IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 547,163, having been rejected under Subsection 47(2) of the Patent Rules, the Applicant asked that the Final Action of the Examiner be reviewed. The rejection has consequently been considered by the Patent Appeal Board and by the Commissioner of Patents. The findings of the Board and the ruling of the Commissioner are as follows:

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COMMISSIONER'S DECISION SUMMARY

C.D. 1201 ....Application No. 547,163 (J70;K20)

Per se claims for microbiologically produced antibiotics

The examiner rejected per se claims for novel antibiotics produced by a microbiological process on the grounds that Section 39(1) of the Patent Act as it read at the time did not allow an applicant to make such claims; process dependent claims being the only type allowed. On the recommendation of the Board the rejection of the per se claims was withdrawn by the Commissioner.

This decision deals with the Applicant's request that the Commissioner of Patents review the Examiner's Final Action on patent application number 547,163 (Class 195-89) which was filed on September 17, 1987 for an invention entitled "GLYCOPEPTIDE ANTIBIOTICS A82846 FROM NOCARDIA ORIENTALIS". The inventors are Robert L. Hamill, James A. Mabe, David F. Mahoney, Walter M. Nakatsukasa and Raymond C. Yao and the application was assigned to Eli Lilly and Company. The Examiner in charge issued the Final Action on December 2, 1991 refusing claims 5 to 12 and 16 to 18, claims 1 to 4 and 13 to 15 being declared allowable. The Applicant replied on June 2, 1993 requesting a review by the Commissioner and an oral hearing before the Patent Appeal Board. Consequently an oral hearing was held on August 10, 1994 at which Mr. David Watson and Dr. John Rudolph of Gowling, Strathy & Henderson represented the Applicant, Dr. Isaac Ho and Dr. Michael Gillen represented the Patent Branch and the Board was comprised of Mr. Peter Davies as chairman and Dr. Michael Howarth as member.

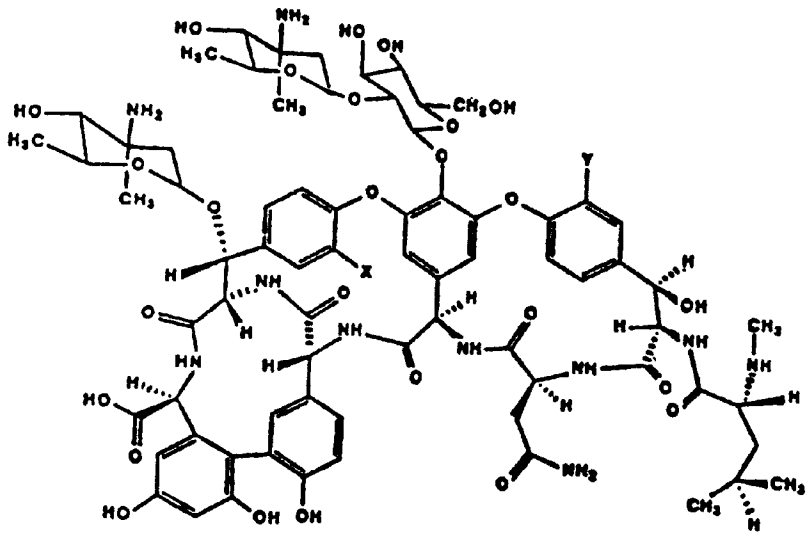
The application is directed to novel glycopeptide antibiotics of the vancomycin group. In particular it relates to antibiotic A82846, to its individual components A82846A, A82846B and A82846C and to their preparation by cultivation of novel strains of the micro-organism Nocardia orientalis designated as NRRL 18098, NRRL 18099 and NRRL 18100 in a culture medium containing assimilable sources of carbon, nitrogen and inorganic salts. Antibiotic A82846 is structurally similar to vancomycin but is disclosed to have improved in vitro and in vivo activity against Gram-positive bacteria as well as improved pharmacokinetics resulting in a much longer half-life than that of vancomycin.

