COMMISSIONER'S DECISION

SECTION 41 & 36: Anti-arthritic Steroids

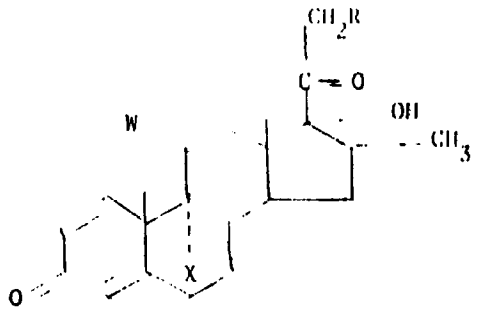
The applicant's invention related to a microbiological process to make certain steroids, followed by extraction with chemicals to obtain the medically useful form of the product. His claims to the final product satisfied Section 41, but he also claimed the intermediate or unpurified product in per se form. The intermediate product was held to be intended for medicine, to be made by a chemical process, and as failing to define the invention made. Certain process claims were refused for failing to define the invention adequately, and as broader than the invention disclosed.

FINAL ACTION: Affirmed

The Final Rejection of two applications for patent assigned to Merck & Co. Inc. were referred to the Patent Appeal Board for consideration. The applications were 154365 (Class 260/69), for 16-Methyl-1, 4-Pregnadiene-17α-ol-3, 20-Dione Compounds (Glen E. Arth et al, inventors) and 154366 (Class 260/69) for 11,21-Bis-oxygenated-17α-Hydroxy-16β-Methyl steroid-3,20-Diones (David Taub et al, inventors). There was a hearing before the Board on November 27, 1974, at which Mr. David Watson, Q.C., and Mr. Bassford of the Merck company represented the applicant. The two applications are cognate, dealing with essentially the same issues, so that the findings on one will apply mutatis mutandis to the other.

Our first consideration is application 154365. It contains 195 claims directed to certain pregnadiene compounds (their exact chemical structure need not concern us), and processes for preparing and extracting them. It is a division of Canadian Patent 914151 which affords the applicant protection for the pregnadienes when prepared by certain chemical processes. The compounds possess therapeutic properties, and are useful to treat arthritis. Claims 1, 44, 90, 134, 154 and 167 which are given below, illustrate various aspects of the protection sought.

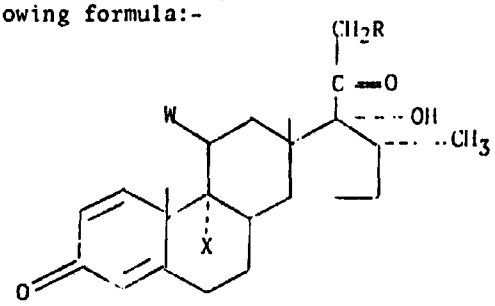
1. A pharmaceutically impure 16α-methyl-11, 21-bis-oxygenated-1, 4-pregnadiene-17α-ol-3, 20-dione having the following formula:-



wherein X is hydrogen or fluoro, W is keto or α-hydroxy; and R is hydroxy, phosphoryloxy or lower hydrocarboncarbonyloxy.

...

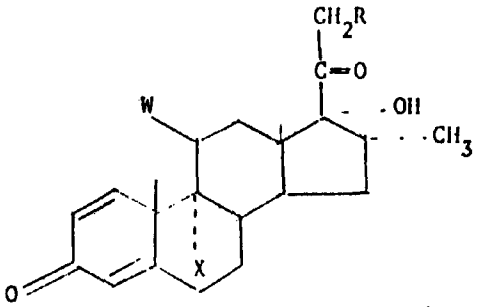
44. A method of making a pharmaceutically pure 16α-methyl-11, 21-bis-oxygenated-1, 4-pregnadiene-17α-ol-3, 20-dione having the following formula:-



wherein X is hydrogen or fluoro, W is keto or α-hydroxy; and R is hydroxy, phosphoryloxy or lower hydrocarboncarbonyloxy, which comprises subjecting the corresponding pharmaceutically impure compound to an extraction process, whereby to remove the impurities therefrom.

...

