

Section 41(1): The compound of the application, the role of which is to eliminate parasites in animal hosts, including destructive and potentially fatal parasites, is covered by the definition of the term medicine within the meaning of section 41. Rejection of the petition affirmed.

This decision deals with Applicant's request for review by the Commissioner of Patents of the Final Action on application 329,159 (Class 260-479.1). The application, filed June 5, 1979 and assigned to ROUSSEL UCLAF, is entitled CYCLOPROPANE CARBOXYLIC ACID ESTERS SUBSTITUTED WITH CYANALCOHOL, THEIR PROCESSES OF MANUFACTURE, THE PESTICIDE COMPOSITIONS CONTAINING THEM AND THEIR APPLICATION AS A MEDICINE FOR VETERINARY USE. The inventors are Jacques Martel and Jean Tessier. The Examiner in charge issued a Final Action on February 10, 1982.

In her Final Action, the Examiner refused to allow claims 1 to 7 in the application in view of section 41(1) of the Act, which reads as follows:

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.

The Examiner stressed that pages 8 to 10 and examples 22 and 23 of the specification indicate that the compositions disclosed may be used "as veterinary medicine and administered orally as well as in admixture with compound animal feeds".

Applicant acknowledges that this assertion is taken from the disclosure, and that the said disclosure incorporates data covering the treatment of animals. He firmly maintains, however, that his compositions should not be subject to the requirements of s. 41(1), that is, those limiting the application to the process of

manufacture. The Applicant argues that the primary use of his compounds is not as a veterinary medicine but as an insecticide. He considers the terms used in chapter 9.02.06 of the Manual of Patent Office Practice vague. He noted the absence of the term "invasion" in the aforementioned chapter, and reasons that this situation is explained by the fact that the use of compounds comparable to those claimed in the subject application have no effect on an animal's metabolism. He compares the said compositions to saccharin and other similar artificial sweeteners which do not qualify as food, and maintains that the substances claimed do not affect metabolic behaviour either. Applicant relies on a number of earlier judgments and previous Commissioner's rulings.

The Board must decide whether claims 1 to 7 are allowable only when they are dependent on a process, in accordance with the requirements of s. 41 of the Patent Act, or whether they are allowable in their present non-restrictive form.

Claim 1 reads as follows:

1. Compounds of formula (I):

[see original French for formula]

in which n is an integer equal to 1, 2 or 3, the configuration of the acid copula is (1R, trans) or (1R, cis), and that of the alcohol copula is (S).

The members of the Board first looked to the Supreme Court of Canada decision in Parke, Davis & Co. v. Fine Chemicals of Canada Ltd. [1959] S.C.R. 219, including the passage cited by the Applicant. We have read Applicant's two observations on this subject and we fail to see how either the passage cited or the comments thereon can substantiate his viewpoint on the applicability of s. 41(1). The said passage deals solely with the applicability of former section 41(3), and it merely mentions that if the practical value of an invention is to apply to two sectors, that is, food and medicine on one hand, and a sector unrelated to food and medicine on the other hand, the invention

is subject to the licensing provisions of section 41 insofar as its use as food or medicine is concerned. Nowhere in Parke, Davis does the Supreme Court state that the limitation to process set out in s. 41(1) does not apply to inventions of this nature.

On the contrary, the judges are silent on this subject. The Board's interpretation is that the judges' intent was to explain the scope of the licensing provisions; they even discuss inventions that could well be viewed as not "relating to substances", which would in itself exclude them from the operation of s. 41(1). We quote here from Mr. Justice Rand's observations in this decision, which read in part as follows:

I agree with Thurlow J. that the word "medicine", as used in Section 41 of the Act, should be interpreted broadly...

We shall come back to this later.

As for the two decisions of the Commissioner published in the Patent Office Record and cited by the Applicant, the Board is not convinced of their relevance to the instant case. In both these decisions, the Commissioner assesses the applicability of s. 41(1) in relation to the intermediate compounds used in a process, that is, compounds having no medical or therapeutic value. According to the disclosure of the subject application, the compounds do indeed possess active medical properties, and there is no doubt that they can be used in the treatment of animals with no further chemical transformation. We are not of the view that these Commissioner's rulings substantiate Applicant's viewpoint because they deal with different issues. While it is true that in these previous decisions the Commissioner determined that the sole purpose of the finished products in question was medicinal, thus making it easier to rule on the issue of the intermediates used in their preparation, he does not state that their

active compounds are excluded from the operation of s. 41(1) when they can be used for non-medicinal purposes. Furthermore, in the same two decisions, the Commissioner found that s. 41 must be interpreted in its broadest sense, and that subsection (1) should apply to the intermediates.

Applicant refers to the ruling handed down by the Supreme Court of Canada in Burton Parsons Inc. v. Hewlett-Packard Ltd. [1976] I S.C.R. 555 to substantiate his claim that not everything administered to the human body is necessarily a medicine, that a distinction has been made between the primary and secondary uses of a product, and that this distinction must be considered in determining the applicability of subsection (1). In Burton Parsons, the Supreme Court refers to its judgment in Tennessee Eastman v. Commissioner of Patents [1974] S.C.R. 111, which reads in part as follows:

It is clear that a new substance that is useful in the medical or surgical treatment of humans or of animals is an "invention". It is equally clear that a process for making such a substance also is an "invention". In fact, the substance can be claimed as an invention only "when prepared or produced by" such a process.

