Section 2, Inhibition of Undesired Effects of Platinum (II) Compounds

Additional claims submitted at and after the Hearing were found not to have full support in the application. The rejected claims were considered to be directed to a medical treatment, not merely to a chemical reaction. Rejection affirmed

This decision deals with Applicant's request for review by the Commissioner of Patents of the Final Action on application 383,442 (Class 167-256) filed August 7, 1981. It is assigned to Regents of the University of Minnesota. The inventor is Richard. F. Borch. The Examiner in charge issued a Final Action on April 11, 1985 refusing to allow the application. A Hearing was held on May 11, 1988, and arguments were made by his Patent Agent, Mr. R.H. Barrigar, assisted by Messrs. D.M. McGruder and R. Scott. Subsequent to the Hearing, the Applicant submitted further comments by letter dated July 6, 1988.

The application relates to a method for inhibiting platinum (II) toxicity in multicellular organisms, e.g. a live mammal being treated by a physiologically active platinum (II) (Pt(II)) compound. Within 0.5 to 6 hours after administering the toxic Pt(II) compound, a platinum-binding dithiocarbamic (DTC) compound suitable for non-oral administration is introduced into the multicellular organism or mammal. The platinum-binding compound reacts to inhibit certain undesired effects of the platinum such as bonding irreversibly to useful substrates, and nausea in a mammal, but permits the platinum to continue to inhibit tumor growth.

In taking his Final Action, the Examiner said, in part, as follows:

> ...
>
> The applicant argues that the process claims are not directed to a method of medical treatment because the claims in the present application set out no steps of medical treatment. This argument however cannot overcome the objection because as stated in the last Office Action, the purpose of the process of this application is to administer platinum-binding dithiocarbamic compound to a human who is undergoing cancer chemotherapy treatment with platinum compounds in order to reduce the undesired side effects caused by the platinum compounds. This purpose is clearly taught in the disclosure (see page 16, lines 23 to 27 for example).

The applicant's argument that the claims are directed to a method of forming a stable, square planar Pt(II) complex from the components comprising a Pt(II) compound and a dithiocarbamic compound and therefore they are not directed to a method of medical treatment is unacceptable. According to the disclosure, all the reaction takes place within a body of a human who is undergoing chemotherapy treatment and therefore in order for the reaction to proceed, both Pt(II) and a thiocarbamic compound must be administered to a body of a human who is suffering from a cancer. It is clear from the disclosure that when a dithiocarbamic compound is administered to a cancer patient who is undergoing Pt(II) chemotherapy, the said dithiocarbamic compound acts as a drug in reducing or removing the side effects caused by Pt(II) compounds. Furthermore the disclosure teaches no reaction, other than the reaction of dithiocarbamic compound within a body of a human cancer patient. It is clear from the disclosure that the displacing of the platinum complexing ligand from the complex by means of a dithiocarbamate can only proceed when the dithiocarbamate is administered to a patient who is undergoing Pt(II) chemotherapy.

In order for an alleged invention to be patentable, the Act requires that the said alleged invention has an utility. The utility taught in the disclosure is for reducing or removing side effects caused by Pt(II) compound. It is therefore clear to this examiner that the process claims, even though the applicant argues that they fail to mention medical treatment steps and therefore not a method of medical treatment, are directed to a method of medical treatment because of the teaching of the disclosure and the lack of any evidence that the present process is useful in any other situation.

...

In his response, the Applicant argues, in part, as follows:

...

It is respectfully submitted that the reactions to which reference is made in the claims, insofar as they are <u>in vivo</u> reactions, do not necessarily occur in human beings. <u>In vivo</u> reactions may occur in animals as well as humans and even in test tubes or petri dishes.

Furthermore, the applicant submits that a method of medical treatment using drugs involves preliminary diagnosis by the physician, the administration of the appropriate medicine and evaluation of its effects on the patient. The medicine may bring about a chemical reaction in the body of the patient, but the mere occurrence of a chemical reaction does not amount to a method of medical treatment. The claims in the present application set out no steps of medical treatment.