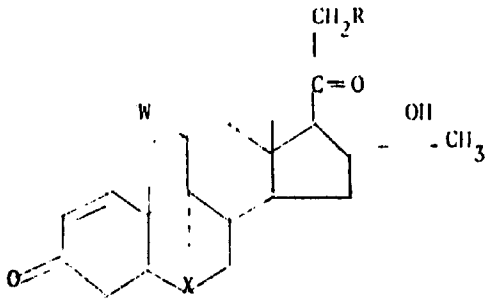
90. A pharmaceutically pure 16α-methyl-11, 21-bis-oxygenated-1,4-pregnadiene-17α-ol-3,20-dione having the following formula:-



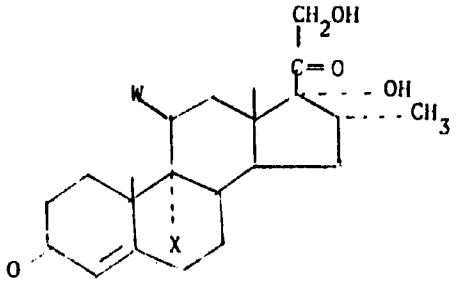
wherein X is hydrogen or fluoro, W is keto or α-hydroxy; and R is hydroxy, phosphoryloxy or lower hydrocarboncarbonyloxy, whenever prepared or produced by the process of Claim 44.

...

134. A process for the production of a pharmaceutically pure 16α-methyl-11,21-bis-oxygenated-1,4-pregnadiene-17α-ol-3,20-dione having the following formula:-



wherein X is hydrogen or fluoro; W is keto or β-hydroxy; and R is hydroxy,phosphoryloxy or lower hydrocarbon carbonyloxy which comprises subjecting a compound of the formula:-

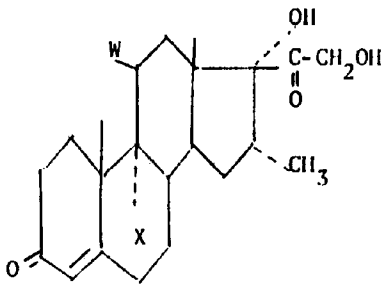


where W and X are as above or a 21 ester thereof to the dehydrogenating activity of Schizomycete microorganisms, and when R is required to be phosphoryloxy reacting the product obtained with a phosphorylating agent and when R is required to be lower hydrocarbon carbonyloxy reacting the product obtained with a lower hydrocarbon carboxylic acid acylating agent, and subjecting the resulting product to an extraction process.

...

154. A process for the production of a pharmaceutically impure ring unsaturated 16α-methyl-11-oxygenated-steroid-17α-ol-3,20-dione compound of the pregnene series where there is unsaturation in both the 1,2 or 4,5 positions or a 21-ester thereof where the 21-ester substituent is selected from phosphoryloxy or a lower hydrocarbon carbonyloxy which comprises contacting the corresponding pregnene compound with unsaturation only in the 1,2 position to the dehydrogenating activity of Schizomycete micro-organisms and when the 21-ester is required esterifying the 21 hydroxy group in the product.
...

167. A 16-methyl-11,21-bis-oxygenated-4-pregnene-17α-ol-3,20-dione having the following formula:



wherein X is selected from the group consisting of hydrogen and fluoro; and W is selected from the group consisting of keto and β-hydroxy.

The claims cover a series of steps and products, viz, a bacteriological process for dehydrogenating pregnenes to produce dehydrogenated pregnenes (cl. 154 and others); impure products resulting from such dehydrogenation claimed in independent (per se) form (cl.1 to 43); the step of purifying the impure products by extraction with chemical solvents, or by chromomatic adsorption or by crystallization (cl. 44 etc.); the purified products (such claims are made dependent upon the extraction step) (cl. 90 etc.); the starting compounds used in the dehydrogenation process (cl. 167 etc.); the process of bacteriological dehydrogenation coupled with extraction (cl. 134 etc.); and chemical processes for preparing the starting materials (claims 172-195).

The examiner refused all the product claims not dependent upon the process of preparing them for failure to comply with the requirements of Section 41 of the Patent Act. He also objected to the claims to the extraction (or purification) step for failing to satisfy Section 36. In addition he noted that Section 38 was contravened by virtue of the variety of processes and products claimed. The applicant has accepted the validity of that objection, and there is no need for the Board to pursue it. It may be resolved at the conclusion of the current proceedings.

The examiner expressed his objections made under Sections 41 and 36 in the following terms:

> The objection to claims 167 to 171, 174, 176, 178 and 187 to 195 is maintained and the reason for such objection is that the compounds claimed in the aforementioned claims are considered to be governed by Section 41(1) of the Act. Since the courts have consistently maintained during the last few years that the word, "medicine", for the purpose of Section 41(1) must be interpreted in the broad and ordinary sense it is the Patent Office position that the term, "medicine", includes not only those substances which are intended for direct use as medicines but also those substances which are capable of being used for the preparation or production of medicines. The compounds claimed in claims 167 to 171, 174, 176, 178 and 187 to 195 are compounds which fall within the latter category i.e. they are substances which are capable of being used for the preparation of medicines and which are prepared by chemical processes and as such are considered to come within the scope of Section 41(1) of the Act.