The application contains claims 1 to 3 directed to processes for producing the disclosed antibiotics, claim 4 directed to a biologically purified culture of the disclosed Nocardia orientalis strains, claims 5 to 7 and 13 to 15 directed to the antibiotics claimed in process dependent manner, claim 8 directed to the glycopeptide antibiotic which can be produced by fermentation of Nocardia orientalis, claims 9 to 12 directed to the disclosed antibiotics in per se form, claims 16 and 17 directed to compositions containing the novel antibiotics and claim 18 directed to the use of the novel antibiotics as antimicrobial agents. Claims 5, 8 and 9, which are typical of the claims rejected, are as follows:

> 5. Antibiotic A82846, A82846A, A82846B or A82846C, or a pharmaceutically acceptable salt thereof, whenever prepared by a process according to claim 1, or by an obvious equivalent thereof.

8. The glycopeptide antibiotic which can be produced by submerged aerobic fermentation of Nocardia orientalis NRRL 18098, NRRL 18099 or NRRL 18100 in a culture medium containing assimilable sources of carbon, nitrogen and inorganic salts.

9 Antibiotic A82846, having the following structural formula



wherein X is H or Cl and Y is Cl or H.

In the Final Action two objections to the claims were made; firstly, the Examiner rejected process dependent product claims 5 to 7 for the use of the expression "or by an obvious equivalent thereof" and secondly the Examiner rejected claims 8 to 12 and 16 to 18 for not being in the form required by Subsection 39.(1) of the Patent Act.

In rejecting claims 5 to 7 the Examiner stated that:

> Claims 5 to 7 are rejected as being indefinite and lacking support within the disclosure. The term "obvious equivalent thereof" renders the scope of the claim indefinite and must therefore be avoided. Further, Applicant provides no support for any methods of producing the antibiotics of the instant application, other than that defined in claim 1.

Both in its response to the Final Action and at the Hearing the Applicant has submitted that it is entitled by law to include the rejected expression in the claims and has referred to the acceptance by the Patent Office of the use by applicants of the term "obvious chemical equivalents" in chemical product by process claims, which wording tracks the wording of Subsection 39.(1) of the Act [Patent Act R.S., 1985, c. P-4]. The subsection at the time the application was filed and prior to its repeal read 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 Applicant has adopted the words "obvious equivalents" rather than "obvious chemical equivalents" as being more appropriate in this case since the processes in question are microbiological processes rather than chemical processes. In Applicant's submission the claimed wording reflects the protection to which the Applicant is entitled to as a matter of law. Thus, whilst the repeal of the subsection with the 1987 amendments to the Patent Act merely made it unnecessary to claim products intended for food or medicine in process dependent form it is contended that it did not take away the Applicant's rights to claim obvious equivalents. In support of its submission the Applicant has referred to two court decisions where the term "obvious chemical equivalent" was present in the claims considered.

Firstly in the Exchequer Court decision in C.H. Boehringer Sohn v. Bell-Craig Ltd. 39 C.P.R. 201, affirmed 41 C.P.R. 1 the Court, in deciding whether claim 8 of the patent in question had been infringed by the defendant, had to consider whether the defendant's process was an obvious chemical equivalent of the claimed process. In coming to its conclusion that the defendant's process was not an obvious chemical equivalent of the process described in the patent the Court however gave no indication that the use of the term "by any obvious chemical equivalent" in the claim was anything other than acceptable practice.

The second case referred to by the Applicant is the Exchequer Court decision in Jules R. Gilbert Ltd. v. Sandoz Patents Ltd. 64 C.P.R. 14; 8 C.P.R. (2d) 210. In this decision it was held that claim 9, which claimed a therapeutically tolerable salt of 3-methylmercapto-10-[-2'-(N-methyl-piperidyl-2'')-ethyl-1'-]-phenothiazine whenever prepared by the process of claim 5 or by any chemically equivalent process, was invalid because the process of claim 5 had not been properly disclosed. In the Supreme Court this finding was reversed and claim 9 was found to be valid. In both of these decisions there was no indication that the use of the term "chemically equivalent process" in claim 9 went to the root of the issue.