...

What may be unpatentable is a series of steps which, taken as a whole, constitute a method of medical treatment. But that does not necessarily place any particular individual step or subcombination of steps outside the realm of statutory subject matter. To understand this, let us take a different example. Suppose that a method of medical treatment comprises the steps of

(a) defining a cutting line forming a closed loop on the skin;

(b) burning an area of skin on either side of the cutting line to carbonize the skin;
(c) cutting along the cutting line through the carbonized area;
(d) removing the area of skin defined by the closed loop; and
(e) performing surgical incisions in the flesh in the area from which the skin has been removed.

Now suppose that the subcombination of steps (a), (b), (c) is novel and unobvious as applied to any layered organic material, including skin. An applicant could then claim as follows:

-- A method of cutting and removing layered organic material, comprising:

(a) defining a cutting line forming a closed loop on the outer surface of the layered organic material;
(b) burning an area of the layered organic material on either side of the cutting line to carbonize the material along the cutting line; and
(c) cutting along the cutting line through the carbonized material. --

Now the foregoing claim does not exclude skin, and does not exclude the possibility that the subcombination of the claimed steps is part of a method of medical treatment. Yet the claim is clearly statutory, involving as it does the everyday physical steps of burning and cutting.

Equally the claims of the present application are statutory. They say nothing whatever of a method of medical treatment. We are talking here of chemical reactions. If there was ever a type of process clearly within the realm of statutory subject matter, it is a chemical reaction. The plant and animal world is filled with wonderful organisms which can perform a whole hose (sic: host) of organic chemical reactions - conversion of starches to sugars, generation of acids, oxidation reactions of many types. But that does not mean that every time an applicant applies to patent a chemical reaction invention, one must then go on to enquire whether the reaction could be an *in vivo* reaction. Nor does one need to enquire whether it could be conceivably part of a method of medical treatment. So what if it could be? It remains a chemical reaction. A chemical reaction is *not*, repeat *not*, a method of medical treatment any more than the physical steps of cutting and burning are *per se* methods of medical treatment. To have a method of medical treatment, we must go on to enquire: Does the claim call expressly or by necessary implication for a human patient? Does it call for some diagnostic procedure, or some administration of specified doses of defined medicines to the patient? If these last two questions are answered affirmatively, then the claim may define a method of medical treatment.

But that is not the case here. The claims refer to formation of certain platinum (II) complexes. The steps are defined in terms of chemical reactions in a defined physical-chemical environment. Nothing is said about a patient. Nothing is said about medicines or dosages or administering same to a patient. Nor are any of these last-mentioned concepts present by necessary implication. Claim 17 admittedly calls for "administering" a certain defined chemical substance "to the dithiocarbamate-degrading system", but such system need not be within a human patient, or even within an animal. Other verbs than "administering" could have been used equally well - "introducing" or "adding", for example.

When we reach claim 22, we find that the environment includes certain agents "encountered in a living biological system". But the system need not be human. and again there is no notion of a patient nor the administration of medicines or dosages to a patient. If any physician were asked "would you regard claim 22 as an adequate definition or even any definition of a medical treatment or procedure?", the physician would clearly respond "no - it defines a biochemical reaction that might be of some value in a medical treatment or procedure, but it certainly does not define any such treatment or procedure".

In fact, the inventor has actually conducted experiments in vitro with DNA, platinum compounds, and a dithiocarbamic "rescue" agent of this invention, more specifically DDTC. He has also conducted experiments with enzymes blocked or inactivated by platinum and has successfully used DDTC to re-activate these enzymes. Although the claimed method can be carried out in vivo, it can also be carried out in vitro, with the necessary agents, including those "encountered in a living biological system", being introduced into the in vitro environment. There is nothing in the language of the claims except claims 13 and 34, restricting the method to an in vivo environment.

