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.

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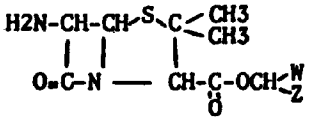
Under Section 46(5) of the Patent Rules, the applicant has requested a review of the examiner's Final Action of August 23, 1973, rejecting certain claims in patent application 965,900 (Class 260/235.2). The application was filed on July 20, 1966 giving Lee C. Cheney et al as inventors, with the title "Preparation of 6-Aminopenicillanic Acid Esters". The Patent Appeal Board held a hearing on the rejection on April 10, 1974, at which Mr. David Watson, Q.C. and Mr. E.J. McKhool represented the applicant, the Bristol-Myers Company.

The examiner has rejected claims 21 to 30 for failure to comply with the requirements of Section 41 of the Patent Act. These claims cover certain new esters of 6-aminopenicillanic aid of the general formula:



where W and Z represent certain defined radicals. 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 penicillin compounds that are therapeutically active, though the intermediates themselves are not therapeutically active. The new compounds provide an alternate and in some ways a better route to manufacture both previously known and new therapeutically active penicillins.

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 at issue to be determined by the Board is whether Section 41(1) is applicable or not.

The reason advanced in the final action for the rejection was that it is

> ... incorrect to regard the medicinals proper as the only substances which are "intended for medicine". When a multi-step synthesis is devised the intention throughout is really directed to chemotherapy and does not begin with the last substance. Therefore all substances participating in the synthesis of a drug are truly "intended for medicine" and the claims would properly be rejected for lack of utility in the absense of a statement of such intention.
>
> In consequence, it has been decided that, as the only possible interpretation of the words and spirit of Section 41(1), substances whose only disclosed utility resides in the synthesis of drugs are "intended for medicine" and subject to process limitations.

and

> ... with the development of synthetic methods involving a number of steps the grant of an unrestricted monopoly on any of the substances involved in the synthesis creates a virtual monopoly on the whole processes and ultimately on the final product. This is a breach of the intent of the Section.

In his own response of November 21, 1973, the principal points made in reply by the applicant were:

> Applicant wishes to point out that the intermediates with which we are concerned in this case do not themselves have therapeutic activity and are not themselves intended for medicine. The intermediates involved here may be unacceptable from a pharmaceutical point of view or may be lacking in pharmaceutical utility.
>
> It will be clear that a number of possible routes are available under modern technology for the preparation of therapeutic products. An intermediate involved in the preparation of a pharmaceutical compound by one route does not necessarily prevent other routes using different intermediates from being developed by subsequent research.

It has been the policy of the Patent Office for many years dating back to the inception of the section to regard intermediates of the type claimed in this case as being outside the scope of Section 41(1) and the position now taken by the Examiner represents a change in a long-standing policy of the Patent Office. In spite of such long-standing practice and the occurrence of legislative amendments to the other parts of Section 41, there has been no legislative change to the wording of Section 41(1).

The Commissioner of Patents has issued numerous compulsory licences purporting to be authorized by Section 41(4) with respect to patents containing product claims covering intermediates.

The Examiner has in his argument relied heavily on the policy of Section 41 and on the influence of technological advances in chemistry to justify what he refers to as "a re-assessment of the interpretation of Section 41(1)" as seen in the third paragraph of his letter. It is submitted on the contrary that the policy of the section and the effect of the advances in technology are an important consideration in applicant's favour. It is further submitted that what the Examiner refers to as a re-assessment is in fact an amendment to the section.

The Section 41(1) of the Act which is involved here was derived from a British Statute which has long since been repealed. It would be desirable if the Canadian section were also repealed. However, in the absence of such a repeal it is submitted that the sections should certainly not be construed broadly, in order to carry out some undefined "spirit of Section 41(1)".

It is submitted that under modern technology a number of possible routes are available for the preparation of a therapeutic product. Accordingly, patent protection for an intermediate of the type claimed in this case is even less likely than in the days of simpler technology to provide in effect a domination of the final therapeutic substance.

and

It is not seen how the number of steps in the process has any bearing on the patentability of individual steps in the process, and in the nature of the grant which is permitted by the Patent Act. Indeed it appears to applicant that with the development of synthetic methods involving a number of steps it becomes less and less possible to obtain an unrestricted monopoly on the production of the final pharmaceutical compound by blocking one of the multiple paths available to a manufacturer.

It is submitted that the Examiner's extension of the section to substances which are not themselves intended for medicine is an amendment of Section 41(1) and that the extension of the scope of this section so as to discourage product invention should not be made at this late state by distorting the wording of the Statute and reading the Statute as if it included words which are not there. The Examiner's view

would be applicable if the Statute applied to "substances intended for medicine or for the preparation or production of medicine". This is not however, how Section 41(1) of the Patent Act reads. That is how Section 41(4) of the Patent Act reads on the other hand. It seems likely that the difference in wording between Sections 41(1) and 41(4) is intended to convey some significance, and this difference has been appreciated in the past by the Commissioner and by our courts. If the legislature had intended to expand Section 41(1) to apply to intermediates it would have been simply enough to have provided this in sub-Section (1). The Examiner states that the grant of an unrestricted monopoly on a substance involved in the synthesis of a pharmaceutical compound creates a virtual monopoly on the whole process and that this is a breach of the intent of the Section. Even if this were so, which is denied, it is up to the legislature to make the necessary amendments to Section 41(1) of the Patent Act. The Patent Office should apply this section as it stands and as it has been understood by the Patent Office and by the courts for many years, and not apply it as if it had been amended in accordance with the Examiner's conceptive of desirable policy. The Patent Office must also consider carefully the effect of this serious change in practice, and must not proceed as though it were interpreting a new provision of the Statute, which had not previously been considered by the court.