While these two court decisions show that reference to obvious chemical equivalents was acceptable when the legislation specifically referred to it the Board is not convinced that the

same can be said of the term "obvious equivalent" since there is no reference to that term in the section that replaced former Subsection 39.(1). It is the Board's opinion that if it had been Parliament's intention that a patentee be allowed to claim the obvious equivalents of a microbiological process it would have included the term in the new subsection. The fact that the term was not included can therefore be taken to mean that an applicant cannot as a matter of course employ language in a claim to cover obvious equivalents. The Board therefore considers that the Applicant is not by law entitled to use the term "obvious equivalent" in the claims.

It is therefore the Board's view that the term "or obvious equivalents" must be considered on its own merits using the general principles of claim construction. In this regard the Board finds that the inclusion of the term "or obvious equivalents" introduces an ambiguity into the claim. It cannot be determined what these equivalents are and as stated by the examiner, and not contradicted by the Applicant, the disclosure does not provide any information as to what these obviously equivalent processes might be. The Board therefore finds that the term renders the claims indefinite and recommends that the rejection of claims 5 to 7 be affirmed.

Turning now to the rejection of claims 8 to 12 and 16 to 18 for non-compliance with the requirements of Subsection 39.(1) of the Act the Examiner in her Final Action stated that:

> Contrary to Applicant's arguments, applications that are governed by the provisions of subsection 39(1) of the Patent Act and that were filed prior to October 1, 1989, the proclamation date of the Act to amend the Patent Act, may not be issued containing per se product claims even after this subsection ceased to have effect on November 19, 1991.
>
> Section 27 of the Act to amend the Patent Act, which is a transitional section, specifies that applications filed before the coming into force of the amended Patent Act "shall be dealt with and disposed of" according to the Patent Act as it read immediately before October 1, 1989.
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> Since subsection 39(1) came into force upon Royal Assent on November 19, 1987, prohibiting the inclusion in the specification of claims to the naturally occurring substances intended for food or medicine and prepared by, or significantly derived from microbiological processes, this subsection as it now reads was in effect when the amended Patent Act was proclaimed on October 1, 1989.
>
> Consequently, all applications filed before October 1, 1989 are to be dealt with and disposed of in accordance with the prohibition of subsection 39(1), notwithstanding the expiry of this subsection on November 19, 1991.

Since Subsection 39.(1) deals with inventions which relate to naturally occurring substances produced by microbiological processes the remainder of the Final Action was concerned with the question of whether or not the substances disclosed in the application are in fact naturally occurring substances within the meaning of the subsection. It is the Applicant's contention that the disclosed antibiotics are not naturally occurring and therefore not within the subsection. In its response to the Final Action the Applicant submitted claims 19 to 26 which are directed to pharmaceutically acceptable salts of the disclosed antibiotics and asked that they be considered by the Commissioner. These claims are said to be clearly directed to substances which cannot be said to be naturally occurring since they are prepared by the chemical reaction of the antibiotics with a suitable salt forming reactant.

At the hearing in presenting the case for the allowability of claims 8 to 12 and 16 to 18 Mr. Watson dealt with whether or not the disclosed antibiotics are naturally occurring and also with the interpretation of Subsection 39.(1) while Dr. Rudolph dealt with the effect of the North American Free Trade Agreement (NAFTA) on the interpretation of the subsection. After considering the material filed in this case and the presentations given at the hearing the Board has concluded that the Examiner's position is based on a misinterpretation of the provisions found in the statute, particularly in the transition clause.

