

COMMISSIONER'S DECISION

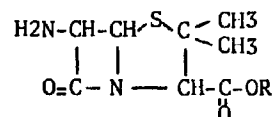
SECTION 41(1): Includes Intermediates "Intended for Medicine"

Section 41(1) applies to chemical substances not themselves medicinally or nutritionally active, where their intended use is conversion into medicines or foods, but not if the intended use is otherwise. That the subsection refers to substances "intended for medicine", is taken as meaning more than if it referred simply to "medicines".

FINAL ACTION: Affirmed.

Under Section 46(5) of the Patent Rules, the applicant has requested a review of the examiner's Final Action of August 30, 1973, rejecting certain claims in patent application 946,848 (Class 260/235.2). The application was filed on Dec. 2, 1965 and has the title "6-Aminopenicillanic Acid Esters". The inventors are Arthur A. Patchett et al. The Patent Appeal Board conducted a hearing on the rejection on May 1, 1974, at which Mr. Roger Goudreau represented the applicant, Merck & Co., Inc.

The examiner has rejected claims 1 to 6 for failure to comply with the requirements of Section 41 of the Patent Act. These claims cover certain new esters of 6-aminopenicillanic acid of the general formula:



where R represents various substituents. The exact chemical structure of these compounds is immaterial to the issues involved. Suffice it to say that these new compounds are intermediates which can be converted into novel penicillin compounds that possess antibacterial activity against microorganisms. According to the applicant the intermediates themselves are not medicines.

In conformity with directives of the Patent Office to its examining staff (Patent Office Record, Aug. 29, 1972, p.viii and Section 9.02.03 of the Manual of Patent Office Practice) the examiner rejected the product claims because the claims do not include a restriction to the process by which they are manufactured, such as would be necessary if the compounds come within the ambit of Section 41(1) of the Patent Act. The point to be decided by the Board is whether Section 41(1) is applicable. It is agreed, at least

for the purposes of this appeal that the intermediates are not medicines, and that they are made by chemical processes. What must be determined, however, is whether they are "substances intended for medicine".

In the final action it was stated:

... any process (involving several steps is) a unitary concept, regardless of the number of individual operations. This is consistent with the manner in which most research programs are evolved: when a scientist undertakes to synthesize a drug his intentions concern the medical field from the beginning. And later, when a patent application results, the very patentability of the products will rest precisely on the intended use disclosed. The intention is therefore an essential, sine qua non, condition and this intention is directed to the medicinal field exclusively.

The application of the process limitations to intermediates is therefore consistent with the wording of Section 41(1). It is also in line with the spirit of the Section of, inter alia, loosening the bind created by the existence of a patent, since an unrestricted monopoly at one point in a sequence may effectively block the complete sequence.

Applicants have invoked the difference in wording between subsection 1 and 4 of Section 41 in support of their position and they appear to believe that the language "capable of being used in the preparation of medicine" in subsection 4 covers the intermediates, whereas the absence of such language in subsection 1 excludes intermediates. This is not necessarily the case: in fact it is equally logical that "intended for medicine" includes intermediates in both sub-sections and then, the inventions "capable of being used in the preparation of medicine" in subsection 4 are "processes" since without doubt, processes were intended to be subject to licensing.

In his response of February 12, 1973, the applicant argued that:

... The position that the expression "intended for medicine" includes intermediates is believed to be illogical and unfounded. It is submitted that intermediates are not intended for medicine but are inventions intended for the preparation of medicine or in some cases capable of being used in the preparation of medicine. It is submitted that the expression "intended for medicine" is really equivalent to the expression "useful as medicine".

and It has been well established by the Courts that the scopes of Sub-section 1 and Sub-section 4 were different. While Sub-section 1 is concerned mainly with one class of inventions, i.e. substances prepared by a chemical process and intended for food or medicine, Sub-section 4 includes three other classes and eliminates the restriction of the preparation by a chemical process. The various groups of inventions governed by Sub-section 4 are as follows:

- a) Inventions intended for medicine
- b) Inventions capable of being used as medicine
- c) Inventions intended for the preparation of medicine; and
- d) Inventions capable of being used in the preparation of medicine.

In order to illustrate the type of inventions which are covered by Section 41(4) the applicant would like to submit the following examples:

Inventions Intended for Medicine:

In this group it is submitted that two types of inventions are concerned. First there are the inventions which are medicines but not prepared by a chemical process, for example an invention relating to a mixture of pharmaceutical products, and secondly, inventions prepared by a chemical process yielding a medicine, for example antibiotics, diuretics, etc. It is submitted it is only this type of invention which can be intended for medicine.

Inventions Capable of Being Used for Medicine:

This type of invention would be represented by the discovery that a compound, capable of an industrial application, had also been found to be capable of being used for medicine. For example, a dye which, when discovered, was intended to be used as a colouring agent, may subsequently become an invention capable of being used as an antibacterial agent.

Inventions Intended for the Preparation of Medicine:

In this group one will find inventions relating to alternate processes for preparing known drugs and one will also find inventions relating to intermediates whose only known utility is in the preparation of medicine.

