

Section 2; New Use for known compounds:

In view of Shell Oil v Commissioner of Patents (1982) SCR 536, the refusal of claims 1 to 4 for a new use of a known compound, and claims 7 to 9 directed to the use of a compound, were considered acceptable. Rejection withdrawn.

This decision deals with Applicant's request for review by the Commissioner of Patents of the Final Action on application 400,261 (class 167-238) filed March 31, 1982. It is assigned to Wayne State University and is entitled "Method for Treating Tumor Cell Metastasis and Growth". The inventors are W.D. Busse, K.V. Honn, E. Moller and F. Seuter. The Examiner in charge issued a Final Action on June 6, 1985 refusing to allow the application. A Hearing was originally requested but it was subsequently withdrawn by Applicant's letter dated June 2, 1988.

The subject matter of the application relates to a therapeutic method for reducing metastasis and neoplastic growth in a mammal. A therapeutically effective amount of 3-Methyl-1-[2-(2-naphthyloxy)-ethyl]-2-pyrazolin-5-one or a pharmaceutically acceptable salt is administered to the patient.

In the Final Action the Examiner refused allowance of claims 1 and 4 based on the teaching of United States Patent 4,053,621 and claims 7 to 9 on Section 2 of the Patent Act. That action stated (in part):

The applicant in his letter argues that claim 1 is patentable because it is directed to a pharmaceutical composition for reducing metastasis and neoplastic growth in a mammal. This argument however, does not overcome the objection to claim 1. As stated in the last Office Action, the composition of this application is the same as the composition taught in the United States patent even the dosage form (the reference is made to page 6 of this application and that of the U.S. patent). The examiner recognizes that the applicant has made a discovery, namely a new use for an old composition however, this newly discovered use does not make the old composition new and patentable.

The applicant's argument against the rejection of claim 4 has been noted however, it does not overcome the objection because again the active ingredient is known and the effective dosage form is taught in the reference cited above therefore, the direction does not make this claim patentable. The only difference between claim 4 and the teachings of the cited reference is the intended use and this difference is not enough to make claim 4 patentable.

Claims 7 to 9 directed to the use of a compound are not within the definitions for patentable invention in Section (2) of the Patent Act. The use is neither a process nor a composition. The applicant argues that the use of the active ingredient should be construed as extending to cover activities which can be regarded as "industrial" in character but not extending to the actual treatment of disease by administration of the active ingredient. This argument does not overcome the objection because as already mentioned above, the use describes neither the process nor the product (composition).

In response to the Final Action the Applicant added new claims 10 to 17.

That response stated (in part):

Applicant's invention resides in the determination that the compound 3-methyl-1-[2-(2-naphthyloxy)-ethyl]-2-pyrazolin-5-one or a pharmaceutically acceptable salt of this compound can be used for reducing metastasis and neoplastic growth. Applicant has therefore made an important invention. Indeed, the Examiner recognizes that Applicant has made a useful discovery. Considerable expense has been incurred in determining and proving the invention, and Applicant is naturally anxious to obtain whatever patent coverage is available to protect the invention. Clearly it is the intention of Parliament that, except in certain specified categories, inventions shall be the subject of patent protection. Furthermore, it is clearly the intention of Parliament that an Applicant for patent shall be accorded the benefit of any doubt as to whether he is entitled to a patent; see Section 42 of the Patent Act and also the words of Pigeon J. in Monsanto v. Commissioner of Patents in the Supreme Court of Canada. It is asserted, and the Examiner apparently agrees, that Applicant has made a valuable invention. Applicant is therefore entitled to a patent unless the invention falls within one of the aforementioned categories for which patent protection is not available. While, of course the Examiner is not permitted to allow claims to an invention which falls within one of the aforementioned categories, it is respectfully submitted that the Examiner should himself be anxious to allow claims to a valuable invention if he is permitted to do so.

Claims 1, 4 and 7 to 9 are rejected in the final action of June 6, 1985. They are rejected for reasons which were previously expressed in an Official Action of December 19, 1984. A detailed response to that Official Action was filed on March 19, 1985. Without repeating all the arguments of the letter of March 19, 1985, we wish to adopt them as part of the present response.

Applicant now puts forward additional claims for protecting different aspects of the invention. New claim 10 is directed to a method for determining antimetastatic or antineoplastic activity in vitro on particular tumor cells. This aspect of the invention is clearly not disclosed in the

cited United States Patent No. 4,053,621, which contains no mention of metastasis or neoplastic growth. It is therefore respectfully submitted that this subject matter is clearly allowable.

The issue before the Board is whether or not claims 1 and 4 patentably differentiate over the cited reference and claims 7 to 9 are within the definitions for patentable invention under Section 2 of the Patent Act.

