application and have carefully reviewed the recommendation of the Patent Appeal Board. In the circumstances I have decided to refuse claims 1 and 14 in their present form. I will however, accept claims when amended as suggested by the Board. The applicant has six months within which to appeal my decision under the provision of Section 44 of the Patent Act.

J.H.A. Gariepy
Commissioner of Patents

Dated at Hull, Quebec
this 22nd day of August, 1977

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