An Act to amend the Patent Act and to provide for certain matters in relation thereto [Chapter 33 (3rd Supp.) R.S. 1989] will hereinafter be referred to as Bill C-22. Bill C-22, which was given Royal Assent on November 19, 1987, made a number of changes to the *Patent Act*, one of which was to what had been Subsection 39.(1). This subsection had required an applicant for a patent relating to a substance produced by a chemical process and intended for food and medicine to claim the substance in process dependent form. The new subsection introduced in Bill C-22 however required an applicant for a patent relating only to a naturally occurring substance which had been prepared by a microbiological process and intended as a food or medicine to claim the substance in process dependent form. The change was clearly intended to increase the patent protection afforded to the inventors of substances intended for food or medicine and prepared by non-microbiological processes by allowing them to claim the substances without any process limitations, i.e. in per se form.

Clause 14 of Bill C-22 which detailed the new subsection reads as follows:

> 14. Subsection 39(1) of the said Act is repealed and the following substituted therefor:
>
> "39.(1) In the case of inventions relating to naturally occurring substances prepared or produced by, or significantly derived from, microbiological processes and intended for food or medicine, the specification shall not include claims for the resulting food or medicine itself, except when prepared or produced by or significantly derived from the methods or processes of manufacture particularly described and claimed.
>
> (1.1) Subsection (1) ceases to have effect four years after the coming into force of that subsection."

The Board agrees with the Examiner that Subsection 39.(1) came into force on November 19, 1987 when Bill C-22 was given Royal Assent and ceased to have effect according to the provisions of Subsection 39.(1.1) on November 19, 1991. However the Board disagrees with the Examiner's interpretation of transition clause 28 of Bill C-22. Clause 28 is as follows:

> 28. Applications for patents filed before the coming into force of the provisions of this Act referred to in subsection 33(1) shall be dealt with and disposed of in accordance with the *Patent Act* as it read immediately before the coming into force of those provisions.

The Examiner in her Final Action has taken the position that the Act in general was proclaimed on October 1, 1989 and that transitional clause 28 somehow modifies the application of Subsection 39.(1) of the Patent Act to pending applications. The Examiner contends that Section 28 states that any application filed before the coming into force date October 1, 1989 must be dealt with in accordance with the Act as it read immediately before that date. Since it is accepted that new Subsection 39.(1) was in force on October 1, 1989 it is argued that all applications pending at that date must be dealt with under that subsection, notwithstanding the provisions of Subsection 39.(1.1). In other words any applications filed before October 1, 1989 relating to naturally occurring substances prepared by microbiological processes should not be allowed with anything but process dependent product claims. The expiry of the subsection in November 19, 1991 is said not to apply to applications filed before October 1, 1989.

In the Board's opinion this interpretation of the amended Patent Act is based on an apparent misinterpretation of transitional Clause 28. Transitional Clause 28 sets out how applications for patents are to be treated during the changeover from the old to the new legislation. However a reading of the section demonstrates that the section is concerned only with certain parts of Bill C-22, namely the provisions referred to in Subsection 33(1) of the Bill which appears in Bill C-22 under the heading "Coming Into Force". Transitional Clause 33 is as follows:

> 33.(1) The definition of "priority date" in section 2 of the *Patent Act*, as enacted by subsection 1(2) of this Act, sections 2, 5, 7 to 13 and 16 to 25 and subsection 27(1) of this Act, or any of those sections or subsections, shall come into force on a day or days to be fixed by proclamation.
>
> (2) Sections 39.1 to 39.25 of the *Patent Act*, as enacted by section 15 of this Act, or any of those sections, subsections 27(2) and (3) of this Act or either of those subsections, and section 31 of this Act shall come into force on a day/or days to be fixed by proclamation.

The effect of these coming into force provisions was to divide the legislation into three principal parts with each part having a separate coming into force date. The first part relates to those sections of Bill C-22 which are not mentioned in Subsections 33(1) and (2) and which therefore came into force upon Royal Assent on November 19, 1987. Since this first part included Clause 14 of Bill C-22 relating to the changes under consideration new Subsections 39.(1) and (1.1) clearly came into force on November 19, 1987. The second part is described/in Subsection 33(2) of the coming into force provisions and relates to the compulsory licensing provisions of Sections 39.1 to 39.25 as enacted under Clause 15 of Bill C-22. These provisions came into force by royal proclamation on December 7, 1987. The third part of Bill C-22 as described in Subsection 33(1) of the coming into force provisions came into force by royal proclamation on October 1, 1989. In the Board's opinion these three parts of Bill C-22 were explicitly designed to operate independently of each other to provide for full flexibility in the implementation of the differing provisions/of Bill C-22.