Furthermore to permit an applicant to claim an intermediate whose use is for the preparation of a medicine in "per se" form would be to allow a circumvention of the intent and spirit of Section 41(1). In the case of Tennessee Eastman v. Commissioner of Patents, Supreme Court, 1972 it was stated that inventions relating to medicine must comply with the requirements of Section 41(1) of the Act and that to permit applicants to claim a medicinal invention in "per se" form by means of a method of medical treatment would be to negate the intent of Section 41(1) and would give the applicants an easy way out of the restrictions of the Section. Since the present situation with regard to intermediates capable of being used for the preparation of medicines is considered to be analogous to the situation which occurred in the Tennessee-Eastman case cited above the philosophy behind said case is considered to apply to the medicinal intermediates as well i.e. that only claims which comply with the requirements of Section 41(1) will be allowed. Claims 167 to 171, 174, 176, 178 and 187 to 195 must therefore either be amended to comply with the requirements of Section 41(1) or be deleted in their entirety.

The objection to claims 1 to 43, which are directed to pharmaceutically impure compounds, is maintained and the reason for such objection is that the claims are not restricted to impure compounds when produced by applicant's claimed microbiological processes but cover the said impure compounds when produced by any process, chemical or microbiological. To maintain, "per se", type claims to the impure products described in claims 1 to 43 the applicant must include in the claims the limitation that the said impure compounds are produced by microbiological processes since otherwise the claims cover the impure compounds when prepared by chemical processes and are not allowable since they fail to comply with the requirements of Section 41(1) of the Act for the reason given earlier in this Final Action. The applicant must therefore either amend claims 1 to 43 by including in the claims the limitation that the impurities are those which arise from the disclosed microbiological processes or by making the claims dependent on process claims describing the disclosed microbiological processes.

The objection to claims 44 to 89 (equivalent to former claims 87 to 132) is maintained and the reason for such objection is that the claims do not define processes in the clear and explicit manner required by Section 36(2) of the Act in that they do not define the purification processes used in sufficient detail and do not state that the impurities being removed are those which arise from applicant's disclosed microbiological processes. Furthermore the claims as written apply to any process for preparing the compounds in question and would, if allowed, give the applicant a monopoly over every process, chemical or microbiological, known or unknown, thus allowing the applicant to evade the restrictions of Section 41(1) of the Act. Since one of the purposes of Section 41(1) is to encourage the discovery of new processes for the preparation of medicines claims which give an applicant a monopoly over a particular medicine either by a "per se" product claim or by a process claim

which is so broad as to be almost equivalent to a "per se" product claim cannot be allowed. Claims 44 to 89 must therefore either be amended to refer only to the purification of compounds obtained by applicant's microbiological processes or be deleted in their entirety along with dependent claims 90 to 133.

Because of the large number of claims, it may be useful to indicate their status in tabular form.

Refused	Not Refused
1 - 43 - Product claims, - impure form	
44 - 89 - Process claims, - extraction	
90 - 133 - Product claims, dependent on cls. 44 - 89	
	134 - 166 - Process cls. bacteriological with extraction
167 - 171- Product cls., starting material	
	172 - 173 - Chemical process clms. to make starting material
174 - Product claim, starting material	
	175 "
176 "	
	177 "
178 "	
187 - 190 "	179 - 186 "
191 - 195 "	

The applicant's countering arguments were presented in comprehensive detail in his response of April 25, 1974, in his appeal brief, and as part of his oral submissions to the Board. Because those submissions were so extensive it would be impractical to reproduce them fully here, and we will content ourselves with summarizing them as we proceed to discuss the rejection of the various groups of claims.

At the hearing Mr. Bassford stressed the importance of drug research and the need to promote such research. He also represented that his company was a responsible firm making important contributions to the

advancement of medical science. With that there can be no quarrel and we second such statements. We are concerned here, however, with narrower issues. We must decide whether the applicant is legally entitled to the various aspects of the invention claimed, and in what manner they may be claimed. We must limit our attentions to the legal requirements of the Patent Act, and to the jurisprudence interpreting such legislation.

Many of the issues raised in this case have already been considered by the Board and by the Commissioner of Patents in a decision published in the Patent Office Record of January 21, 1975, beginning at page xiii. We have not been persuaded that those findings were incorrect in so far as they apply here and to the extent that they apply here. In the interest of brevity we do not think we need cover the same ground a second time, and consequently reference should be made to the earlier decision for the reasoning given in it.

The applicant has agreed that the compounds covered by claims 167-171 and 187-190 are themselves active medicinally, is willing to place them in process-dependent form, and has withdrawn his appeal with respect to them (Appeal Brief, page 2). Consequently they need not be considered further.

