

### COMMISSIONER'S DECISION

Patentable Subject Matter:    Pharmaceutical Package

The claims were for a package of contraceptive pills so arranged as to be adapted to the use to which they would be put. The examiner had considered the package to be an artificial manner of claiming a method of preventing conception, which method he considered to be unpatentable. The Board concluded that the package was a novel application of the discovery made by the applicant, with the pills so arranged in the new daily order to take advantage of that discovery.

FINAL ACTION:   Reversed

This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated September 14, 1973, on application 003,772 (Class 167-191). The application was filed on October 30, 1967, in the name of Gerrit L. Ijzerman and is entitled "Method For Stimulating Anovulatory Cycles And Pharmaceutical Packages."

The application relates to a package of pills particularly arranged so that they may be used in a method for stimulating anovulatory cycles in females by administering oestrogenic and progestative substances during a certain period of such cycles.

In the Final Action the examiner rejected all the claims for the reason that:

- a) The oestrogenic and progestative to be used are known compounds as applicant agrees in his reply of June 1, 1972.
- b) Applicant's alleged invention appears to reside in the method of using the known active ingredients in a defined sequence i.e. "The Normophasic method for controlling anovulatory cycles". A method of treating females mammals does not constitute a patentable subject matter. The claimed package is an artificial manner of claiming that method.

In that action the examiner stated (in part):

Applicant argues that:

"Such a position appears to be unreasonable as it could always be argued that any product needs a process to prepare it and can be used in a method of carrying out some desired operation".

This argument is not very well founded. Applicant in the disclosure at page 2 starting at line 14 touches:

"An entirely new method of treatment (emphasis added) has now been found which has proved to be fully reliable and which imitates as accurately as possible the hormonal ratios during the normal ovulatory physiological cycles of the subject, so that, for example, the built up of the uterine membrane and the changes in the cervical membrane also follow the physiological pattern which is not the case in the methods that have been adopted so far".

And continues from lines 22 to 30 to explain that:

"The method according to the invention consists in that the treatment with oestrogenic and progestative compound (emphasis added) covers a period ....."

Therefore applicant appears that he discovered a new method for stimulating anovulatory cycles to a female mammal by using known oestrogenic and progestative compounds in a way to imitate the physiological ratios and timing of hormones of a female subject and the statement that "Applicant's claimed package is an artificial manner of claiming that method" is well founded.

- c) In claim 1 the claimed pack containing discrete units of two different active ingredients acting in sequence and independently of each other and the printed instructions represents an aggregation of known components and does not represent a novel composition of matter and furthermore the statement in claim 1 "together with written or printed indications or directions, the indications or directions and the manner of packing being such as to provide guidance in relation to and to facilitate the taking...." is functional and indefinite thereby contrary to Section 36(2).
- d) A doctor can prescribe the two different discrete dosage units and write a detailed instructions or directions for the sequence the patient has to follow to obtain the expected from the "Normophasic method" of stimulating an ovulatory cycles results and in doing that provide the necessary guidance. Applicant in claim 1 describes an arrangement of known medicaments as a convenient way of carrying out a medical expert's directions.

The applicant in his response dated December 13, 1973 relies on his previous argument in support of the patentability of claims 1 to 10. His response of June 1, 1972 reads in part:

Applicants are well aware of the fact that the medicinal compounds that are specified in the claims are known in the art. However the "Normophasic Method" and the application thereof in the form of the claimed package certainly cannot be considered to be known matter. Such a package containing oestrogenic and progestational pills in a ratio and a sequence as indicated in the specification and as set out in the claims has never been made or used before the present invention was made.

This "Normophasic Method" has been proved to be very reliable in that no pregnancy occurs which is a claim that cannot be made with any real basis for any of the previously known methods. A further and very important advantage of the present method (which consists in a particular arrangement and respective particular numbers of both types of pills) as applied in the package of this invention, is that the hormonal balance corresponds with that of the normal menstruation cycle resulting in the same physiological changes in the female body as those occurring in the normal ovulatory cycle. It will be clear, that this will only be possible, by using pills having different effects, which pills must be present in a particular ratio and in a particular sequence to make sure that they are taken in the right order (by means of a special construction of the package and/or indications).

Although the present invention cannot be considered a composition in the usual sense, applicants do not consider that their invention is concerned with a single medicinal compound nor with a mere two component package. As indicated above it is the very combination obtained by composing the described claimed package which gives the remarkable result of absolutely excluding unwanted pregnancy. The use of only one type of the pills or the use of both types in the wrong order or over an other period will not do this. Hence it is applicants opinion that the present invention contains all the requirements to be patentable.

The question which the Board must consider is whether the applicant has made and properly claimed a patentable advance in the art. Claim 1 is directed to:

A pack of between 20 and 27 discrete dosage units such as tablets, pills or capsules for human oral administration at the rate of one unit per day over a period of between 20 and 27 successive days in order to stimulate anovulatory cycles, comprising a tube, box or chart in or on which units of two different kinds are packed in a particular order together with written or printed indications or directions, the indications or directions and the manner of packing being such as to provide guidance in relation to and to facilitate the taking of the said rate first of 6 to 13 units containing an oestrogenic compound only as a hormonal substance and subsequently 14 to 16 units containing a combination of an oestrogenic compound and a progestative compound.