Inventions Capable of Being Used in the Preparation of Medicine:

It is submitted that before an invention can be capable of being used for the preparation of medicine it must be capable of doing something else, otherwise such an invention would not be capable of but be only intended for the preparation of medicine. Such an invention would include, for example, a patented process used in general chemistry but which could under certain conditions be used for the preparation of medicine. It could also be for a produce which has already an industrial use but which could be a useful intermediate in the preparation of a medicine and finally it could even be for a machine having other industrial applications but for which there would be an application in the preparation of medicine.

It is again submitted that the expression "intended for medicine" as used in Section 41(1) and as used in Section 41(4) is identical but it cannot be interpreted as including other expressions such as "intended for the preparation of medicine", otherwise to argue that these two expressions are equivalent would be saying that in fact Parliament has used two different expressions to express the same intention. This point was clearly stated in the case of Charles E. Frosst & Co. vs Carter Products, 18 Fox Patent Cases at page 60, where the former Commissioner stated clearly as follows:

"Furthermore, if Section 41(3) had been intended to apply only to patents coming under the ambit of Section 41(1) there would have been no point in using different language or in adding the word "any" before the word "patent". Parliament does not usually use different wording to express the same intention".

There are many other decisions where the Courts or the Patent Office have held that there is a difference in scope between Sections 41(1) and 41(3). For example, in the case of Parke Davis vs Fine Chemical of Canada, 18 Fox Patent Cases, page 133, Martland J. indicated as follows:

"It seems to me that Section 41 must be construed as a whole. Sub-section 1 applies to inventions relating to substances prepared or produced by chemical processes and intended for food or medicine. Sub-section 3 goes somewhat further and also applies to any patent for an invention capable of being used for the preparation of food or medicine." (Underlining ours)

As can be appreciated, a clear-cut distinction has been made between intended for medicine and capable of being used for the preparation of medicine and again it is submitted that an intermediate is not intended for medicine but is only, at the most, capable of being used for the preparation of medicine.

In other words, it is the conversion of an intermediate to a medicine which constitutes an invention intended for medicine, while the conversion of a starting material to a new intermediate useful in the preparation of medicine can only be an invention intended for the preparation of medicine.

and

That the scope of Section 41(1) and Section 41(4) are not the same even as far as the expression "intended for medicine" is also to be drawn from the language used in the French part of these two sub-sections. The Patent Office' attention is drawn to Sub-section 1, where the claims of the invention are defined as those "destinées à la médication", while Sub-section 4 refers to

"une invention destinée à des médicaments"

ou

"une invention destinée à la préparation de médicaments"

ou

"une invention susceptible d'être utilisée à de telles fins", (c.a.d. à des médicaments ou à la préparation de médicaments)".

It is submitted that the expression "destinée à la médication" can in no way be interpreted to include "une invention destinée à la préparation de médicaments" which is the case of an intermediate. In French the verb "destiner" means to have a use determined in advance (fixer d'avance pour être employé à un usage). On the other hand, "médication" means, in French, "emploi systématique d'agents médicaux dans une intention précise".

Section 41(1) requires 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." Since the invention relates to a substance produced by a chemical process, what we must consider is whether these intermediates are "intended for food or medicine".

Section 41 is derived from Section 38A of the British Patents and Design of 1919. There are differences between the corresponding British and Canadian sections and care must be exercised in correlating the two (vide Commissioner of Patents v Winthrop Chemical Co., 1948 S.C.R. 46). Nevertheless it is of assistance to look to British jurisprudence interpreting those parts of the legislation which are in fact similar.

In the matter of application for Patents by W et al, 39 RPC 263, (1922), it was held that the expression "intended for food" is not confined to foods so as to exclude inventions which are to become foods, or substances which are used in and to advance the preparation or production of food. (We are of course concerned with medicines, but the principle is analogous.) To quote from the decision:

Turning back to sub-section (1), I cannot accept the argument that it covers foods only, and not subjects of inventions which are to become foods, or substances which are used only in, and to advance, the preparation or production of food. "Intended for food" are the words used - a phrase to my mind of very wide significance. Very few substances that are within the section need no further preparation before they are to be consumed as food. Indeed I think it was conceded that mere cooking would not prevent a substance being a food within sub-section (1); but, if one mode is permissible, why not others? In my judgement, therefore, all substances fall within sub-section (1) and are "intended for food

or medicine" whether they are completely ready for consumption or can be rendered ready by various operations, or are to be used in the preparation or production of the article so to make it ready for consumption. "Intended for food or medicine" means to be used, not necessarily immediately and as they are, but after due preparation - to be used when the intention has ultimately been carried into effect, by the preparation be it by cooking, mixing or other preliminary steps, which lead up to effecting their ultimate purpose, namely, user (sic) as food.