In addition, the only objection to claims 90-133 is that they are dependent on rejected claims 44-89, and their allowability will stand or fall with those claims. Consequently they need not be reviewed.

Claims 174, 176, 178 and 191-5 are for chemical compounds, made by chemical processes, which are intermediates to prepare medically active products, but which are themselves therapeutically inactive. For that reason, the applicant contends, Section 41 does not apply to them. It is his position that chemical compounds are not "intended" for medicines if they themselves are not useful medicinally. To quote:

> But this objection is unsupported in law since it would require interpreting the words "intended for...medicine" in Section 41(1) as having the same meaning as the words "intended or capable of being used for medicine or for the preparation or production of medicine" in Section 41(4). Such interpretation is directly contrary to the decision of the Supreme Court of Canada in Parke Davis & Co. vs Fine Chemicals (1959) 30 C.P.R. 59, at page 67, where Martland, J. with whom Locke and Cartwright JJ, concurred, states:-
>
> > "It seems to me that s. 41 must be construed as a whole. Subsection (1) applies to inventions relating to substances prepared or produced by chemical processes and intended for food or medicine. Subsection (3) goes somewhat further and also applies to any patent for an invention capable of being used for the preparation or production of food or medicine."
>
> Accordingly, former subsection 41(3), which contained similar language to Section 41(4), was specifically interpreted as going further than Section 41(1).
>
> The interpretation adopted by the Examiner is also contrary to well established principles of statutory interpretation. Thus, Maxwell on Interpretation of Statutes" 12th Edition (1969) at page 282 states:
>
> > "From the general presumption that the same expression is presumed to be used in the same sense throughout an Act or a series of cognate Acts, there follows the further presumption that a change of wording denotes a change in meaning."

The applicant also referred to Magor v. Newport (1952) Appeal Cases 189, which, he says, "shows that the wording of the statute (Section 41) is to be applied as it reads and that to 'fill in gaps' is to legislate." In other words, he contends that to take the words "intended for medicine" as being applicable to substances which are to be made into medicine is contrary to the plain meaning of that phrase, and that to so interpret them would be to legislate. With this we do not agree. The situation corresponds to what was considered in the published decision, in which, after reviewing numerous earlier decisions we concluded as follows (p.xviii):

> The decisions 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 medicine should be considered as "intended for medicine."

Mr. Watson has suggested that the examiner has been improperly troubled with the legislative intent behind Section 41. That concern, however, was also dealt with in the earlier decision, again at p. xviii:

> 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."

When considering the differences in wording between the various subsections of Section 41, it must be remembered that subsections (3) and (4) deal with "inventions" broadly, while subsection 1 is limited to inventions which are substances. We believe this explains the statement from Parke, Davis v. Fine Chemicals quoted above by the applicant that subsection (3) goes further than subsection 1. The two latter subsections would cover, for example, a mechanical blender capable of being used for the preparation of a medicine. Such a blender would not be a "substance" within the meaning of subsection (1), but it would be an "invention" capable of being used for the preparation of a food or medicine within the meaning of subsections (3) and (4).

The applicant has made a further argument, which we quote:

> It is furthermore submitted that the interpretation of Section 41(1) to include not only substances intended for medicine, but also those capable of being used for the preparation or production of food or medicine, is entirely inconsistent with the theory and philosophy underlying the Section, and would bring all substances, not only medicines, within the ambit of Section 41(1). The first subsection of Section 41 is intended, as has been held by the Courts, to encourage process inventions by limiting the inventor of a new medicine, when prepared by a chemical process, to protection for that medicine only when prepared by that chemical process, thus leaving open to others the opportunity of contributing improved alternative chemical processes for preparing the said medicine. Section 41(1) certainly did not intend that such process limitation should be extended ad infinitum to intermediate after intermediate merely because such intermediates are "capable of being used for the

> preparation of ...medicine" To so construe the word "medicine" as used in Section 41, even when "interpreted in the broad and ordinary sense" is clearly unwarranted since, under such construction, almost any substance could be alleged to be capable of use in production of medicine; and the proposed interpretation would abrogate for Canada all per se product protection for any substance whatsoever. (underlining added)

We point out, however, that we are not concerned with inventions"capable of being used for the preparation of medicine," as the applicant puts it, but those which are intended to be used for the production of medicine. This in no sense means that all new chemical compounds are subject to Section 41 because they are capable of being made into medicine and might in some unseen eventuality be used to make a medicine. If it is intended that they be used for another purpose, Section 41 would not apply. However when the only possible known use for them is conversion into a medicine, whether that be one or several steps removed, then in our view they are intended for medicine.