Claim 1 reads as follows:

A pharmaceutical composition in dosage unit form suitable for oral or parenteral administration for reducing metastasis and neoplastic growth in a mammal, which comprises as active ingredient 3-methyl-1-[2-(2-naphthyloxy)-ethyl]-2-pyrazolin-5-one or a pharmaceutically acceptable salt thereof in an amount effective to reduce metastasis and neoplastic growth in a mammal, in admixture with a suitable pharmaceutically acceptable diluent or carrier.

Considering first the refusal of claims 1 and 4 based on the teaching of United States Patent 4,053,621. From the Final Action we are informed that the composition of the application is the same as that of the cited patent but the Examiner recognizes that the applicant has made a discovery "namely a new use for an old composition". He states that the "only difference between claim 4 and the teaching of the cited reference is the intended use and this difference is not enough to make claim 4 patentable".

The applicant argues that his invention resides in the determination that the compound 3-methyl-1-[2-(2-naphthyloxy)-ethyl]-2-pyrazolin-5-one or a pharmaceutically acceptable salt thereof can be used for reducing metastasis and neoplastic growth. He states that considerable expense was incurred in determining and proving the invention and that he is entitled to a patent since it is the intention of Parliament that, except in certain specified categories, inventions shall be the subject of patent protection.

We have reviewed the position of the Examiner and the arguments submitted by the Applicant. The comments of Mme. Justice Wilson in Shell Oil v. Commissioner of Patents Supreme Court of Canada November 2, 1982 are applicable when she stated the following:

If I am right that the discovery of a new use for these compounds which is capable of practical application is an "invention" within the meaning of the definition, I can find nothing in the statute which would preclude a claim for these compositions. Section 36 does not seem to present a barrier because the inventive ingenuity here lies in the new use for the old compounds and not in the compounds themselves. Having discovered the use, the appellant has then combined the compounds with the appropriate carriers for their application to plants. It is not, in my view, necessary in the case of the discovery of a new use for an old compound that the combination of the compound with the adjuvant be itself novel in any sense other than that it is required in order to give effect to this particular use of the compound. This is not a case where the inventive ingenuity is alleged to lie in the combination; the combination is simply the means of realizing on the newly discovered potential of the compounds. This is a case where the inventive ingenuity is in the discovery of the new use and no further inventive step is required in the application of the compounds to that use, i.e. in the preparation of the appropriate compositions.

Consequently we find that a new use for the known compound is an invention which may be entitled to patent claim protection. We recommend that the rejection of claims 1 and 4 be withdrawn.

Turning now to the rejection of claims 7 to 9 as "directed to the use of a compound are not within the definitions for patentable invention in Section (2) of the Patent Act". The rejection states that the use described in the rejected claims describes "neither the process nor the product (composition)".

The applicant maintains that he has complied with the requirements imposed under Section 36(2) of the Act as he claims in explicit terms the things or combinations that he regards as new. Additionally he states that if the best way of complying with the requirement under Section 36 is to express the claim in terms of a use, then it is appropriate to do so. He argues that rejection of the claimed use as not patentable subject matter is not justified as many inventions involve the use of substances or artifacts.

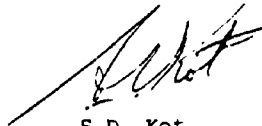
While it is true that the rejected claims do not describe a process or a product this does not in this case make them fall outside of the definition of invention set forth in Section 2 of the Patent Act. The Applicant has argued that the claims to the use of the active ingredient should be construed as extending to cover activities which can be regarded as "industrial" in character. In the Final Action it is acknowledged that the applicant has made a discovery "namely a new use for an old composition". We believe that since the Applicant has a new use for an old composition he should be entitled to claim that use. The fact that the claims do not describe a process or a product does not by itself constitute a valid basis for rejection of these claims. Therefore, in our view, the refusal of claims 7 to 9 should be withdrawn.

We make no comment with respect to claims 10 to 17 which were added to the application in response to the Final Action.

In summary we recommend that the refusal of claims 1 and 4 and claims 7 to 9 be withdrawn.

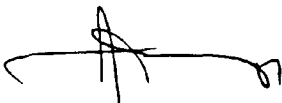


M.G. Brown
Acting Chairman
Patent Appeal Board



S.D. Kot
Member

I have reviewed the prosecution of the application. I concur with the findings and recommendations of the Patent Appeal Board. Accordingly, I withdraw the Final Action, and I am remanding the application to the Examiner for prosecution consistent with the recommendation.



J.H.A. Gariépy
Commission of Patents

Dated at Hull, Quebec
this 20th day of September 1988

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