While there are phrases in the above passage which imply "intended for medicine" is to be interpreted broadly, the facts of the case (the substance was a dough to be made into bread) and other phrases could be taken to suggest that the decision goes no further than to cover materials which, while they require further preparation to become foods or medicines, are still foods in an elementary form, much as it was found in Parke-Davis v Fine Chemicals (1957) Ex. C.R. 300 at 307 and (1959) S.C.R. 219 that substances in bulk form are nevertheless medicines even though they required further modification of a simple nature to adapt them to the dosage form in which they are administered. This conceivably, however, might exclude chemical intermediates which require a molecular change before they are converted into the compounds possessing therapeutic properties and which are those actually used as medicines.

In the matter of an Application for Patent by E.M., 41 RPC 590 (1924) the matter was explored further. Claims for baking powder which is used in the making of bread were held to be within the ambit of Section 38. This then makes it apparent that substances 'intended for food' are not restricted to elementary forms of food, but extends to other substances "... to be used in the preparation or production of (an) article of food..."

The Canadian Courts have also given a broad interpretation to "medicine". See, for example, Tennessee Eastman v. Commissioner of Patents, S.C.R. Dec. 22, 1972, p.8, Imperial Chemical Industries v. Commissioner of Patents (1961) 1 Ex. C.R. 57, and Parke, Davis v. Fine Chemicals (supra) at 226.

An important submission made by the applicant hinges upon the differences in the language used in Section 41(1), 41(3), and 41(4) of the Act. These are tabulated below.

- 41(1) - intended for food or medicine
- 41(3) - intended or capable of being used for the preparation of food.
- 41(4) - intended or capable of being used for medicine or the preparation or production of medicine

It is his submission that the latter two subsections reflect a difference between substances which are themselves medicines, and others which are intended for being used to prepare medicine. To quote from his response:

"...a clear-cut distinction has been made between intended for medicine and capable of being used for the preparation of medicine..."

It must be remembered, however, that there are other differences, in wording between subsections 41(3) & (4) and subsection 41(1). The former deal with "inventions" broadly, while the latter (41-1) deals with inventions which are substances. This explains the statement made in Parke Davis v Fine Chemicals (supra) at 327, and quoted by the applicant, that 41(3) goes somewhat further than 41(1). Sections 41(3) & (4) would cover, for example, a mechanical blender intended for the preparation of a medicine or capable of being used for the preparation of medicine. They are not restricted to "substances," as is 41(1). While we fully agree with the applicant that the subsections are of different scope, we do not see that the results flowing from those differences are those which he has ascribed to them.

The applicant pointed out that these intermediates are not medicines. Since the examiner did not contend that they were, and since we are only concerned with whether the intermediates are "intended" for medicines (as distinct from "being" medicines), we need not consider that point further.

The applicant has advanced another interesting argument based upon the French text of the Patent Act, which of course is as equally authoritative as the English version. It is his contention that the phrase "destinées à la medication" in 41(1) can in no way be interpreted to include "une invention destinée à la preparation de medicaments." As in the case of the English text, however, we must recognize that in 41(1) we are concerned with "substances... destinées à la medication" while in 41(3) & (4) we are concerned with "une invention destinée à la preparation de médicaments. Consequently we can draw the same distinctions between the subsections as that which has already been made in considering the English text.

The compounds claimed in the application are precursors for the preparation of medicinal substances, i.e. certain novel penicillins. By chemical conversion they are made into such medicinal substances. The decision of both the Canadian and British Courts suggest that "medicine" and "intended for medicine" should be given broad interpretations, and on that basis we conclude that intermediates whose only utility is for conversion into medicines should be considered as "intended for medicine". Whether it would also apply to chemical substances whose intended use is non-medicinal but which may also be capable of being used to prepare medicines within the meaning of Parke, Davis v Fine Chemicals (supra) 219 at 227 we need not determine here. If the disclosure is to be believed (page 1 and example 8) these intermediates provide a route to make certain previously unknown penicillins which are active against microorganism resistant to previously known penicillins. To grant per se protection to these intermediates would preclude others from developing alternate procedures for making the intermediates and manufacturing the new penicillins from such intermediates without being obliged to obtain a license, whether

voluntary or compulsory, from this applicant. In that sense, and to that extent, a per se claim would effectively block the way to manufacture the new penicillins.

If it had been meant that Section 41(1) applied only to substances which are themselves medicines, we believe the subsection would have read "substances prepared or produced by chemical processes which are foods and medicines." The fact that the expression "intended for food or medicine" was used suggests instead that something more was meant.

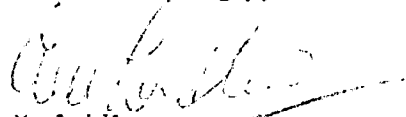
The Board is of the opinion that the rejection made under Section 41 should be affirmed.



G.A. Asher
Chairman, Patent Appeal Board

I concur with the findings of the Patent Appeal Board. Claims 1 to 6 in their present form are refused. The applicant has six months to amend the claims as required by the Examiner, or to appeal this decision under the provisions of Section 44 of the Patent Act.

Decision accordingly,



A.M. Laidlaw,
Commissioner of Patents

Dated at Hull, Quebec
this 5th day of June,
1974.

Agent for Applicant

Goudreau, Gage & Associates