We see no need to belabour further the points made in the earlier decision. We consider that the rejection of this group of claims (174, 176, 178 & 191-5) for failure to comply with Section 41 was proper.

That brings us to claims 1-43, those for "pharmaceutically impure" compounds. These claims would cover compounds no matter how they are prepared, including chemical processes. With respect to them the applicant stated:

> The Examiner has objected to claims 1-43, which are directed to pharmaceutically impure 16α-methyl-11,21-bisoxygenated-1,4-pregnadiene-17α-ol-3,20-diones, on the ground that applicants "must include in the claims the limitation that the said impure compounds are produced by microbiological processes since otherwise the claims ...fail to comply with the requirements of Section 41(1)". But the pharmaceutically impure compounds defined in claims 1-43 are not medicines. This was established in Laboratoire Pentagone vs. Parke Davis & Co. (1968) 55 C.P.R. 111, at page 114, where Pigeon, J. who delivered the judgment of the Supreme Court stated:
>
> > It is clearly proven that this antibiotic, chloramphenicol, is secreted by micro-organisms in the culture medium, but it is diluted, mixed with numerous impurities and not usable in this impure state. The extraction process is indispensable

> for obtaining a usable substance for therapeutic purposes, the evidence demonstrates this and the respondent has admitted it before this Court. Consequently, the whole litigation on the second question comes down to deciding whether the fermentation and extraction be chemical processes within the meaning of the Patent Act, as the appellant claims, or as the respondent and its experts maintain, that the fermentation is a biological process and extraction a purely physical process."
>
> Moreover, in the Tennessee-Eastman case (1974 S.C.R.111), it was held that, for a substance to be intended for medicine, such substance must be usable in the treatment of disease. If this principle is considered in conjunction with the Laboratoire Pentagone case, wherein the Court held that the impure product of a microbiological process is not usable for medicine, it will be clear that, according to existing jurisprudence, claims 1-43 are not claims for medicine, and do not fall within Section 41(1) of the Patent Act.

Read carefully, and properly, neither the Laboratoire Pentagone case nor the quotation from it relied upon by the applicant say that the pharmaceutically impure compounds "are not medicines." What they say is that such a substance is not "a useable substance for therapeutic purposes." That is an important distinction.

The applicant's suggestion that the compositions are not medicines is specious, and comparable to what was rejected by the Supreme Court in Parke, Davis v. Fine Chemicals, 1959 S.C.R. 219 at 221, when it discarded the proposition that a substance was not a medicine because it was in bulk form. Whether in bulk form, or in impure form, the substance in question is a medicine.

In any event, there is no doubt in our mind that it is a substance "intended" for medicine, for the same reasons as we advanced above against the other product claims.

In the immediately preceding quotation from his response, the applicant stated:

> Moreover, in the Tennessee-Eastman case, it was held that for a substance to be intended for medicine, such substance must be useable in the treatment of disease.

We have reread the Tennessee decision (1971 S.C.R. 111) several times, and have not located any passage justifying such a statement. If the applicant wished to predicate that in the Tennessee-Eastman case it was held that for a substance to be a medicine, such substance must be useable in the treatment of disease, his interpretation would be more reasonable. But that is far different from stating the decision holds that for a substance to be intended for medicine it must itself be useable in treatment. As we stressed before, there is an important difference between "medicine" and "intended for medicine." We suppose the applicant had in mind the following passage, which does appear in the decision:

> There is no doubt that when a new substance is claimed as an invention of a 'medicine', it has to be shown that it is active and non-toxic in therapeutic doses.

If so, his interpretation of it is much broader than we think is justifiable.

Having determined that claims 1-43 cover substances intended for medicine, we must next consider whether they are prepared by chemical processes within the meaning of Section 41(1). The applicant's arguments on that point were put as follows:

> Furthermore, the pharmaceutically impure 16 -methyl-11, 21-bis-oxygenated-17 -ol-3,20-diones of claims 1-43 are substances produced by a microbiological process, not by a chemical process. The Quebec Court of Appeals in the Pentagone case followed the decision of Continental Soya vs. Short Milling 2C.P.R. 1., (1942 S.C.R. 187) in which the Supreme Court held that a biological process is not a chemical process; and this ruling was not disturbed by the Supreme Court in its decision on the Pentagone appeal.

This issue presents several interesting questions. First, we must square the Continental Soya decision (supra) with both Laboratoire

Pentagone (supra), and with Dairy Foods v. Co-operative Agricole de Granby 4 C.P.R. (2d) 58 and 8 C.P.R. (2d)1. We must also decide whether it is permissible to break up a complete invention which is governed by Section 41 into bits and pieces, and by approving claims to non-chemical portions effectively circumvent Section 41.