In the experiments with DNA/Pt complexes, it was found that the DDTC did not remove any platinum. In short, the present inventor is believed to be the first to discover that DDTC is a platinum-complexing agent which is just strong enough to reverse the blocking of enzymes or the like by platinum, but not so strong as to remove platinum from DNA. Accordingly, our existing claim 1 includes ordinary test-tube chemistry.

...

It is, of course, acknowledged by the applicant that the processes claimed are applicable in connection with the treatment of living animals, but it is respectfully submitted that this by itself is not a bar to the patentability of the claims. In this connection, the Commissioner's attention is respectfully directed to the case of Re Application No. 880,719 (Patent No. 994,693), (1973), 18 C.P.R. (2d) 114 (PAB), at page 119, where the following is stated:

> "Since the subject-matter of the present process is in the "means", as distinct from the "end", it should be entitled to a patent within the meaning of a manual or productive art as stated in Lawson v. Commissioner, supra. The fact that the relevance of the end result of the present process may be applied in connection with the treatment of living animals is incidental to the subject-matter of the present invention, it is a fact that the present process does not apply any pharmaceutical properties of a substance to effect a curative or preventive treatment of an ailment. That patentability should be denied merely because treatment of a living animal is a prerequisite of the usefulness of the end product is untenable since it would be wide enough to exclude medicines as well as their processes of manufacture intended to be governed by s.41(1), new and obvious tests for quality assurance of industrially produced pharmaceuticals, and such other inventions intended to have medical and surgical application. The foregoing conforms to the S.C.C.'s decision in Tennessee Eastman v. Commissioner of Patents (on appeal from the Exchequer Court's decision on the

> same case, supra) when it stated that the process then under consideration or applying an adhesive substance to body tissues" ... is clearly in the field of practical application" as opposed to a mere scientific principle or abstract theorem excluded by s.23(3) (sic: s.28(3)) of the Patent Act. ...
>
> In any event the present claims distinguish factually from the claims then under consideration in that no step of medical or surgical treatment is set out in the claims.".

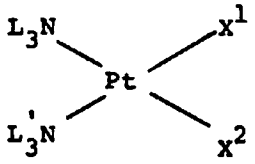
...

It is further submitted that the treatment of cancer patients is not the only utility contemplated by the inventor. The applicant admits that this is one utility of the invention. However, the inventor considers that his invention, when practised in an in vitro environment, or in vivo in microorganisms, has significant utility as a research tool. Although this use is not explicitly discussed in the specification, it is clear that the application contemplates the practice of the invention in an environment which is not limited to humans or animals....

...

The issue before the Board is whether or not the subject matter of claims 1 to 37 of the application is patentable under Section 2 of the Act. Claim 1 reads:

> A method for forming a stable, square planar Pt(II) complex from the components comprising (a) a Pt(II) compound, and (b) a dithiocarbamic compound, wherein said method is carried out in the presence of
>
> agents which can inactivate dithiocarbamic compounds through degradation or conjugation, and
>
> platinum-complexing ligands which occur in complex multi-cellular organisms;
>
> at least some of the Pt(II) compound reacting to form a complex with a said platinum-complexing ligand, said Pt(II) compound having the formula:



> wherein X^1 and X^2 are the same or different and represent anionically ionizable leaving groups, or, taken together, X^1 and X^2 can constitute a cyclic difunctional leaving group, and L_3 and L_3^1 are the same or different and represent the residues of ammine or amine ligands, or, or (sic) in combination, L_3 and L_3^1 together represent the residue of aliphatic or cycloaliphatic diamine ligand;

> said method comprising displacing the platinum-complexing ligand from said complex by means of a dithiocarbamate in the form of an anionic species formed from the dithiocarbamic compound
>
> R^1R^2NCSM
>
> wherein R^1 and R^2 are the same or different and represent electro-donating lower aliphatic or lower cycloaliphatic radicals, and M is (1) hydrogen, (2) an electropositive, ionically bonded metal, in which case the remainder of the dithiocarbamic compound is negatively charged, or (3) the
>
> radical $-S-CNR^3R^4$, R^3 and R^4 being defined in the same manner as R^1 and R^2; thereby forming said stable square Pt(II)
>
> complex, in which the functional group $R^1R^2N-C-S-$ is coordinately bonded to the platinum in place of the enzyme or ligand.