The claim covers any type of package, for example, a tube, box or chart, in which the pills are contained. The only limitation is that the number of the two types of pills should fall within the ranges given, and that they should be arranged in a particular order. Such a package is to contain "oestrogenic and progestational pills having different effects, and in a particular ratio and a particular sequence to make sure they are taken in the right order."

The applicant claims to have discovered an important improvement in the so-called (and known) "sequential" treatment to prevent conception. The known treatment involves the taking of an oestrogenic compound from the 2nd to 5th day after the beginning of the menstrual period until the 20th day and then taking a combination of oestrogenic and progestative compounds from the 20th to the 25th day. The applicant's improvement, which he has named the "Normophasic" method, also involves two successive phases. Preferably it extends for 22 days, beginning not later than the 5th day after the onset of the last menstruation. In the first period of seven days an oestrogenic compound is taken. In the second phase lasting 15 days a combined oestrogenic and progestative compound is taken. The Normophasic method is also claimed to be fully reliable in producing protection against pregnancy.

The applicant has discovered a new method for chemically induced contraception. Invention must, however, be differentiated from discovery. Discovery may add to existing knowledge, but without anything further cannot amount to a useful invention. A discovery, just as the apprehension of a desideratum, may be the basis for and progenitor of an invention and, once perceived, the method of applying the discovery to produce a new and useful result is what constitutes invention. The application of the discovery may be quite simple. once the discovery was made. As Lord Simonds observed in Raleigh Cycle Co. Ltd. et al v. H. Miller & Co. Ltd.: (1948) 1 All, E.R. 308 et 311.

The patentee, having made this discovery, proceeded to make an article which gave effect to it. It achieved... an immediate commercial success, and, though, I think, no great ingenuity was needed for the construction of the article, I am not prepared to dissent from the view taken by the Court of Appeal that here there was subject-matter to support a patent. The discovery was the inventive step which gave to the invention the necessary merit.

On the same subject Rinfret J. in Electrolier Manufacturing Co. Ltd. v Dominion Manufacture Ltd. (1943) S.C.R. 436 at 442, stated:

The merit of Pahlow's patent is not so much in the means of carrying out the idea as in conceiving the idea itself (Fawcett v. Homan (1896) 13 R.P.C. 398. He produced an improved thing as the result of the ingenious application of a known elastic material (Gadd and Mason v. Mayor, etc., of Manchester); and, to our mind, there was just as much inventive ingenuity in his discovery as there was in the adoption of tubular wire braids in making bristles, held by the House of Lords to have been good subject-matter of a patent (Thomson v. American Braided Wire Company), the result attained being a complete article, effective and capable of being assembled cheaply and expeditiously. The advance may have been slight - although, as pointed out by Fletcher Moulton on Patents (p.22), "the general tendency of the mind is to minimize the difficulty of a discovery after it has been made" - but there was a real inventive step upon "what went before"; and the new result which was obtained was of sufficient importance to make it a genuine invention. It follows that the patent should be held good and valid.

It was argued that the pack or card with the attached pills represents an invention because no one has suggested such a pack or card with these pills in that order before. The card, it is said, is useful because it gives the purchaser the protection she wants. Further the card is not obvious because no one would have thought of arranging these particular pills in that daily order unless and until he knew of the Normophasic method. The discovery of a new method of chemical treatment to avoid or suppress conception may, in our view, give rise to patentable subject matter in the form of a pack or card of pills adapted to the carrying out of that method if there is something novel in the constitution of the pack or card itself, or in the idea of a card with the different pills arranged in the new daily order particularized for the newly discovered method of treatment. It may be that the significant discovery lies in the method of treatment rather than in the arrangement of the pills on the card. It can not be said, however, that the arrangement or sequence of pills on the card was obvious to those who did not know of the Normophasic method.

In our view claim 1 defines a combination which represents the novel and practical application of a new discovery for a chemically-induced

contraceptive method. The printed instructions referred to in the claims are, we are satisfied, of no patentable significance, because the claims also recite "... and the manner of packing being such as to provide guidance in relation to and to facilitate the taking of said rate first of ...." The printed instructions are therefore not a prerequisite to the patentability of the combination claimed.

We are therefore satisfied that the claims relate to new and useful "subject matter" which define a patentable advance in the art, and we recommend that the Final Action be withdrawn.

We note that the corresponding British application was initially refused, but granted after appeal for the same reasons that we have adopted. See In the Matter of Organon Laboratories Ltd., Patents Appeal Tribunal, Graham J., as in 1970 R.P.C. 574.

  
J.F. Hughes,  
Assistant Chairman,  
Patent Appeal Board.

I concur with the findings of the Patent Appeal Board and withdraw the Final Action. The application is returned to the examiner for resumption of the prosecution.

Decision accordingly,

  
A.M. Laidlaw,  
Commissioner of Patents.

Dated at Hull, Quebec  
this-4th. day of  
July, 1975.

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