The applicant relies upon the Continental Soya decision as holding that microbiological processes are not chemical. It is correct that faced with the particular facts before it, both the lower Court (1941) Ex.C.R. 69) and the Supreme Court concluded that the process in question was not chemical, and Section 40 (now 41) did not apply. That process, however, was for the preparation of a soy-bean flour from soy beans in such a manner that the flour retained an enzyme which pre-existed within the bean. The enzyme was useful to bleach wheat flour, but previous methods for preparing the flour led to destruction of the enzyme (1941 Ex.C.R. 84, lines 27-34). The enzyme was neither created by the patentee's process, nor destroyed by it. The finding of the court was predicated upon the conclusion that the invented substance (i.e. the enzyme) had not been prepared by a chemical process. Whether the Continental Soya decision has wider implications has been questioned in the Dairy Foods case (supra). Mr. Justice Noel stated (4 C.P.R. (2d), p. 100):

> There really are but two decisions which may be of some assistance in determining whether plaintiff's process is chemical or not within the meaning of s. 41(1) of the Patent Act and these are Continental Soya Co. Ltd. v. J.R. Short Milling Co. (Canada) Ltd. (1942), 2 C.P.R. 1 at p. 5, (1942) 2 D.L.R. 114, (1942) S.C.R. 187, where it was held that the application of heat for drying alone was not chemical nor was the addition of water to stimulate germination as this was a vital process. The nature of the evidence, however, in the last case, is not clear and it may well be that the matter of whether biological processes can still be considered as chemical, is still open, if one considers that in the decision of the Supreme Court of Canada in Laboratoire Pentagone Ltée v. Parke, Davis Co. (1968), 55 C.P.R. 111 at p. 118, 69 D.L.R. (2d) 267, (1968) S.C.R. 307 the first phase of

> the production of an antibiotic by means of living organisms (i.e., a vital process) was not considered. It was indeed decided in this case that as an examination of the extraction process was sufficient to dispose of the appeal, it was not necessary to consider the fermentation process. The extraction process consisted of alternatives of solvent extraction or the use of activated charcoal to separate the product. The evidence here was that the processes of extraction by absorption or by solvents are in the field of physical chemistry. It was also held that extraction by a solvent use(s) the chemical properties of a chemical substance and it is of some interest to point out that the Court noted with approval that fractional distillation (which is merely the heating up of something and the distilling it over) is a chemical process as was a process for the manufacture of activated charcoal.
>
> A passage from Maclean, J., in the Continental Soya case, supra, which decision was approved by the Supreme Court, indicates the difficulties involved in determining the line of demarcation between what should be considered as a chemical process within the meaning of s. 41(1) and what should not. It was pointed out in the J.R. Short Milling Co. Ltd. v. Geo. Weston Bread and Cakes Ltd. et al., (1940) 4 D.L.R. 579, (1941) Ex.C.R. 69 (affirmed (1942), 2 C.P.R. 1, (1942) 2 D.L.R. 114, (1942) S.C.R. 187), that it was not because a chemical reaction occurred in the application of a process that it had to be held to be a chemical process, even though a chemical reaction took place, as happens in all kinds of ordinary operations such as in the making of bread and the ordinary biological processes which no one classifies as chemical processes in everyday language. (underlining added)

On appeal the decision was affirmed, with special consideration given to whether the process would be considered chemical in the "popular" sense. To quote from Chief Justice, Mr. Jackett (8 C.P.R. 1 at 4):

> Counsel went on to submit that the learned trial Judge had over-emphasized the importance of the chemical reactions which occur in the process and bring about the formation of the aggregates and had not addressed his mind to the question of whether the process as described was a chemical process in the popular or ordinary sense.
>
> In dealing with the question, however, the learned trial Judge appears to me to have considered not only the fact that several reactions, which are properly regarded as chemical reactions and which are essential to the formation of the product, are involved in the process but as well the fact that what he refers to as the "instrumentalities of chemistry" are put to work to achieve the desired result....
>
> ...On the facts as found by him I reach the same conclusion. It is clear from the Continental Soya and Pentagone cases that the matter is not to be resolved simply by reference to the fact that chemical reactions occur in the process. But the fact that chemical reactions do occur in the process and in addition

> bring about the result must be of some importance in the situation as a whole and cannot be disregarded entirely.
>
> Here is no mere process of nature. Nor is it akin to the purely mechanical process of sawing logs into lumber or grinding grain into flour. Nor yet is it like the baking of bread which, while involving chemical reactions, is not popularly regarded as a chemical process. On the other hand it is a process which besides involving chemical reactions to produce the desired result, employs the substances involved in particular proportions and exploits their chemical characteristics in sequential stages under particular conditions at particular temperatures and for particular times. These, to my mind, are things that chemists do in carrying out chemical processes and, as I see it, these things coupled with the fact that important chemical reactions and little else are involved, give the process its character. To my mind these features of the matter are sufficient to indicate that the process is properly called a chemical process in the ordinary sense and I do not think that conclusion is weakened by the consideration that some of the features of the process as a whole are carried out by mechanical means or that technicians or operators can be trained to carry out the process efficiently without their becoming chemists.