We comment briefly on the example of the method claim with step (a) to (c) for cutting and removing a layered organic material which the Applicant presents and discusses in his response to the Final Action. Steps (a) to (c) relate to, defining a cutting line, burning an area on either side of it, and cutting along the line. The Applicant says this kind of claim is statutory due to the steps of burning and cutting. In view of the decision in Tennesee Eastman v The Commissioner of Patents (1974) S.C.R. 112, we believe such a claim would not be permissible where the invention is for surgical or medical treatment of a living mammal. The purpose of an invention must be looked at in determining whether the invention meets the requirements of Section 2 which reads:

> "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

Moreover, we note the three steps in the example do not deal with removing material such as set out in that claim's preamble. We think the example is not persuasive that this application is acceptable under Section 2.

In dealing with the kind of method in this application, we learn from the description that it comprises two major steps. The first is for administering a Pt(II) complex to attack cancerous cells, and the second is for administering a DTC compound within a certain time period thereafter to prevent nausea that results due to the first step. The first step itself is a method of treating cancer and is a medical treatment. Combining with that the second step, namely, a method of alleviating nausea arising from the first step does not make the method any less a medical treatment.

Following the response to the Final Action and prior to the Hearing, an affidavit by Mr. Borch, the inventor, was filed as a supplement. It sets out that the methods in the application may be carried out in an in vitro environment or an in vivo environment in microorganisms and cell cultures. It describes exposing an enzyme preparation to a platinum drug, monitoring enzyme activity, washing the enzyme preparation free of the platinum drug, and exposing the preparation to diethlydithiocarbamate (DDTC, a DTC compound) for removing platinum from the site, and measuring restoration of enzyme activity. It refers to the chemistry of DDTC and complexes of platinum coordinated to biological macromolecules, noting that platinum bound to adenine is removed by DDTC whereas platinum bound to guanine is unreactive.

As we understand the affidavit, it does not provide for the effect that a living mammal imparts to the DTC after it is administered, nor for the timing of the DTC treatment for preventing irreversible damage.

The application describes the efficacy of using DTC compounds in inhibiting the irreversible bonding of Pt(II) compounds to useful substrates without eliminating the desirable effects of Pt(II). The purpose of the DTC compounds is for inhibiting the toxicity of Pt(II) in order to reduce the severity of nausea. In noting that timing is of great importance in administering the DTC, four beneficial timing periods are set down as being, from 0.5 to 6 hours after the Pt(II), after a certain minimum and maximum of half lives of the Pt(II), prior to 6 hours after the initiation of physiological effects of the Pt(II), after the Pt(II) begins complexing but before it irreversibly damages renal tubules. The utility of the invention is said to be obtained when a Pt(II) complex is introduced into a complex multicellular organism having kidneys and a digestive tract. The results of tests on animal models are described, including reductions in blood urea nitrogen, weight loss, and tumor size. In describing the procedure for the treatment, the Pt(II) complex is administered in a conventional manner, either intravenously or intraperitoneally, and the DTC compounds are administered in a manner taking into account their rapid

metabolism, degradation, or inactivation in acidic media, living biological systems, and others.

On closer comparison of the affidavit to the application, we note the affidavit does not include any information concerning the timing periods for administering a DTC compound. Nor does it refer to reducing the severity of nausea. In our view, it relates to biochemical research and chemical experiments studying desoxyribonucleic acid (DNA) cells grown in culture.