The Burton Parsons judgment in no way disturbs this finding, and states the following at page 570:

It is obviously a matter of some difficulty to draw the line between what is a medicine and what is only a product apt to be used in connection with the treatment of diseases.

In Burton Parsons, the Court ruled that electrode creams could in no way qualify as medicine, while in Tennessee Eastman, the judges determined that the use of a method of bonding human tissues constitutes a medical treatment. Despite its routine use on the skin of patients, the Court considered that the electrode cream did not act as a medicine, but merely contributed to the treatment. It is easy to

follow the judges' reasoning. They found that the cream has no known healing properties, that it does not in itself constitute a treatment, and that its only role, even in surgery, is to improve electrical contact with the skin. It can even be considered a component of the machine to which it serves as an auxiliary. The situation is entirely different in the instant case. In our view, there is an important distinction between the invention of a cream which comes in contact with the skin surface and has electrical but not therapeutic properties, and the invention of a new medicinal compound which can be administered to patients as a therapeutic agent. We are persuaded that, in the present matter, the compound is truly used "in connection" with a medical treatment when administered to animals. The administration of the compound represents the treatment, and its only object is to treat the animal and eliminate parasites. Herein lies the difference between the subject application and the Burton Parsons case.

The Board considered the Applicant's argument, which reads in part as follows:

[translation]

...that section 41(1) was drafted for the purpose of restricting the legal scope of patents relating to substances intended solely or primarily for food or medicine. Section 41(3), on the other hand, was drafted so as to allow any interested party immediate access to a licence for products intended not only specifically for food or medicine but those protected as such for another purpose and capable of being used for food or medicine. The fact of allowing an inventor to obtain product claims per se for chemical substances intended essentially for a non-medicinal use but capable of being used for, or in the preparation of, medicine, in no way renders section 41(3) of the Act inoperative nor does it erode the protection Parliament intended to provide to the public in the highly specific case of inventions relating to food or medicine.

We do not share this opinion. First, section 41(1) had not yet been repealed or amended when, in 1969, subsections (3) and (4) governing the granting of licences were separated so as to distinguish between a licence covering food and a licence covering medicine, which leads us to conclude that Parliament recognized the importance of subsection (1). Furthermore, a licence is not granted on demand as if it were a right. The Commissioner renders a decision which the patentee can then contest and appeal. In addition, any such licence issued creates obligations on the part of the licensee; it is subject to the terms stipulated and its holder is required to pay a royalty. This situation, in our view, justifies the significance of subsection (1). If compounds intended for multiple uses were excluded from the requirements of subsection (1), the latter would be rendered virtually inoperative as this would be an easy way of circumventing the spirit of section 41, as was pointed out in Tennessee-Eastman.

The Board has carefully examined all the other arguments raised by the Agent for the Applicant in his detailed brief. We do not agree with his assertion that the expression "or elsewhere" in chapter 9.02.06 of the Manual of Patent Office Practice lends confusion. Rather, this expression accurately states Patent Office procedure in the sense that a compound which has both medicinal and non-medicinal uses is subject to the restriction set out in subsection (1). As regards the observations on the case published in the Official Gazette of May 23, 1978, we cannot see how it supports Applicant's viewpoint. The question of unity of invention does not enter into play in the subject application. Even if the Applicant had to submit divisional applications, all these would be subject to the provisions of subsection (1) owing to the expression "or elsewhere".

The Board does not share Applicant's view that the compounds do not constitute a medicine even when used to treat animals. Applicant cites Imperial Chemical Industries Ltd. v. Commissioner of Patents [1967] 1 Ex. C.R. 57, and the Food and Drug Act. It would appear that the Applicant interprets the term "medicine" in too narrow a sense. As we mentioned earlier, we consider that the three Supreme Court decisions demonstrate that section 41 is to be interpreted without restrictions. We hold that a compound whose role is to eliminate animal parasites, including harmful and potentially fatal parasites, is effectively covered by the definition of the term "medicine" within the meaning of section 41, whether it be an anti-infective medicine or a pesticide.

Consequently, the Board is persuaded that claims 1 to 7 are subject to the provisions of section 41(1), and that they cannot be allowed unless the Applicant excludes them from the allowable claims on the process. We recommend that the Final Action rejecting claims 1 to 7 be affirmed.

(signed)  
M.G. Brown  
Acting Chairman  
Patent Appeal Board

(signed)  
S.D. Kot  
Member

I have reviewed the findings and recommendations of the Patent Appeal Board and I concur with them. Accordingly, I refuse to grant a patent containing claims 1 to 7. The Applicant has six months within which to appeal this decision under the provisions of section 44 of the Patent Act.

(signed)  
J.H.A. Gariépy  
Commissioner of Patents

Hull, Quebec

August 15, 1986