The decision was appealed further to the Supreme Court, which heard oral submissions last November. While the judgement might provide further assistance in considering the present matter - and we have purposely delayed concluding our recommendation for that reason - as yet no decision has been handed down and we think it would be improper to delay further.

When we look at the applicant process (e.g. claim 154) for preparing the product of claims 1-43, we see that it involves a change in the chemical structure of the starting chemical compound to introduce a double bond into the 4:5 position of the ring. A new chemical compound results, and the change produced is chemical in nature. The change is brought about microbiologically using the microorganism Schizomyctes. Claims 1-43 also cover esters of that product, esters which, to use the words of the specification (p. 12) are made from the corresponding alcohol:

> ...by reaction with an acylating agent e.g. a phosphorylating agent, a lower hydrocarbon carboxylic acid acylating agent such as benzoic anhydride, tertiary butyl acetyl chloride, a lower alkanoic anhydride or lower alkanoyl halide such as acetic anhydride, propionic anhydride, a polybasic acid anhydride such as B,B-dimethyl-glutaric anhydride, succinic anhydride, and the like.

By any standard this is a chemical step and the product of such a step is made by a chemical process. We are consequently, irresistibly drawn to the conclusion that claims such as 1-4, 6-9, and others which cover the esters are subject to Section 41.

We are also inclined to the view that the products of the microbiological step would in the "popular" sense referred to by Mr. Justice Jackett be considered chemical. They involve chemical changes. The starting materials are made by chemical means (see page 4, beginning at line 8 of the specification to the end of page 6). The reaction is carried out in such chemical solvents as dialkyl ketone or acetone (p. 8 line 25). Buffered solutions may be used (p. 7, line 10). Those are significant distinctions serving to differentiate the process here from the more mechanical steps used in Continental Soya.

In any event, there are other reasons why we think Section 41 governs here. But before proceeding to them we refer to the Laboratoire Pentagone vs. Parke, Davis decision, which was also relied upon by the applicant. In the Quebec Superior Court (1968, 46 C.P.R. 171), it was held, despite the hesitation expressed in the quotation which follows, that the fermentation process being considered there was not a chemical process:

> With regard to the fermentation process, there is, in my opinion, no doubt that from a purely scientific philosophical point of view the process is a chemical process or, at any rate, that chemical reactins occur during the process resulting in the excreting by the organism of the chemical compound chloramphenicol, but I am unable to find that this purely scientific description is that which is meant by the phrase "chemical processes" in s. 41(1) of the Patent Act. Despite the fact that such a process would seem to the lay mind or, at any rate, of the mind of the undersigned, to refer to organic chemistry, there is the possibility, which seems to be a very real one, that in the mind of the legislator or, at least, of the draftsman of the Act, of a distinction between a biological and a chemical process.

The Quebec Court of Queen's Bench, Appeals came to

the same conclusion (1968), 53 C.P.R. 236)

The Supreme Court of Canada (1968, 55 C.P.R. 111) explicitly did not decide whether the fermentation process was chemical. We quote from p. 114:

> To decide this appeal, it does not seem necessary to decide the question regarding the fermentation process.

On the other hand it did decide that the subsequent extraction process was chemical, so that taken as a whole, the fermentation step followed by extraction was chemical, and Section 41 applicable. Consequently we do not think that it can properly be said that the Supreme Court's decision stands for the proposition that claims 1-43 are not chemically produced products.

Previously we referred to another obstacle to granting claims 1-43. We have no reservations in holding that the result of the complete process (fermentation followed by extraction) must be considered chemical and governed by Section 41. Both the Laboratoire Pentagone v. Parke, Davis and the Dairy Foods v. Co-op Agricole decisions support that view. If the applicant is entitled by virtue of Section 41 to protect the final purified product (the only form in which it is useful) only by the particular method which he has described and claimed, it would indeed be anomalous if he could by another claim prevent any one else from making that product by any other method whatsoever. Yet that is precisely what claim 1 (and others like it) would accomplish. It is directed to pharmaceutically impure pregnadiene - period, without further restriction or limitation. No matter what other process is devised for making the pregnadiene, such a process must of necessity go through the preliminary step of an impure pregnadiene, and so came within the net of claim 1.