On page 9 of the application, it is said experiments with DNA, platinum, and DTC, show that DTC dislodges platinum from DNA/PT(II) complexes formed in vitro, and that from the experiments it would appear that DTC would be poor for inhibiting PT(II) toxicity since it might be expected the chemotherapeutic effect of the platinum would be reversed. On page 10, it is said such reversal in vitro does not happen in living multicellular systems. One reason given is that DTC compounds are present in vivo as anionic species which have difficulty in penetrating cell membranes. A second noteworthy reason says that the DTC compounds penetrating the cell walls are degraded or conjugated to form non-chelating products before they can access the DNA/Pt(II) complexes within the cell. Reference is made that the biological half life is long enough to provide reversal of the Pt(II) side effects. It is said that acidic media may be stomach acid.

In view of Mr. Borch's affidavit and the application, we see that two methods are under discussion for using Pt(II) complexes and DTC compounds. The first relates for example to in vitro experiments and is referred to in the affidavit. The second involves the two step treatment of living mammals and is set forth in the application with particular reference to prescribed times for administration for the purpose of achieving a chemotherapeutic effect by the Pt(II) complex, and alleviation of nausea by the DTC compounds due to the assistance of the mammal's system. From the affidavit we see the purpose of the first method is to determine enzyme inhibition and to obtain useful information from the testing procedure. From the application, the purpose of the second method in our opinion is for treatment of a mammal. It may be that the application would support

subject matter related to the first method, but such is not present. The method we find now in the application as it relates to treatment of a mammal, in our opinion, is the kind that has been determined not to be acceptable by the decision in the Tennessee Eastman case.

We now look at the groups of claims that are under consideration. Group A comprises claims 1 to 37 rejected by the Examiner. Group B is claim X introduced at the Hearing. Group C, as a result of the letter of July 6, 1988, consists of a suggestion for an amendment to claim X, and although there is no amended claim X on file, we include the suggestion for discussion purposes.

In group A there are three independent claims, 1, 17 and 22. Claim 1 includes the term agents and their function of inactivating DTC compounds. According to the application, the agents include mammals. In our opinion therefore, the presence of a mammal forms part of the claim. Claim 1 refers to platinum complexing ligands occuring in complex multicellular organisms. In the application, a multicellular organism includes kidneys and a digestive tract, and in our view encompasses living mammals to provide the necessary complexing action with the platinum. We think claim 1 relates to a medical treatment. We note claim 1 does not recite the time delay in applying the DTC component to act with the platinum. From the application, we learn this feature provides the effectiveness of the treatment. We think claim 1 lacks definition of the treatment disclosed. We believe however, that since claim 1 pertains to a medical treatment the inclusion of the time delay in the method would not remove claim 1 from the category of a medical treatment.

Claim 17 calls for a DTC degrading system. From the application, such a system includes a living mammal which provides for a certain action on the DTC compound. We find claim 17 is directed to a medical treatment.

Claim 22 is similar to claim 1 in that it calls for agents, and locates them in a living biological system as well as in the complex multicellular

organisms in such a system. We find claim 22 sets forth a medical treatment.

None of the claims in group A present other than a medical treatment, and none of them is allowable.

Group B has only claim X. The Applicant argues that it does not contain any terms that might be construed as limiting the method to a living mammal. To this end claim X omits the references to the agents. After the Hearing, in reviewing claim X and Mr. Borch's affidavit, the Board felt that insofar as claim X might relate to a non medical method, it was not sufficient with respect to carrying out the method in vitro or in vivo with microorganisms such as described in the affidavit. In so informing the Agent, the Board suggested considering the addition to claim X of the phrase relating to in vitro and in vivo activities as found in the inventor's affidavit. Hence, group C a suggestion for possibly deriving an amendment to claim X.