Thus Transitional Clause 28 by referring only to those provisions of the Act referred to in Subsection 33(1) specifically excluded Clause 14 from consideration. In other words Clause 28 does not require that the provisions of Subsection 39.(1) be applied to pending applications filed before October 1, 1989 as contended by the Examiner. In the Board's view the most reasonable interpretation of the transitional sections of Bill C-22 is that

Subsection 39.(1) came into force on Royal Assent on November 19, 1987 and according to Subsection 39.(1.1) ceased to have effect four years later on November 19, 1991. The coming into force date of October 1, 1989 of other sections of Bill C-22 therefore has no influence on the operation of the provisions of Section 39. The effect of this is that any application relating to naturally occurring substances prepared by microbiological processes and pending on November 19, 1991 was allowed to contain claims to the substances without any process limitations whatsoever regardless of its filing date and to issue with those claims.

This same conclusion can be drawn from the clear and ordinary meaning of the language employed in Clause 28 of Bill C-22. Clause 28 stipulates that applications filed before October 1, 1989 are to be dealt with and disposed of in accordance with the *Patent Act* as it read immediately before October 1, 1989. Immediately before October 1, 1989 both subsection 39.(1) and 39.(1.1) were included in the Act viz. subsection 39.(1) which introduced the prohibition on claiming in the microbiological area and subsection 39.(1.1) the repeal of subsection 39.(1). It follows that applications/filed before October 1, 1989 must be dealt with and disposed of taking into account the repeal that came into effect on November 19, 1991.

It is therefore the Board's opinion that subsection 39.(1) came into force on November 19, 1987 and continued in force until the provisions of subsection 39.(1.1) became operative four years later, i.e. on November 19, 1991. From the period November 19, 1987 until November 19, 1991 no patent would be allowed to issue containing claims to a naturally occurring substance intended for food or medicine and prepared by a microbiological process unless the substance was claimed in process dependent fashion. After November 19, 1991 Section 39 ceased to have/effect so that any patent issuing after that date was allowed to contain claims to naturally occurring substances with no process limitations. In other words inventions relating to naturally occurring substances intended for food or medicine and prepared by microbiological processes were to be treated no differently than substances intended for food or medicine and prepared by chemical processes or indeed from substances intended for entirely different uses such as pesticides, insecticides, lubricants. etc.

Since it has been decided that the Applicant is entitled to <u>per se</u> claims for the antibiotics disclosed in its application on the grounds that Subsection 39 of the Act/clearly ceased to have

effect on November 19, 1991 the Board has not found it necessary to consider the other submissions made by the Applicant, such as whether or not the disclosed antibiotics are naturally occurring, whether or not the subsection discriminates against certain applicants and what the possible effect of the recent NAFTA legislation on the subsection might be. Nor has the Board found it necessary to consider claims 19 to 26 which were submitted by the Applicant in its response to the Final Action. The Board therefore recommends that the rejection of claims 8 to 12 and 16 to 18 be withdrawn.

In conclusion the Board recommends that the rejection of claims 5 to 7 be affirmed but that the rejection of claims 8 to 12 and 16 to 18 be withdrawn.

P.J. Davies
Chairman
Patent Appeal Board

M. Howarth
Member
Patent Appeal Board

I concur with the findings and the recommendation of the Board. Accordingly, I withdraw the rejection of claims 8 to 12 and 16 to 18 and uphold the rejection of claims 5 to 7. Consequently I refuse to grant a patent containing claims 5 to 7. Under the provisions of Section 41 of the Patent Act the Applicant has six months within which to appeal this decision to the Federal Court of Canada.

M. Leesti
Commissioner of Patents

Dated at Hull, Quebec
this 13th day of January 1995