COMMISSIONER'S DECISION

Obviousness: Synthetic D-Penicillamine Compositions

The invention is directed to a completely synthetic D-penicillamine composition and is predicated on the discovery of unexpected and surprising properties of synthetic D-penicillamine. The reference relied upon disclosed natural penicillamine. It was decided that an invention has been described, and the application was returned to the examiner to determine what compositions were novel and particularly adapted to the specified new and unobvious use.

Final Action: Reversed in part.

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This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated February 1, 1977, on application 167,082 (Class 167-188). The application was filed on March 20, 1973, in the name of Friedrich Asinger et al, with the title "Process For Producing D-Penicillamine And Preparation Containing Same." The Patent Appeal Board conducted a Hearing on September 6, 1978, at which Mr. N. Hewitt represented the applicant.

The application is directed to a pharmaceutical composition comprising a completely synthetic D-penicillamine and a pharmaceutically acceptable carrier, and is predicated on the discovery of unexpected and surprising properties which the completely synthetic D-penicillamine has been found to have over and above the properties displayed by natural D-penicillamine.

In the Final Action the examiner refused the claims because they "do not differ inventively from prior knowledge." In that action the examiner had, inter alia, this to say:

> ...
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> It is held that the mere discovery of unknown properties of a known compound, with known utility in the treatment of disease, does not confer further patentability to the compound or its compositions with mere carriers or diluents. A new property per se is not patentable unless it can be claimed in the form of a patentable process, apparatus or product. In this case, synthetic D-penicillamine and the process for its production are known, its utility in the treatment of various diseases, for example, poisoning by heavy metals, Wilson's disease and primary chronic

> polyarthritis is the same as that for naturally produced penicillamine (since the active ingredient is the same in each case it is submitted to be obvious that their utility would be similar) and the compositions and processes for producing compositions of synthetic D-penicillamine with a carrier are classical in the administration of such medicines. The discovered fact that synthetic D-penicillamine shows no side effects or lesser side effects upon administration may constitute an advance in the art but does not constitute a patentable improvement under the Patent Act and Rules as far as the present claims are concerned.
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> ...

In response to the Final Action the applicant stated (in part):

> ...
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> As previously stated in the Final Action the Examiner in rejecting the claims has taken the position that claim 1 which is directed to a composition containing completely synthetic D-penicillamine and a pharmaceutically acceptable carrier or diluent does not differ inventively from prior knowledge. The Examiner then sets forth what he considers to be prior knowledge. The prior knowledge is as set forth in the specification on page 1. In particular, D-penicillamine produced from natural penicillin (hereinafter referred to as natural D-penicillamine) is known and has given satisfactory results in the treatment of various diseases such for example as poisoning caused by heavy metals, Wilson's disease and primary chronic polyarthritis.
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> However, it has been found with natural D-penicillamines to cause allergies such as skin reactions, fever and the like and other side effects when administered to the patient. This has greatly restricted the use of natural D-penicillamine in the treatment of the various diseases. Applicants would refer in this direction to pages 4 to 6 of the response of July 5, 1976.
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> Further, as the Examiner states in the Official Action, completely synthetic D-penicillamine and its salts are known. Completely synthetic D-penicillamine is penicillamine produced completely synthetically from synthetic penicillin. However, heretofore while the art may have realized that completely synthetic D-penicillamine could be used for the treatment of the same diseases as natural D-penicillamine, due to the fact inter alia of the difficulty of preparing completely synthetic D-penicillamine and that the cost of such preparation was substantially increased for completel synthetic D-penicillamine as compared with natural D-penicillamine. These disadvantages mitigated against the use of completely synthetic D-penicillamine in the treatment of the aforesaid diseases. Thus to a person skilled in the art at the time of the present invention and before the present invention, natural D-penicillamine was cheaper and more easily made than completely synthetic D-penicillamine and thus had substantial economical advantages in the treatment

> of the aforesaid diseases and thus completely synthetic D-penicillamine has remained a laboratory curiosity and has never been used to the applicant's knowledge in the treatment of the aforesaid disease. Thus a person skilled in the art could only see disadvantages in the production of completely synthetic D-penicillamine for the treatment of the aforesaid diseases, there being no advantages in use apparent to a person skilled in the art to compensate out the aforesaid disadvantages and therefore natural D-penicillamine has been used to the applicant's knowledge, exclusively for the treatment of the aforesaid diseases and the completely synthetic penicillamine has remained a laboratory curiosity. Thus referring to the third paragraph of the final action, applicants would stress the word "same" in the Examiner's comments as heretofore it would have been expected by a person skilled in the art that completely synthetic D-penicillamine would have exactly the same usefulness as natural D-penicillamine with the same side effects and allergic reactions and would have no advantages whatsoever over the natural D-penicillamine.
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> ...

At the Hearing Mr. Hewitt set forth the background of what is, in his view, a patentable advance in the art. He argued strongly that an invention is defined in the claims because of the discovery of "unexpected and surprising properties" of the completely synthetic D-penicillamine.

We have carefully reviewed the prosecution of this application and find no reason to question that the applicant has discovered unexpected and surprising properties in synthetic penicillamine, specifically the absence of, e.g. side effects when used in the treatment of arthritis, even though such product was known for many years. Whether or not this can be claimed as an invention is predicated solely on the condition that the synthetic D-penicillamine was never used before in the treatment of arthritis, because no valid patent may issue for such discovery until in its practical application, a new and useful result has been produced. The inventive step, of course, may lie in such discovery. The problem lies in defining such subject matter in the claims because the applicant is precluded from claiming medical processes (see Tennessee v Commissioner of Patents (1974) SCR 111).

The examiner argued that what the applicant has done "does not constitute a patentable improvement under the Patent Act and Rules as far as the present claims are concerned." We are satisfied however, that such an approach is valid only where the substance was used for the intended purpose previously and/or the claims lack novelty. A novel practical composition particularly adapted to a new use is in our view, patentable. However claims which are directed to a novel composition particularly adapted for the specified new use are the only claims which should be accepted in the present circumstances.

At the present time the applicant is claiming synthetic D-penicillamine and its salts mixed with pharmaceutically acceptable carriers. Unfortunately, as was brought out at the Hearing, synthetic D-penicillamine mixed with Pharmaceutically acceptable carriers is already known, disclosed for example, in the prior Canadian patents cited by the examiner during earlier prosecution, viz:

518069	Sheehan et al	Jan. 8, 1955
499718	Mozingo	Feb. 2, 1974

These patents show synthetic D-penicillamine and its salts mixed with various pharmaceutically acceptable carriers, such as water, ether and alcohol. These are among the carriers included in the applicant's own disclosure, and mixtures of synthetic penicillamine with them are not novel. Moreover the applicant has not shown that any of the other carriers listed in the application are in any way different from the carriers of the prior art, and consequently it cannot be said they are particularly adapted to the new use to which they are to be put.

At the Hearing Mr. Hewitt indicated he was quite willing to limit his claims to novel subject matter. In such circumstances we consequently believe the application should be returned to the examiner to determine whether there are indeed any novel compositions disclosed which are particularly adapted to a new use for synthetic D-penicillamine.

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

I have reviewed the prosecution of this application and agree with the recommendation of the Patent Appeal Board. Accordingly, I return the application to the examiner for further prosecution along the guidelines set out by the Board.

J.H.A. Carlepy
Commissioner of Patents

Dated at Hull, Quebec

this 4th. day of October, 1978