In the letter of July 6, 1988, the Applicant suggests the possibility of an amendment to claim X that would introduce reference to in vitro and in vivo activities in microorganisms or cell structures, but no claim containing such amendment was submitted. The Applicant, however, in retaining the claims of groups A and B, requests that the suggestions for the claim in group C be considered by the Board as one of the claims under review. Our comments hereinafter are made with respect to all the groups.

Mr. Barrigar stresses that all the claims under review should be assessed as representing only chemical reactions. He considers chemical reactions are statutory, patentable subject matter. He argues that regardless of where the chemical reaction occurs, such reactions remain the same whether they be performed either inside or outside the body of a living mammal. In the letter of July 6, 1988, the Agent summarizes his oral presentation at the Hearing, as follows:

a) Chemical reactions are inherently statutory; chemical processes have long been acknowledged to be statutory subject matter.

b) The utility to which any invention is put is not determinative of whether the invention is statutory. The only practical utility of a particular pharmaceutical composition or of a particular surgical implement may be utility for medical treatment, but that does not render the surgical implement or the pharmaceutical composition unstatutory - either may be properly claimed as an invention.

c) While methods of medical treatment involving clinical steps have been rejected as unstatutory, the basis for such rejection in Canada, at least where such methods involved the use of chemical compositions, appears to rest upon the Tennessee Eastman case decided by the Supreme Court of Canada which in turn rests upon the proposition that Section 41(1) of the Patent Act as then in force, prohibited the claiming of pharmaceutical compositions per se. Now that that statutory provision has been repealed, the underpinning for the Tennessee Eastman case has disappeared, and there is no longer any basis for rejection of claims directed to the use of a pharmaceutical composition. A fortiori, there can be no objection to a claim to a chemical process involving the use of a particular chemical composition.

With respect to point (a) where there is merely a chemical reaction, we are in agreement. Concerning points (b) and (c), we do not share the Agent's views. He suggests the Tennessee Eastman case rests upon the proposition that Section 41(1), as it was then in force, prohibits the claiming of pharmaceutical compositions per se. He notes Section 41(1) does not now contain the previous requirement, and therefore there is no basis in existence for the decision taken in the Tennessee Eastman case. In the recent case Imperial Chemical Industries Ltd v The Commissioner of Patents (1986) 9 C.P.R. (3d) 289, (ICI), the Federal Court looked to the Tennessee Eastman case, and in particular to the significance of the then Section 41(1) which Heald J. dealt with, as follows:

> Coming now to the decision of the Supreme Court of Canada, Mr. Justice Pigeon delivered the Court's decision. He commences his reasons by setting out the agreed statement of facts and issues. At page 204 of the report, he reproduces, with approval, that portion of the reasons of Kerr J. set out supra. It is true that he does discuss the impact of Section 41, presumably since that case was a subsection 41(1) case. However, after that discussion, at page 207 of the report, he states:
>
> > Having come to the conclusion that methods of medical treatment are not contemplated in the definition of "invention" as a kind of "process", the same must, on the same basis, be true of a method of surgical treatment.

> In my opinion, this is a clear and unequivocal statement that "...methods of medical treatment are not contemplated in the definition of "invention" as a kind of process...". That was the sole issue before the Court and it is here answered in unmistakeable and unambiguous language. Accordingly, in my view, the force of that pronouncement cannot be restricted merely to factual situations where subsection 41(1) of the Act applies. It follows, therefore, that the Commissioner did not err in considering himself bound by the ratio of Tennessee Eastman. (our emphasis)

In our opinion, Heald J. says that Section 2 is determinative with respect to methods for treating a living mammal, particularly in view of his inclusion of Mr. Justice Pigeon's comments on page 207. Further, from Tennessee Eastman, we note that following his remarks, Pigeon J. then dealt with the relevance of the British case, Swift's Application (1962) R.P.C. 37 and found it not relevant to the situation before him. Pigeon J. drew attention to another British case, Schering A.G.'s Application (1971) R.P.C. 337. He derives direction therefrom by quoting a passage and providing emphasis to a certain portion that was not so emphasized by the British Court in its report, shown as follows:

> Although, however, on a full consideration of the matter it seems that patents for medical treatment in the strict sense must be excluded under the present Act, the claims the subject of the application do not appear to fall within this prohibition and, on the law as it stands today, they should, at least at this stage in our judgment, be allowed to proceed. As Swift's Application (1962) R.P.C. 37 in the Divisional Court of the Queen's Bench Division clearly established, the Office and the Patents Appeal Tribunal are at this stage not deciding the question of "actual patentability", as the phrase was used in that case, and unless there is no reasonable doubt that a manner of manufacture is not being claimed or the application is plainly without justification, it is their duty to allow the claim. The applicants will then have the opportunity in due course, if the matter arises, of having "actual patentability" decided in the High Court. (Emphasis added).

We believe it is helpful in reviewing the Applicant's subject matter to look at Kerr J.'s reasons given in the Lower Court, that were included by Mr. Justice Pigeon in his decision on the Tennessee Eastman case, as follows:

> ...The method lies essentially in the professional field of surgery and medical treatment of the human body, even although it may be applied at times by persons not in that field. Consequently, it is my conclusion that in the present state of the patent law of Canada and the scope of subject-matter for patent, as indicated by authoritative judgments that I have cited, the method is not an art or process or an improvement of an art or process within the meaning of s. 2(d) of the Patent Act.

In comparing the opinion of Kerr J., to that expressed by Pigeon, J. after his consideration of Section 41(1), we see no differences in their viewpoints. The findings by both Courts in Tennessee Eastman, and as followed by the Federal Court in ICI, state that medical and surgical treatments do not merit patent protection under Section 2 of the Act.

We think that the basis of the Tennessee Eastman decision is Section 2, not Section 41(1), and that Section 2 governs the determination of the issue before us. Moreover, we do not share the Applicant's viewpoint that only a chemical reaction is occuring within the mammal's body. We believe that more than that occurs when the purpose of the method is to administer to a mammal's body particular substances for treating the body. There is no doubt a particular component such as a DTC compound may under proper circumstances be patentable itself. However, where the consideration is with respect to a method of treating a mammal, we think the decision in the Tennessee Eastman case directs that such a method is not patentable. We are persuaded that the method described by the Applicant does not propose nor relate to a mere chemical reaction. We are satisfied the application identifies the utility of the method is achieved when a mammal is treated by administering the PT(II) compounds, followed by the DTC compounds in timed relation thereto.

In our view, the affidavit is concerned with a chemical reaction as it is carried out in vitro or in vivo with microorganisms and cell cultures. We cannot make a recommendation that the description in the application deals with the affidavit subject matter since that matter has not been clearly identified in the application at any stage of the prosecution including at and after the Hearing.

In summary, we find the claims in group A are directed to a medical treatment. The scope of the subject matter discussed in groups B and C may be in accord with the inventor's affidavit, but after a careful consideration of all the matter submitted, we are persuaded that scope presently finds no full support in the application.

We recommend that the refusal of claims 1 to 37 of the application be maintained for presenting no more than a medical treatment, and that the scope of claiming for the subject matter discussed in groups B and C not be accepted.

M.G. Brown
Acting Chairman
Patent Appeal Board

S.D. Kot
Member

I have reviewed the prosecution of this application. I concur with the findings and the recommmendation of the Patent Appeal Board. Accordingly, I refuse to grant a patent containing the claims of this application, and I refuse to accept the additional scope of claiming for the subject matter presented at and after the Hearing. The Applicant has six months within which to appeal my decision under the authority of Section 44 of the Patent Act.

J.H.A Gariépy
Commissioner of Patents

dated at Hull, Quebec
this 22 day of November 1988.

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