This we feel would be clearly contrary to the meaning of Section 41. We should not be led astray by the terminology utilized by the applicant. As was said by Mr. Justice Jackett in an as yet unreported decision, Wolfe W. Gruber v. the Queen, June 4, 1975:

> What we are concerned with is the substance of the matter, and we must not let ourselves be misled by the words used.

Though this was not a patent case the principle it expresses seems appropriate.

There are two other objections to claim 1 and those like it which should be mentioned. They are directed to but a preliminary portion of the invention. The impure products are not what is desired, and are useless until purified. They are not for the invention which the applicant made and even if such incomplete inventions might be claimed they are broader than what the applicant has achieved. This impure pregnadiene contains only such impurities as would arise from his particular fermentation process. He never prepared impure pregnadiene where the impurities are those which arose from other fermentation processes or those which would be present if the product were made by chemical syntheses.

For such reasons as we have given, we are satisfied that the refusal of claims 1-43 was proper. The applicant proposed at the hearing (Appeal brief, p. 3) to amend claims 1-43 to refer to the fact that the impurities result from the production of said composition. We see no objection to such an amendment, but its entry is immaterial, since it would in no way alter the objections made, or the refusal of the claims.

Finally we turn to claims 44-89, and those for a process of extracting pure pregnadienes from impure pregnadienes. Once again the applicant has

proposed certain amendments (appeal brief, p. 6), in this case to specify that the extraction is done by two-phase solvent extraction or chromatographic absorption or crystallization. These amendments do add further specificity to the process, and in our view overcome one of the examiner's objections, viz that the steps of the purification are not defined in sufficient detail. We will consider such amended claims and determine whether they satisfy the other objections (for those objections it is immaterial whether the amendments are made or not).

The applicant has argued that the rejection of these claims is contrary to the findings in:

> Commissioner of Patents v. Ciba (1959) 30 C.P.R. 135 at 141 1959 S.C.R. 378,
> General Tire v. Dominion Rubber (1967) 53 C.P.R.
> and Laboratoire Pentagone v. Parke, Davis (supra)

These cases were cited as authority for the proposition that when a chemical product is patentable the process of preparing it would normally be patentable. Accepting that proposition, the process must, of necessity, be properly defined. The examiner has not suggested that the process would not be patentable when properly defined. Indeed he has called for amendments to do so and make the process allowable. He has stated that the starting material has not been properly defined (with which we agree) and that the step of purification has not been adequately defined (we consider that proposed amendment overcomes that branch of the objection). The starting material used in the applicants purification process and to which his purification steps have been found applicable, is one containing such impurities as would exist in the impure product resulting from his particular fermentation procedure. The applicant does not know, or at least did not know at the time of his invention, that the steps he proposes would be successful with pregnadienes made by other still unknown processes, containing different impurities.

We are also persuaded that allowing claims of such breadth as proposed by the applicant is an improper circumvention of Section 41 unless it is tied to the full process of the applicant, i.e. fermentation plus purification. The reasons for that were explained fully above.

For such reasons we find claims 44-89 were properly refused and require amendment.

Turning now to application 154366, we find it contains 56 claims. It is a division of Canadian patent 913613 in which the same products are claimed when prepared according to certain chemical processes. The issues here parallel those raised by the rejection of application 154366 which we have just considered, and the subject matter is cognate, with different isomers of the pregnadiene being covered.

Claims 13, 15, 16, 18, 22, 24, 26, 28, 29 & 44-49 were refused because of Section 41, and are unallowable for all of the reasons we have already advanced. Similarly claims 33-43 should be refused because of the objections we made to claims 44-89 in 154365, unless amended along similar lines. Claims 50-56 stand or fall with claims 33-43.

Claims 30, 31 & 32 were refused because the applicant company had already claimed those processes in his Canadian patent 872,223. In his response of April 25, the applicant indicates he withdraws those claims. He has also proposed certain other minor amendments which do not affect what has been refused. Similar comments apply to the more recent amendments proposed in the appeal brief.

For the reasons given, we consider the refusals made by the examiner should be affirmed.

G.A. Asher
Chairman
Patent Appeal Board

I concur with the findings of the Patent Appeal Board. The claims rejected by the examiner in both applications are refused. If any appeal is contemplated under Section 14 of the Patent Act, it must be commenced within six months of the date of this decision.

Decision accordingly,

A.M. Laidlaw
Commissioner of Patents

Dated at Hull, Quebec

this 29th day of August, 1975

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