If the Patent Office feels that it is serving some social purpose in limiting a monopoly granted to pharmaceutical manufacturers for their new discoveries, this is believed to be unnecessary under the present state of the law. The mere fact that a patent is granted for a pharmaceutical compound does not confer any absolute monopoly of any kind on the patentee, in view of the provisions of Section 41(4) of the Patent Act. On the contrary, the willingness of the Commissioner of Patents to grant licences under Section 41(4) of the Patent Act renders the limitation of Section 41(1) of the Patent Act even more anachronistic, redundant, and academic than would otherwise be the case, in the absence of Section 41(4). As mentioned above, Section 41(1) is believed to be anachronistic in its intent in any case.

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".

As was brought out at the hearing, 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 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 more involved reaction and 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 all substances "...to be used in the preparation or production of (an) article of food..."

The Canadian Courts have also considered that a broad interpretation should be given 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, or Parke, Davis v Fine Chemicals (supra) at 226.

A principal argument developed 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

Le demandeur prétend que l'addition des mots "ou susceptible d'être utilisée à de telles fins" dans les deux derniers paragraphes reflète une différence entre les substances qui sont déjà des médicaments et les autres, qui sont susceptibles de servir à la préparation de médicaments. Voici un extrait de son mémoire à la commission:

> La différence dans l'énoncé des paragraphes 41(1) et 41(3) ou (4) indique qu'il y a une distinction entre les substances destinées à la médication et celles susceptibles d'être utilisées à la préparation ou à la production de médicaments".

Il faut toutefois se rappeler que les paragraphes 41(3) et (4) diffèrent du paragraphe 41(1) sous un autre aspect important. Ils portent sur des "inventions" en général, alors que le paragraphe 41(1) porte sur des inventions qui sont des substances. Ce qui explique l'argument avancé dans Parke, Davis c. Fine Chemicals (327), voulant que le paragraphe 41(3) aille un peu plus loin que le paragraphe 41(1). Les paragraphes 41(3) et (4) pourraient par exemple couvrir un mélangeur mécanique pouvant servir à la préparation des médicaments. Ils ne se restreignent pas aux "substances" comme c'est le cas pour 41(1). Nous sommes parfaitement d'accord avec le demandeur que les deux phrases ont une portée différente, mais nous ne croyons pas que la différence soit celle qu'il leur attribue.

Le demandeur fait longuement valoir que ces intermédiaires ne sont pas des médicaments. Etant donné que l'examinateur n'a pas prétendu qu'ils l'étaient et que nous nous préoccupons seulement de savoir si les intermédiaires sont "destinés" à la médication (et non s'ils sont des médicaments), il n'est pas nécessaire de nous attarder plus longtemps sur ce point.

Le demandeur soutient également que l'examinateur prétend que toutes les substances entrant dans la synthèse d'une drogue sont destinées à la médication. Avec une telle interprétation, toutes les substances du genre seraient régies par l'article 41 (si elles sont fabriquées par des procédés chimiques). A l'examen du rapport de l'examinateur, nous pouvons constater qu'il ne s'applique qu'aux substances elles-même converties en médicaments, c'est-à-dire les intermédiaires chimiques. De toute façon, nous estimons que cela ne devrait pas aller au delà des substances chimiques qui, une fois converties, deviennent des médicaments.

As for the extensive submissions respecting the "spirit and intent" and the "policy" of Section 41 we do not believe it necessary to go into them in detail. We need only consider the wording of the statute itself, and in particular the phrase "intended for medicine." Nor need we consider whether, as suggested by the applicant, the sub-section as a whole is anachronistic. Since it exists in the legislation, it is the responsibility of the examiner to apply it. Admittedly it was at one time the policy of the Patent Office to regard intermediates as being outside the scope of Section 41. If, however, that policy was inconsistant with a proper legal interpretation of the Act, then it should be corrected. Policy is not a matter for stare decisis, and should be corrected if found improper.

The compounds claimed in the application are precursors for the preparation of medicinal substances, i.e. penicillins. By acylation and hydrolysis they are converted into such medicinal substances. The decision of both the Canadian and British Courts suggest that Section 41 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 (p.1) these intermediates provide the only commercial route to make certain previously known penicillins, and the only known route to make other penicillins. To grant per se protection to the intermediates would preclude others from developing alternate procedures for making the intermediates and manufacturing the penicillin without being obliged to obtain a license, whether voluntary or compulsory, from this applicant, if

they wish to manufacture the penicillins themselves. In that sense, a per se claim would effectively (if not completely) block the way to manufacture important penicillin products.

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 instead clearly suggests that something more is involved.

Having explored this problem at length, and examined all the arguments raised by the applicant, we recommend that the rejection made under Section 41 be confirmed.

G.A. Asher
Chairman, Patent Appeal Board

I concur with the findings of the Patent Appeal Board. Claims 21 to 30, 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.

Decision accordingly,

A.M. Laidlaw,
Commissioner of Patents.

Dated at Hull, Quebec
This 31st. day of May
1974.

Agent for Applicant

Gowling & Henderson